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The Legal Structure of UK Biobank: Private Law for Public Goods?

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Abstract

Population biobanks hold promise for improving the health of future generations by providing researchers with a resource of both human samples and data to investigate the linkages between genes, lifestyle and environment in population health. Widespread concern has been expressed in academic and policy literature as to the ongoing ethical, legal and social challenges that are raised by population biobanks, by virtue of their longitudinal nature and broadly set research aims.

To address these challenges, and to balance private interests of the individuals who donate to biobanks, with the public benefit that is believed to derive from the establishment of biobanks, some countries have specifically legislated to establish national biobanks. Alternatively, UK Biobank has been incorporated as a charitable corporation. Potentially, this private legal structure diminishes the public accountability of the project, as well as the protection of donors from personal harm. This thesis analyses the multi-layered nexus of laws within which UK Biobank is embedded and shows the tensions that are associated with using a private legal structure to secure public objectives. UK Biobank is in unchartered legal territory on a number of levels, and this thesis posits UK Biobank as a timely example of a large-scale organisation whose model straddles the public/private divide in law and invites an eclectic mix of corporate, public, charity, contract and tort lawyers into a conversation with ethicists, scientists, policy experts and the public to consider how to effectively progress population health via biobanking. As such, the experience of UK Biobank raises questions as to how best to balance public and private interests in large-scale, public mission organisations in general.

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In loving memory of Bernice Josephine Jefferson and John Smith, my Nana and Grandad, who passed from cancer before UK Biobank was built, and who we miss every day. They would have donated and they would have asked questions.

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United Kingdom

European Union

Estonia

Iceland

Council of Europe

European Patent Organisation

UNESCO

List of Abbreviations

BBMRI	Biobanking and BioMolecular Resources Research Infrastructure
deCODE	deCODE Genetics
DH	Department of Health
DPA	Data Protection Act
DTC	Direct-to-Consumer
ECHR	European Convention on Human Rights
ECtHR	European Court of Human Rights
EGC	Ethics and Governance Council
EGCUT	Estonian Genome Centre University of Tartu
EGF	Ethics and Governance Framework
EGI	EGeen Incorporated
EGP	Estonian Genome Project
EGPF	Estonian Genome Project Foundation
HFEA	Human Fertilisation and Embryology Act
HGRA	Human Genes Research Act
HRA	Human Rights Act
HTA	Human Tissue Act
HSD	Health Sector Database
HSDA	Health Sector Database Act
MRC	Medical Research Council
MTA	Material Transfer Agreement
P3G	Public Population Project in Genomics and Society
WT	Wellcome Trust

Introduction

Background: 'Public' and 'Private' Biobanking

'*UK Biobank embodies the worst form of governance, except all those other forms that have been tried from time to time.'*[1]

The way that biomedical research is carried out has undergone considerable change following the success of the Human Genome Project (HGP) in sequencing the first human genome in 2001.[2] We are now in the midst of a 'new era' of medicine: genetic information is being collected and accessed with increasing ease and cost effectiveness via DNA sequencing, whole genome sequencing of NHS patients, and national and international initiatives for patient data sharing.[3] Increasingly, large consortia that bring together researchers, experts and institutions from many different disciplines are carrying out genomic research in an attempt to translate public health benefits from research.[4] Biobanks, repositories of biological samples with accompanying linked data, are examples of such consortia, and range from

[1] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440.
[2] On 14th April 2003, the International Human Genome Consortium announced successful completion of the project: International Human Genome Sequencing Consortium, 'Finishing the Euchromatic Sequence of the Human Genome' (2004) 431 Nature 931.
[3] For example, England's Care.data: NHS England 'The care.data programme – collecting information for the health of the nation' <https://www.england.nhs.uk/ourwork/tsd/care-data/> and Genomics England: 'Genomics England is delivering the 100,000 Genomes Project' <http://www.genomicsengland.co.uk/> accessed 2 February 2016
[4] Chalmers D, Nicol D, Otlowski M, Critchley C: Personalised medicine in the genome era. Journal of Law, Medicine and Ethics, 2013, 20: 577–594.

small-scale resources created for specific research purposes, to large-scale population biobanks built for broader, undefined research uses.[5]

Over the past two decades, biobanks have proliferated in response to HGP findings. The HGP necessitated further research to understand the interaction between genes, lifestyle and environment.[6] To facilitate such research, biobanks have been established to collect, store and release samples of human materials, which may be linked to individual health records. As such, biobanks are perceived as having the potential to accelerate research by providing efficient access to central repositories of samples and data, rather than requiring researchers to contact and obtain materials on an individual basis. Many countries[7] have invested substantial sums of public and private money in biobanking in view of such potential. In fact, according to a BCC market research report published in 2011, the global biobanking market was worth $141 billion in 2010, and was projected to increase by 30% between 2010 and 2015, to an estimated $183 billion.[8]

In particular, population biobanks have been established on the premise that they are essential tools for population-wide genomic research; deriving their scientific value from their large size and unique capacity to combine samples with health data for longitudinal research purposes.[9] It has been argued that combining genetic and health information for whole populations is justifiable from both a science and industry perspective. Scientifically, biobanks are 'the appropriate next step in translating recent advances… into knowledge of direct clinical and public health relevance.'[10] For industry, biobanks hold the potential to identify new forms of therapeutic

[5] While it is accepted that there is no single definition of a biobank, there is widespread agreement on the broad aspects of what constitutes a biobank: Shaw DM, Elger BS and Colledge F, 'What is a biobank? Differing definitions among biobank stakeholders.' (2014) 85 Clin Genet 223.
[6] Professor Sir Rory Collins, 'Big Data in the UK Biobank: Opportunities and Challenges' (Gresham College Lecture, London, November 2014) <www.gresham.ac.uk/lectures-and-events/big-data-in-the-uk-biobank-opportunities-and-challenges> accessed 6 June 2015
[7] It is noted that investment has mainly been concentrated in scientifically advanced countries, compared to low- middle-income countries.
[8] BCC Research 'Global Market for Biobanking To Surpass $183 Billion in 2015' (BCC Research, August 24, 2011) <http://www.bccresearch.com/pressroom/bio/global-market-biobanking-surpass-$183-billion-2015> accessed 22 January 2016
[9] Rothstein M, 'Expanding the Ethical Analysis of Biobanks' (2005) 33 JLME 89.
[10] Salter B and Jones M, 'Biobanks and bioethics: the politics of legitimation.' (2005) 12 Journal of European Public Policy 710.

interventions for common diseases,[11] enabling rapid pharmaceutical advance and ultimately, the introduction of personalised medical care.[12]

Typically, population biobanks collect samples and data from healthy volunteers, and are therefore more dependent on individual altruism than may be the case for disease-specific research projects.[13] This is because they are designed on a longitudinal basis, which means donors will not themselves benefit from such altruism. Moreover, population biobanks are designed to be available for prospective and as yet unspecified research projects. Early concerns arose out of the challenges that were associated with establishing biobanks, which did not fit neatly within existing research paradigms and the genetic research that was to be undertaken therein. In sum, population biobanks have re-invigorated ethical and moral debates including those regarding property in the body,[14] privacy, consent[15] and benefit sharing.[16]

Originally, while the promise of biobanking seemed readily justifiable from an industry and scientific perspective, the incentives from an individual donor's perspective were less clear. In particular, the publics' perception of genetic research was comparably embryonic, and debates regarding 'genetic exceptionalism' suggested that, 'rightly or wrongly', genetic information derived from human samples was 'seen as more sensitive than other health information.'[17] Early studies of public perceptions of biobanks[18] revealed suspicion as to the storage and use of genetic data compared with other forms of data.[19] Scholars who noted the potential

[11] Beskow LM, Khoury MJ, Baker TG and Thrasher JF, 'The integration of genomics into public health research, policy and practice in the United States' (2001) 4 Common Genetics 2.
[12] Ibid.
[13] Campbell AV, 'The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust' (2007) 18 King's Law Journal 227
[14] Beyleveld D and Brownsword R, 'My body, my body parts, my property?' (2000) 8 Health Care Anal 87.
[15] Greely H, 'Human Genomics Research: new challenges for research ethics' (2001) 44 Perspectives in Biology and Medicine 221.
[16] Dickenson D, 'Consent, Commodification and Benefit Sharing in Genetic Research' (2004) 4 Developing World Bioethics 109.
[17] Holm S, 'Me, Myself, I- against narcissism in the governance of genetic information' in Widdows H and Mullen C, *The Governance of Genetic Information: Who Decides?* (CUP 2009).
[18] Nelkin D and Lindee M, *The DNA Mystique: The gene as a cultural icon* (WH Freeman 1995). Cited in Levitt M and Weldon S, 'A well placed trust?: Public perceptions of DNA databases.' (2005) 15 Critical Public Health 314.
[19] Ibid Pg 314. In interviews, reasoning was twofold: in some instances the 'sacred' character of genetic data was determinative: 'I consider that absolutely sacrosanct, that's *ME*, really the inner me they're looking at.' Second, lack of understanding of medical research caused unnecessary concern,

for misuse of genetic data signalled ethical dangers: 'Family members, the State, researchers and employers could all claim an interest in knowing the genetic information relating to individuals.'[20] Concerns were raised over the protection of individual privacy[21] and the potential for genetic discrimination.[22]

Furthermore, in some countries an environment of distrust in medical research and healthcare in general compounded such early scepticism.[23] In the UK, the 'Alder Hey' public inquiry revealed that three children's hospitals had been harvesting organs from deceased children without their parents' informed consent. This scandal, which was first revealed in 1998, led to a legislative response. Parliament enacted 'reactive' statutory legislation and established a corresponding statutory authority to regulate and supervise the collection, storage and use of human tissue.[24] The events at Alder Hey brought issues of consent, organ and tissue use and storage under the spotlight; the Human Tissue Act 2004 was seen as necessary to reassure public confidence and maintain altruistic organ donation.[25]

In response to the many ethical, legal and social challenges and to justify broad consent regimes, biobanks have developed comprehensive governance regimes. In the midst of a proliferation of different types of biobanks around the world,[26] certain governance best practices have been identified which are believed to tackle such concerns.[27] Importantly, the international biobanking community learnt lessons from the experience of the Icelandic national database, whose commercial basis and

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influenced by 'media hype' or 'science fiction': 'I don't want people meddling with part of me without telling me. I could have another me wandering around- 'who are you?' That's the downside of giving a sample of DNA.'

[20] Laurie G, *Genetic Privacy: A Challenge to Medico-Legal Norms* (CUP 2002), 20

[21] Ibid. See also Taylor MJ and Townend D, 'Issues in protecting privacy in medical research using genetic information and biobanking: the PRIVILEGED project' (2010) 10 Med Law Int 253; Taylor MJ, *Genetic Data and the Law: A Critical Perspective on Privacy* (Cambridge University Press 2015).

[22] GeneWatch UK 'Biobanks' (GeneWatch UK) <http://www.genewatch.org/sub-507674> accessed 26 January 2016

[23] Levitt M and Weldon S, 'A well placed trust?: Public perceptions of DNA databases.' (2005) 15 Critical Public Health 314. A specific example includes the Alder Hey organ retention scandal: BBC News 'Organ scandal background' *(BBC News Health*, 29 January 2001) <http://news.bbc.co.uk/1/hi/1136723.stm> accessed 5 August 2010.

[24] Human Tissue Act 2004; Human Tissue Authority: <https://www.hta.gov.uk/> accessed 26 January 2016.

[25] BBC News 'Q&A: Human Tissue Act' (*BBC News*, 30 August 2006) <http://news.bbc.co.uk/1/hi/health/4944018.stm> accessed 24 January 2016.

[26] Chalmers D, 'Genetic Research and Biobanks' in Dilner J (ed), *Methods in Biobanking* (Springer 2010).

[27] Knoppers BM and Zawati MH, 'Biobanks' in Chadwick R (ed) *Encyclopaedia of Applied Ethics* (San Diego Academic Press 2012) 246.

statutory opt-out consent provision exemplified the difficulties in balancing the interests of the individuals who consent to donate to biobanks, and the public good that is believed to derive from such research.[28] The database was never created.[29]

Over time, the expansion of biobanking across public and private spheres[30] has meant that these ethical and legal questions are arising on an ongoing basis. The benefits to be derived from cooperation and collaboration between 'private' and 'public' research models for future public health have been emphasised.[31] The biobank community has dedicated resources to identifying common principles for governance frameworks[32] and building networks of a broad range of biobanks to increase efficacy and excellence in research of European interest.[33]

Most recently, the issue of biobank sustainability has been brought to the fore.[34] Biobanks are not only expensive to establish, they are expensive to maintain, and this has been illustrated by the closure of the under-utilised[35] Singapore Bio-Bank (originally known as Singapore Tissue Network).[36] Arguably biobanks are subject to an 'underlying belief that at some point, [they] should be capable of becoming 'self-sustaining…'[37] but this goal is not often achieved.[38] Commercialisation is one way

[28] Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80.
[29] As will be discussed in Chapter 2 of this thesis.
[30] In the commercial field, privately organised biobanks such as PXE International are also enjoying success: PXE International <https://www.pxe.org/> accessed 26 January 2016.
[31] It has been argued that biobanks are most effective when they can 'link up and learn from one another': Laurie G, 'Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law' (2011) 130 Hum Genet 347, 348.
[32] For example, PG3: P3G 'About us' (P3G) <http://www.p3g.org/about-p3g> accessed 30 January 2016.
[33] For example BBMRI-ERIC: Biobanking and BioMolecular resources Research Infrastructure. BBMRI-ERIC 'The History' <http://bbmri-eric.eu/history> accessed 1 September 2015.
[34] Watson P and others, 'A Framework for Biobank Sustainability' (2014) 12 Biopreservation and Biobanking 60.
[35] It is believed that the national database was under-utilised because of the availability of existing tissue banks which researchers were already accustomed to using: Ibid.
[36] Chan TW, 'The Closure of the National Bio-bank in Singapore' (2012) 16 Asia-Pacific Biotech News Journal 40.
[37] Watson P and others, 'A Framework for Biobank Sustainability' (2014) 12 Biopreservation and Biobanking 60.
[38] Vaught J, Rogers J, Carolin T and Compton C, 'Biobankonomics: Developing a Sustainable Business Model Approach for the Formation of a Human Tissue Biobank' (2011) 42 J Natl Cancer Inst Monogr 24.

of securing funding, but the literature has highlighted issues associated with such commercialisation in biobanking.[39]

Thus, it is observable that to establish population biobanks, the task primarily for policy makers is to develop legal frameworks which are responsive to these ethical challenges, are built to last, and which successfully balance the interests of individual donors who provide their samples and access to their data, while fostering the public interest in carrying out lawful and ethical research[40]. Examples of governance frameworks can be observed around the world but these models have not been uniform in their approach.

For example, as previously mentioned, in Iceland the Act on Health Sector Database was enacted to create a Health Sector Database. The Act granted an exclusive licence over the biobank resource to a private for-profit company: deCODE Genetics. Following political, judicial, professional and public opposition, the database was abandoned and deCODE have been forced to re-strategize. To an extent, operating on a commercial basis also threatened the downfall of Estonia's population biobank. Just as Iceland had established a biobank specific statute, Estonia enacted the Human Genes Research Act (HGRA) for the Estonian Gene Bank, alongside a publically funded Estonian Genome Protect Foundation to co-ordinate and govern the biobank. The Foundation granted a 25-year exclusive licence to a private company to form a public-private partnership, which led to a period of bankruptcy. Today, still regulated by the HGRA, the biobank is entirely publically funded and operates within the University of Tartu, Estonia.[41]

Thus, at the time of UK Biobank's development (1999-2006[42]), Iceland and Estonia were two comparative examples of governance models for population biobanking. Combined, these experiences highlighted two crucial questions: how should a population biobank in the UK be funded, and how should it be regulated?

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[39] Caulfield T and others, 'A review of the key issues associated with the commercialisation of biobanks' 2014 Journal of Law and the Biosciences, 94.
[40] Beyleveld D, 'Data Protection and Genetics: Medical Research and the Public Good' (2007) 18 King's Law Journal 275; Campbell AV, 'The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust' (2007) 18 King's Law Journal 227; Brownsword R, 'Genetic Databases: One for All and All for One?' (2007) 18 King's Law Journal 247.
[41] University of Tartu Estonian Genome Centre:
<http://www.geenivaramu.ee/en> accessed 24 January 2016.
[42] Recruitment between 2006-2010: UK Biobank 'About UK Biobank' (*UK Biobank*)
<http://www.ukbiobank.ac.uk/about-biobank-uk/> accessed 30 January 2016.

While there was precedent in the UK for enacting specific statutory legislation in response to emerging new biotechnologies,[43] UK Biobank was instead established with a £62 million investment from a mix of public and private funding,[44] and supported by a private legal structure that is embedded into the existing regulatory framework for research in the UK. UK Biobank was 'a natural progression'[45] of the key involvement of the (publicly funded) Medical Research Council (MRC) and the Department of Health (DH) and charitable company the Wellcome Trust (WT) in the HGP, as a means of capitalising on HGP findings and translating benefits for the UK population. UK Biobank is a prospective cohort study, which has recruited over half a million donors aged 40-69.[46] Volunteers have donated samples of blood, urine and saliva for long-term storage and analysis, and agreed to have their health monitored for their lifetime. The project aims to improve the prevention, diagnosis and treatment of a wide range of some of the most common and serious life-threatening illnesses; including cancer, heart disease, diabetes, arthritis, and dementia.

In view of the scale of the resource and its longitudinal basis, the ethical and legal question for the funders was how to ensure that the structuring of UK Biobank on a private law basis could adequately reflect the interests of the donors and realise the public mission of the resource. In response, an 'Ethics and Governance Council' (EGC) was developed to oversee UK Biobank's adherence with an 'Ethics and Governance Framework' (EGF) governing policy, with a specific remit to represent the interests of the public and donors in the running of the resource.[47]

At the time of its creation, UK Biobank's legal structure and governance framework were unique worldwide. As such, they hold promise as an exemplar for similar ventures. Yet, the governance model of UK Biobank has since been shown to give rise to a number of critical issues, including the extent to which the interests of donors and the public are engaged in the running of the resource. Concerns have

[43] For example, the Human Fertilisation and Embryology Act 1990 and corresponding Human Fertilisation and Embryology Authority: <http://www.hfea.gov.uk/> accessed 26 January 2016
[44] UK Biobank 'About UK Biobank' (*UK Biobank*) <http://www.ukbiobank.ac.uk/about-biobank-uk/> accessed 26 January 2016
[45] Dr Mike Dexter, Director of the Wellcome Trust: <http://www.wellcome.ac.uk/News/Media-office/Press-releases/2002/WTD002895.htm> accessed on 8 August 2010
[46] As of as of 7 July 2010: UK Biobank 'About UK Biobank' (*UK Biobank*) <http://www.ukbiobank.ac.uk/about-biobank-uk/> accessed 8 August 2010
[47] UK Biobank Ethics and Governance Council: <http://egcukbiobank.org.uk/> accessed 26 January 2016

been expressed that a lack of adequate engagement may cause donors to 'vote with their feet' and withdraw from UK Biobank if they are unhappy with the way the project is run, potentially undermining the value of the resource. On this basis it has been argued that if donors (and members of the public) were more involved in the governance process, UK Biobank project goals will be better achieved.[48]

Research questions and aims

Given the ambitious nature and scale of UK Biobank and the novel research it will facilitate, the critical question is whether, and to what extent, the choice of legal structure for the resource will resolve the tension between public and private interests in biobanking. To answer this research question, this thesis will analyse the legal basis of UK Biobank and critically evaluate the legal avenues for donors and the public to hold UK Biobank to account. Further, this thesis will ask which additional mechanisms are available from the perspective of private and public common law. In so doing, this thesis will uncover the complex legal architecture of UK Biobank in charity and company law, and raise important further questions as to the adequacy of the governance framework for biobanking in the UK and other public mission organisations worldwide.

These questions are inspired by the advice of esteemed scholar Brownsword, who has opined:

> If I were trying to direct legal researchers... I would suggest that they should focus on two fundamental questions- one question concerning effectiveness and the other concerning legitimacy- and that they should pursue these questions in the context of global governance.[49]

With this in mind, this thesis aims to answer the following research questions:

[48] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 449; Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).

[49] Brownsword R, 'An Introduction to Legal Research' (2006) <http://eprints.uwe.ac.uk/18856/1/TPA%20Smith%20-%20'The%20Zealous%20Advocate%20in%20the%2021st%20Century'.pdf> accessed 27 January 2012, 23.

i) To what extent does the dual legal structuring of UK Biobank as a private charity company facilitate the realisation of UK Biobank's stated public good mission?

ii) What avenues of accountability and redress are available (and to whom) by virtue of the nexus of laws in which UK Biobank is embedded?

iii) How do these accountability mechanisms ensure that the private legal framework of UK Biobank meets the ethical challenges of large-scale population biobanking regulation in the 21st Century?

Methodology

i) Doctrinal approaches

In pursuit of the above research questions, this thesis adopts a predominantly doctrinal approach to analyse the complex and multi-layered legal structure of UK Biobank. Standard library and internet based research techniques have been used to identify primary and secondary legal resources to inform analysis, including: Statutory legislation, common law jurisprudence, international guidelines, 'soft-law' guidelines and policies, governance documents, academic journal articles and textbooks.

Doctrinal research is the most traditional approach to legal research. Cownie[50] defines this methodology as 'based upon a conception of law as an internally coherent body of rules, analysed using the same techniques of precedent and statutory interpretation that are used by judges in courts.'[51] Doctrinal researchers ask: 'what does the law say on the matter?' They are concerned with the law as a body of value free rules[52] and conceptualise the law as autonomous, with clear boundaries between law and other subjects; separating 'legal' issues from other moral, political and social issues.[53] Doctrinal methodology assumes that the law is in the text, or rather, the law is the text.[54] Doctrinal methodology uses interpretative methods to examine sources of law 'in an attempt to seek out, discover, construct or reconstruct rules and principles. It then systematises and employs them to conduct descriptive

[50] Cownie F, *Legal Academics: Culture and Identities* (Hart 2004).
[51] Ibid. 49
[52] Ibid. 50
[53] Ibid.
[54] Ibid.

analysis and normative evaluation of the process of decision making...'[55] Formalist assumptions of traditional doctrinal analysis maintain that law is a body of rules that exist within a framework independent of external issues; the law is the text of cases and statutes and analysis enables us to answer social problems through construction and systemisation of these existing rules and principles.

According to this approach, the parameters of the law can be divided into 'public' and 'private' law, which will now be discussed in more detail because of the relevance to this thesis.

Defining 'public' and 'private' law and 'public' and 'private' interests

> What is it that one intends to contrast with what, when one distinguishes private law from public law, and what is one's purpose in doing so?[56]

In this thesis, the regular reference to, and analysis of, the language of both 'private' and 'public' law necessitates a clear and upfront statement of the respective definitions and understandings upon which the thesis is founded.[57] It has been recently acknowledged that the relationship between public and private law is an 'immense topic' and that 'statements of the relationship are also notoriously complicated by a lack of terminological clarity.'[58] Traditional conceptions of the divide distinguish the body of positive law that governs relationships between private individuals (natural or otherwise) i.e. 'private law,' from 'public' law. In contrast, public law governs the relationship between individuals and the state acting in its capacity as the mediator of the public good.[59] Within this definition, the substantive fields of private law include: charity law, property law, corporate and commercial (finance law), the law of torts and the law of private law remedies.[60]

However, with the rise of new public management techniques the overlaps between the two fields have become multiple.[61] As a result, traditional conceptions of public and private law have come to be challenged in a number of respects, including by

[55] Banakar R and Travers M (eds) *Theory and Method in Socio-Legal Research* (Hart 2005).
[56] Barker K, 'Private law: Key encounters with public law' in Barker K and Jensen D, *Private Law: Key Encounters with Public Law* (CUP 2013), 3.
[57] Ibid.
[58] Ibid.
[59] Ibid. 4
[60] Ibid.
[61] Gamble A and Thomas R, 'The Changing Context of Governance: Implications for Administration and Justice' In Alder M, *Administrative Justice in Context* (Hart 2010).

those adhering to a 'decentred' understanding of law. Decentred understandings of law are more widely concerned with the regulation of governance arrangements that are not formally found in statute.[62] Most pertinently, it is argued that:

> There is currently a mismatch between legal doctrine, which maintains a public/private dichotomy, and socio-political analysis of decentred regulation, in which that dichotomy has broken down. The result is that the classification of 'public' in legal doctrine excludes those who are exercising the same regulatory function as government.[63]

As such, a decentred understanding of regulation is not limited to a clear distinction between public and private, governance and government. For example, it has been argued that nothing of much substance may turn on this divide, as 'public law' values are also present in private law.[64]

To answer the research questions outlined above, this thesis principally follows the traditional definitions of 'private' and 'public' law, as a means of ordering analysis of the complicated and layered nexus of laws within which the legal structure of UK Biobank is embedded. Analysis of charity and company law, together with the tort law of negligence is therefore conceived within the 'private' realm. In addition, 'public' law avenues of redress are also considered, in view of the potentially 'public' nature of UK Biobank (for reasons that will be shown herein). In so doing, however, the overlaps in the protection of public and private interests are noted. Questions are also raised for future research as to the appropriateness of a public/private law divide in the context of UK Biobank, as a result of the considerable discretion with which UK Biobank operates and the interests which it serves to protect.

On the matter of defining 'public' and 'private' interests, it could be argued that where definitions of public and private law are conceptualised according to the relationship between either private individuals or private individuals and the State, it is consequential that the 'interests' which the laws serve to protect are respectively 'public' and 'private'. However, this separationist approach has been questioned in

[62] Black J, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World' (2001) 54 CLP 103, 144.
[63] Ibid.
[64] Oliver D, *Common Values and the Public-Private Divide* (Butterworths 1999).

recent literature, particularly in relation to corporations, which may be 'so powerful and so influential… that there may be good reasons for subjecting them to public levels of scrutiny and accountability.'[65]

Indeed, such separation has been argued to be problematic in the context of biobanking and genetic research, for reasons that will be considered in this thesis. In brief, there is growing acceptance that there is both a private interest in respecting privacy in the process of sound scientific research, as well as a public interest in respecting the private privacy interests of individuals in this context to realise the ultimately public interest in scientific research taking place.[66] Potentially, such overlap gives rise to difficulties in terms of which set of laws should operate to protect which set of interests.

ii) Socio-legal and comparative approaches

For lawyers, recourse to law is the natural reaction to new social challenges.[67] However, since the comprehensive Icelandic Act on Biobanks[68] was declared unconstitutional, biobank policy makers have proceeded with caution and learnt from this experience,[69] concluding that legislation may not guarantee the necessary and effective protection of the interests at stake. Longitudinal population biobanks raise ongoing challenges, and this makes 'biobanking and the law uneasy bedfellows.'[70] They are entrenched in a social, political and economic nexus that is far from static[71] and in light of this constant development it is necessary to engage with such innovation on a continuous basis. Regulation and governance must therefore operate in real time, adapting and changing according to context. For this

[65] Barker K, 'Private law: Key encounters with public law' in Barker K and Jensen D, *Private Law: Key Encounters with Public Law* (CUP 2013), 8. As will be discussed in more detail in Chapter 8 of this thesis.
[66] Nuffield Council on Bioethics, *The collection, linking and use of data in biomedical research and health care: ethical issues* (Nuffield Council 2015) < http://nuffieldbioethics.org/project/biological-health-data/> accessed 05th Feb 2016; Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315; Taylor MJ and Townend D, 'Issues in protecting privacy in medical research using genetic information and biobanking: the PRIVILEGED project' (2010) 10 Med Law Int 253.
[67] Laurie G, 'Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law' (2011) 130 Hum Genet 347, 350
[68]Biobanks Act, No. 110/2000 (Iceland) as amended by Act No. 27/2008 and Act No 48/2009
[69] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440.
[70] Laurie G, 'Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law' (2011) 130 Hum Genet 347
[71] Gottweis H and Petersen A, *Biobanks: Governance in comparative perspective* (Routledge 2008).

reason, a common response to biobanking has been policy led; involving an increased number of stakeholders in multi-level policy initiatives that aim for 'adaptability'[72] or 'reflexivity'[73] in line with trends in genetic governance as a whole.[74]

In direct response to the ethical, legal and social challenges raised by biobanks, the origins of UK Biobank are characterised by extensive public debate, consultations and engagement activities. On this basis, in addition to a doctrinal approach, this thesis also uses socio-legal and comparative analysis to examine the series of (political) events which led to the genesis of UK Biobank, and the key drivers for a population biobank in the UK, as well as UK Biobank's own internal policy framework.

Arguably, socio-legal methodology is more difficult to define than doctrinal methodology, primarily because of the diversity of research carried out under this heading; each approach challenging the idea that the law is composed of an autonomous, coherent body of rules free from values and context.[75] In general, this methodology is concerned with analysing how the law operates in society, and has been defined as:

> An approach to the study of law and legal processes... [which] covers the theoretical and empirical analysis of the law as a social phenomenon.[76]

A socio-legal approach to research recognises that the law may also be understood as a reflexive social institution and as such, requires looking beyond the rules of law to explain and understand legal frameworks. In this thesis, the use of socio-legal methodology facilitates an examination of the context of population biobanks, which are embedded in a social as well as legal context. For example, the role of UK Biobank's core funding bodies is crucial to critical analysis of UK Biobank's legal structuring. Socio-legal analysis will therefore contextualise the origins of UK Biobank and the reasons behind the chosen model. This approach enables a more thorough analysis of the legal structure of UK Biobank as a charity company, and an

[72] O'Doherty and others, 'From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks.' (2011) 73 Social Science & Medicine 367.
[73] Laurie G, 'Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law' (2011) 130 Hum Genet 347.
[74] Bunton R and Petersen A, *Genetic Governance* (Routledge 2004).
[75] Banakar R and Travers M (eds) *Theory and Method in Socio-Legal Research* (Hart 2005).
[76] Cownie F, *Legal Academics: Culture and Identities* (Hart 2004), 51.

analysis of the theoretical underpinnings of this structure which may go some way to explaining how UK Biobank would be treated in UK public and private law.

In addition to doctrinal and socio-legal approaches, this thesis uses comparative methodology to highlight the alternative legal frameworks that were available at the time of UK Biobank's development, and particularly uses examples of comparable European population biobanks in Iceland and Estonia. Both biobanks were established on a statutory footing, with a mix of public-private funds. In the biobank community, crucial lessons were learnt from the experiences of these biobanks, and therefore, analysis of their regulatory and funding models is justified to inform contextual analysis of the origins of UK Biobank.

Overall, it is observable that the context of UK Biobank's development will contribute to doctrinal analysis in this thesis, and accordingly this methodological approach corresponds with Twining and Miers' definition of socio-legal research:

> The approach adopted in this book is sometimes referred to as 'contextual.' We accept this label if it is taken to mean that law is our primary discipline: that legal rules, institutions, processes, personnel and techniques are the primary subject of study, but that, for reasons of understanding, rational criticism or developing basic skills, legal ideas and phenomena are nearly always best viewed in some broader context rather than studied in isolation as if they were things in themselves. Furthermore, we believe that legal concepts, rules and institutions often do not themselves provide the best starting point for study. 'Context first' is a good working rule of thumb, provided that it is not interpreted or applied too rigidly.[77]

Contribution to existing scholarship

Research questions should contribute to existing knowledge and have some importance for the 'real world'.[78] To date, literature in this field has extensively considered the evolving ethical, legal and social challenges that arise from population biobanking (as previously mentioned). Substantial comparative legal analysis has been undertaken to compare and contrast international regulatory frameworks for biobanks and identify best practices.[79] Considerable socio-legal

[77] Twining W and Miers D, *How to Do Things With Rules* (5th edn, CUP 2010).
[78] Epstein L and King G, 'The Rules of Inference' (2002) 69 University of Chicago Law Review 1.
[79] For example, Deschênes M and Sallée C, 'Accountability in Population Biobanking: Comparative Approaches' (2007) 33 JLME 40.

research has also been dedicated to the extent to which donors and members of the public ought to be engaged in the governance of biobanks, given their altruistic donations and to adequately 'represent' their interests in the operation of the resource over time. In particular, Winickoff[80] and Hunter and Laurie[81] have debated how parties with 'interests' in UK Biobank ought to be represented or involved in the governance framework of UK Biobank. This debate will be particularly considered in this thesis to inform an understanding of the theoretical corporate governance[82] framework of UK Biobank and the potential of 'shareholder' versus 'stakeholder' approaches for UK Biobank governance.

However, hitherto, the existing biobanking scholarship has not engaged in a detailed analysis of the legal structure of UK Biobank as a charity corporation, and the extent to which this existing 'private' legal structure may operate in law to protect donor's interests and accommodate the 'public' dimensions of the resource. Such a study is all the more pertinent and pressing because outside the biobanking context, it has been observed that where there has been a reduction in public law accountability following corporatisation, there is prima facie a case for redressing this loss, whether by administrative law or other means.[83] In light of the range of legal structures open to UK Biobank, including the possibility of public statute, this thesis will analyse the avenues of accountability that exist within and outwith UK Biobank's dual legal basis as a charitable company to show the extent to which this legal structure, which was novel of its time, is sufficiently robust to achieve its public good mission and protect the interests of donors. By exploring some of the legal avenues that may be available in public and private law, this thesis contributes an original addition to the existing scholarship on UK Biobank by identifying novel legal avenues that may be pursued to strengthen legitimacy and accountability.

[80] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 449

[81] Andriof J, Waddock S, Husted B and Rahman R, *Unfolding Stakeholder Thinking: Theory, Responsibility and Engagement* (Greenleaf 2002), cited in Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C, *The Governance of Genetic Information: Who Decides?* (CUP 2009) 174.

[82] For an overview of the historical development of how corporations moved from laws of usury (broadly concerned with monetary loans) to laws of partnership see: Ireland P, 'Company Law and the Myth of Shareholder Ownership' (1999) 62 MLR 32.

[83] Vincent-Jones P, 'Citizen Redress in Public Contracting for Human Services' (2005) 68 Modern Law Review 887, 901.

This thesis also raises questions as to whether the charity company structure is still the most appropriate legal structure for UK Biobank as well as wider theoretical questions about the tensions and challenges of large-scale organisations established with public objectives and a private legal architecture. In so doing, this thesis informs the debate as to how best to link private legal structures, including biobanks such as UK Biobank Ltd,[84] with the general public and society, and contributes to a growing debate as to the evolving role of corporations in society today.[85] This debate considers the potentially 'public' aspects of 'private' corporations, which may invite into their private law responsibilities a range of stricter 'public' standards.[86]

Thesis outline

The thesis is comprised of three parts: Part 1 sets UK Biobank in context, shows its contemporary significance and considers the ethical and legal challenges of population biobanking. Chapter 1 summarises the evolution of population biobanking and identifies the key ethical issues that are raised by these research resources and which has been the subject of extensive academic and policy debate. Chapter 2 analyses some of the comparable regulatory approaches that had been adopted to respond to such challenges at the time of UK Biobank's development. Chapter 3 considers the origins of UK Biobank and identifies the key motivations and drivers for a world-leading population biobank in the UK. The purpose of Part 1 is to inform and contextualise Part 2's analysis of the parameters of the legal structure of UK Biobank and the ways in which this structure operates to protect donors' interests and achieve public objectives.

In Part 2 of this thesis, Chapter 4 analyses UK Biobank's governance structure and the wider regulatory environment in which UK Biobank is embedded. Chapter 4 also identifies the 'private' legal structure of UK Biobank and highlights some of the potential difficulties in protecting the public mission of UK Biobank and the private

[84] But also noting the establishment of Genomics England a company wholly owned by the Department of Health: Genomics England 'About' (Genomics England) <http://www.genomicsengland.co.uk/about-genomics-england/> accessed 24/01/2016

[85] Low C, 'A framework for the governance of social enterprise' (2006) 33 International Journal of Social Economics 376.

[86] Barker K, 'Private law: Key encounters with public law' in Barker K and Jensen D, *Private Law: Key Encounters with Public Law* (CUP 2013), 3; Gamble A and Thomas R, 'The Changing Context of Governance: Implications for Administration and Justice' In Alder M, *Administrative Justice in Context* (Hart 2010).

interests of the donors in the private model. Considering the ethical challenges discussed in Part 1 and analysis of the governance structure of UK Biobank in Chapter 4, Chapter 5 presents proposals that have been made in the socio-legal literature for increased donor and public involvement, to improve the existing UK Biobank governance model. These proposals are framed by theories of corporate governance, but arguably presuppose examination of the legal structure of UK Biobank as a corporation and the implications of this private structure for the interests at stake. Therefore, Chapter 6 critically analyses the legal structure of UK Biobank as a charity company, and avenues of accountability that arise by virtue of the dual legal basis of UK Biobank in UK charity and company law. Chapter 6 shows that although there are mechanisms to hold UK Biobank to its public good mission, these are complex and limited in scope, particularly in terms of protecting the private interests of UK Biobank donors and providing redress for any personal harm or loss suffered.

Part 3 explores in detail how a range of legal avenues within both private and public law may be available to assert these interests and hold UK Biobank to account. Chapter 7 uses the specific example of donors' private interests in the return of individual research findings to analyse the potential for redress in the private law of negligence. Chapter 8 analyses the applicability of public law to UK Biobank's legal structure and considers whether the discretion with which UK Biobank operates is 'public' for the purposes of judicial review. Together, Chapters 7 and 8 illustrate how UK Biobank's legal structure straddles the public/private divide in law and will raise questions as to the appropriateness of the divide in this context.

Part 1

Population biobanking: Ethical and legal challenges

Chapter 1: Biobanking: Scientific Opportunity and Ethical Challenges

1.1 Introduction

This chapter will situate this thesis' investigation into UK Biobank's legal structure in the broader, socio-legal context of biobanking and global science.

First, this chapter will describe the original scientific drivers behind the development of population biobanks, most significantly following the launch of the HGP in 1990. The HGP succeeded in mapping and sequencing the human genome (announced in 2003[87]) and as a result, it was widely accepted that further work was needed to capitalise on the new data generated by the project. There needed to be an improved understanding of how genetic material influences the workings of the body at a molecular level and the way that individuals are affected by the interaction between their genetics, their environment and lifestyle.[88] For meaningful results, large

[87] On 14 April 2003, the International Human Genome Consortium announced successful completion of the project: International Human Genome Sequencing Consortium, 'Finishing the Euchromatic Sequence of the Human Genome' (2004) 431 Nature 931.
[88] Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57).

prospective association studies were needed;[89] longitudinal collections of larger amounts of data which linked different types of data. As a result, biobanks (repositories of biological samples with accompanying linked data)[90] have progressed from small-scale repositories of samples used for specific and limited research purposes, to large–scale population biobanks created for a number of research purposes.

Next, this chapter will provide an overview of the ethical issues raised by population biobanks. In particular: how to protect the privacy of the individual's information that is gathered, stored and disseminated; how to protect and further donor's rights and interests in the collection, storage and use of their personal information and samples; and how to design a resource that is fit for purpose, and will sustainably benefit both public and private stakeholders.[91] In biobanking literature, extensive attention has been paid over the years to the ethical, legal and social implications of population biobanking. Challenges such as the nature, scope and adequacy of consent;[92] the importance of protecting privacy;[93] the impossibility of guaranteeing anonymity;[94] establishing and maintaining trust;[95] participant and public engagement;[96] and the inadequacy of existing legal mechanisms to accommodate some or any of these features,[97] have founded academic and policy debate. More recently, the possibility of returning research results to biobank participants has

[89] Professor Sir Rory Collins, 'Big Data in the UK Biobank: Opportunities and Challenges' (Gresham College Lecture, London, November 2014) <www.gresham.ac.uk/lectures-and-events/big-data-in-the-uk-biobank-opportunities-and-challenges> accessed 6 June 2015.
[90] Empirical research has demonstrated that there are differing definitions among biobank stakeholders: Shaw DM, Elger BS and Colledge F, 'What is a biobank? Differing definitions among biobank stakeholders' (2014) 85 Clin Genet 223.
[91] Including the general public: Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).
[92] Otlowski M, 'Developing an appropriate consent model for biobanks: in defence of 'broad' consent' in Kaye J and Stranger M (eds) *Principles and practice in biobank governance* (Ashgate 2009).
[93]Taylor MJ and Townend D, 'Issues in protecting privacy in medical research using genetic information and biobanking: the PRIVILEGED project' (2010) 10 Med Law Int 253; Schroder C, Heidtke KR, Zacherl N, Zatloukal K and Taupitz J, 'Safeguarding donors' personal rights and biobank autonomy in biobank networks: the CRIP privacy regime' (2010) 12 Cell Tissue Bank 233.
[94] Lowrance WW and Collins FS, 'Identifiability in genomic research' (2007) 317 Science 600.
[95] Sutrop M, 'Trust' in Hayry M, Chadwick R, Arnason V, Arnason G, (eds) *The ethics and governance of human genetic databases* (Cambridge University Press 2007) 190.
[96] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C, *The Governance of Genetic Information: Who Decides?* (CUP 2009).
[97] Gibbons SMC, 'Are UK genetic databases governed adequately?' (2007) 27 Leg Stud 312.

challenged biobanking practices.[98] And now, the challenges and opportunities raised by 'big data' i.e. data sets so large or complex that traditional data processing applications are inadequate, are dominating bioethical discussions.[99]

The final purpose of this chapter is to situate biobank development in the wider context of the globalisation of genomics research. Following the success of the HGP, human genomics research is becoming global and we are moving from a one researcher, one project and one jurisdiction approach,[100] to a complex, interdependent, collaborative research environment.[101] Researchers are now striving to share data and samples internationally.[102] Indeed, biobanks have been described as global goods.[103] However, existing legal regimes governing human subject research overlap and interact at a local, regional and international level. This can give rise to problems associated with data overflowing national boundaries, causing tension between national ethical preferences and international harmonisation goals. Therefore, a number of international consortiums are being established to harmonise standards and approaches to enable sharing between biobanks worldwide.[104]

Overall, population biobanks like UK Biobank are not fixed in any 'cultural or temporal way'[105] and this raises ongoing challenges to be understood, governed and in some cases, regulated. This chapter's introduction to biobanking is intended to provide background to Chapter 2's analysis of some of the models of biobank governance that were available at the time of UK Biobank's inception and which shaped UK Biobank's eventual model.

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[98] Wolf SM and others, 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets' (2012) 14 Genet Med 361.

[99] Professor Sir Rory Collins, 'Big Data in the UK Biobank: Opportunities and Challenges' (Gresham College Lecture, London, November 2014) <www.gresham.ac.uk/lectures-and-events/big-data-in-the-uk-biobank-opportunities-and-challenges> accessed 6 June 2015; Davies G, Frow E and Leonelli S, 'Bigger, faster, better? Rhetorics and practices of large-scale research in contemporary bioscience' (2013) 8 BioSocieties 386.

[100] Kaye J, 'From single biobanks to international networks: developing e-governance' (2011) 130 Hum Gen 377.

[101] World Health Organisation, Governance for Health in the 21st Century: a study conducted for the WHO Regional Office for Europe (WHO 2011) EUR/RC61/Inf.Doc./6.

[102] Bedard K, Wallace S, Lazor S and Knoppers BM, 'Potential Conflicts in Governance Mechanisms used in Population Biobanks' in Kaye J and Stranger M (eds) *Principles and practice in biobank governance* (Ashgate 2009).

[103] Ibid. Describing 'human genetic databases'; terminology which I will use interchangeably with 'biobank'.

[104] P3G (Public Population Project in Genomics). <http://www.p3g.org> accessed 15 October 2011

[105] O'Doherty KC, Burgess MM, Edwards K, Gallagher RP, Hawkins AK, Kaye J, McCaffrey V and Winickoff DE, 'From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks' (2011) 73 Social Science & Medicine 367.

1.2 Scientific Ambition: Human Genome Project success and a 'New Generation'[106] of Biobanking

> The completion of the mapping and sequencing of the human genome in 2001 was not the end of a project, but the beginning.[107]

On 14 March 2000 (then) President, Bill Clinton (US) and Prime Minister, Tony Blair (UK) announced their agreement to open access to the first draft of the human genome.[108] Widespread media coverage surrounded the race to sequence the first human genome between the public project led by John Sulston at the UK Wellcome Trust Sanger Institute, and the private project led by Craig Venter in the US. The success of the HGP means that the three billion chemical letters that make up an individual's DNA have been sequenced. Ultimately, this success has moved scientific research a step closer to predicting and preventing disease, rather than our historically curative approach to medicine.

Population biobanks like UK Biobank are heralded as a 'post-genome challenge' response to the success of the Human Genome Project (HGP). Biobanks have become increasingly popular as the primary means for translating genomic findings into practical health benefits. While the practice of researchers collecting information from subjects to understand their characteristics is certainly not new, the ability to analyse whole DNA sequences has opened important new possibilities for human genetics research and now technological advances have made it possible to create biobanks that contain more data, both genotypic and phenotypic, from more donors.[109] The meaning of 'biobank' has therefore expanded to include both traditional small-scale genomic resources and a 'new generation' of large-scale population biobanks. First generation biobanks have been utilised for many years,

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[106] Greely HT, 'The Uneasy Ethical Underpinnings of Large-Scale Genomic Biobanks' (2007) 8 Annu Rev Genomics Hum Genet 343.
[107] Einsiedel E, *Whose Gene, Whose Safe, How Safe? Publics' and Professionals' Views of Biobanks* (Canadian Biotechnology Advisory Committee 2003); Widdows H and Mullen C, *The Governance of Genetic Information: Who Decides?* (CUP 2009) 178.
[108] Wallace H, *Bioscience for Life?- Appendix A; The history of UK Biobank, electronic medical records in the NHS, and the proposal for data-sharing without consent* (Genewatch UK 2009) < www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/UK_Biobank_fin_2.pdf> accessed 31 Jan 2016, 26.
[109] Greely HT, 'The Uneasy Ethical Underpinnings of Large-Scale Genomic Biobanks' (2007) 8 Annu Rev Genomics Hum Genet 343.

but the 'new generation' biobanks have proliferated more recently.[110] Combined, it has been argued that biobanks have the potential to become key tools in personalised medicine.[111]

First generation genomic biobanks are comprised of research projects often looking at a particular health issue, for example breast cancer, aided by relevant biological samples including DNA collected from affected individuals and their family members.[112] Researchers establish long-term relationships with these individuals, whose interest in the research is clearly identifiable; donating in the hope that this research could provide useful knowledge for interventions for themselves or their relatives.[113] However, the first generation of biobank has limited uses because of the defined data collected within them, and its availability only to certain users.

On the other hand, the findings derived from the HGP have made clear that while many common diseases have some genetic component, only in a few cases do single genes seem to contribute strongly to disease risk. Even there, any strong genetic component is limited to a small percentage of those with the disease.[114] Furthermore, many life-threatening and disabling diseases are caused by many different exposures that might each have effects and interact with each other in complex ways.[115] To investigate these exposures, extensive information needs to be collected from donors via questionnaires and physical measurements, as well as by storing biological samples that allows many different types of assay (e.g. genetic, proteomic, metabonomic, or biochemical).[116]

Furthermore, recent technological progress in genotyping has meant that genome wide scans are no more expensive or time consuming than genotyping for a particular disease.[117] In the past, relatively inefficient and expensive genetic sequencing technologies limited researchers to targeted genetic research, focussing

[110] Gottweis H, Kaye J, Bignami F and others, *Biobanks for Europe; A Challenge for Governance* Luxembourg (European Commission, 2012) doi:10.2777/68942, 15.
[111] Hood L, Rowen L, Galas DJ and Aitchison JD, 'Systems biology at the Institute for Systems biology and the future of medicine' (2011) 3 Wiley Interdisciplinary Review of Systems Biology Medicine 619.
[112] Ibid.
[113] Ibid.
[114] Ibid. 346
[115] M Manolio TA, Bailey-Wilson JE and Collins FS, 'Genes, environment and the value of prospective cohort studies' (2006) 10 Nature Review Genetics 812.
[116] Collins R, 'What makes UK Biobank special?' (2012) 379 The Lancet 1173.
[117] Ibid.

only on the most promising genes or genomic regions, hence the first generation of biobanking. More recently, however, new next-generation sequencing technologies have 'broken through this data bottleneck.'[118] With these technologies rapidly advancing[119] and a $1000 genome recently announced,[120] researchers have begun to sequence whole genomes instead of targeted genetic analysis.[121] This has led to significant progress in identifying genes in common and genetically complex diseases ('susceptibility genes'), as well as facilitating dramatic progress in the development of testing for such conditions.[122]

Today, diverse conditions are being shown to have a genetic basis and genetic research has led to the identification of single gene diseases (for example Huntington's disease) and genetically complex diseases (like coronary heart disease and diabetes). The former are rarer and can more accurately be predicted by heritage. The latter, which affect a far greater number, are influenced by DNA sequence variation in conjunction with environmental factors and lifestyle.[123] Therefore, investigating the linkage between personal health information and genetic material has been the next step in genetic research. Population studies like UK Biobank are established to develop our understanding of this complex interplay, so that in the future it might be possible to prevent multifactorial disorders by tailoring one's lifestyle or avoiding environmental toxins. To deliver statistically meaningful and reliable results data from a large population is required[124] and accordingly, there is a need for larger biobanks with more donors, information and users.

Thus, the biobanking field is developing. There exists a range of different types of biobank that vary according to size, research design, funding, types of biological samples collected, the method of sample collection, processing and storage, and the

[118] Ibid.
[119] For example, DNA microarray technologies enable simultaneous measurements of hundreds of thousands of DNA molecules. This allows gene function to be characterised on a genome scale, as opposed to earlier methods that made measurements on and individual, gene-by-gene basis.
[120] Paul Rincon, 'Science enters the $1000 genome era' (*BBC News*) <www.bbc.co.uk/news/science-environment-25751958> accessed 25 Jan 2014.
[121] For example see the 100,000 Genome Project underway in England: <http://www.genomicsengland.co.uk/> accessed 5 February 2016
[122] Hall A, Finnegan T and Alberg C, *Realising Genomics in Clinical Practice* (PHG Foundation 2014) <www.phgfoundation.org/reports/16447/> accessed 06 Feb 2016
[123] Cirulli ET and Goldstein DB, 'Uncovering the roles of rare variants in common disease through whole-genome sequencing' (2010) 11 Nature Reviews Genetics 415
[124] Burton PR, Hansell AL, Fortier I and others, 'Size matters: just how big is BIG? Quantifying realistic sample size requirements for human genome epidemiology' (2009) 38 International Journal of Epidemiology 263.

research focus. Some biobanks are privately funded, others are established with government funding. Many biobanks will have a clear purpose and end point while others are open-ended. Indeed in some cases, governments and funding bodies have established and committed funding to population biobanks with the aim of using these as 'biorepositories' for unspecified research purposes.[125]

In terms of sample size, large-scale biobanks are generally used for prospective and longitudinal molecular epidemiology research projects. The main research objective of a population-based biobank is to discover biomarkers for disease susceptibility within a specific population through prospective molecular epidemiology research strategies.[126] These types of biobank recruit healthy participants who are representative of a region, country, or specific ethnic group.[127] Large-scale population biobanks like UK Biobank,[128] the Estonian Biobank[129] and deCODE associated Biobank[130] 'derive their scientific value from their massive size, capacity to aggregate specimens by various biological criteria, and ability to link the specimens with individual medical records.'[131] They present unique and challenging characteristics: they are diverse, both in terms of samples and structural approaches; inherently uncertain and designed to be open-ended, often giving rise to a tension between protection of participant interests and promotion of the resource; and temporal, in that benefits are only realised in the long term, requiring that the longevity of the biobank is ensured whilst at the same time remaining fit for purpose over time with respect to public and private interests at stake.[132]

Alternatively, disease-orientated biobanks store a heterogeneous collection of biological materials, usually collected during clinical care.[133] Biological materials found in such biobanks are usually collected from patients, and can lead to eventual re-sampling at follow up visits in the course of their disease treatment. An example

[125] Kaye J, 'From single biobanks to international networks: developing e-governance' (2011) 130 Hum Genet 377.
[126] Ibid.
[127] Gottweis H, Kaye J, Bignami F and others, *Biobanks for Europe; A Challenge for Governance* (European Commission, 2012) doi:10.2777/68942.
[128] <http://www.ukbiobank.ac.uk/> accessed 6 May 2015
[129] <http://www.geenivaramu.ee/en> accessed 6 May 2015
[130] <http://www.deCODE.com/> accessed 6 May 2015
[131] Rothstein M, 'Expanding the Ethical Analysis of Biobanks' (2005) 33 JLME 89, 99
[132] Laurie G, 'Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law' (2011) 130 Human Genetics 347.
[133] Gottweis H, Kaye J, Bignami F and others, *Biobanks for Europe; A Challenge for Governance* (European Commission, 2012) doi:10.2777/68942.

of a disease-orientated biobank is the PXE International biobank, which promotes research and supports individuals affected by pseudoxanthoma elasticum (PXE).[134] PXE is a non-profit foundation devoted to driving research on the rare tissue disorder. Case-control biobanks are collections of matched individuals with a given disease with compatible health controls and tissue banks which encompass diverse collections of tissue specimens, usually collected (with consent) by hospital pathology departments following medical procedures.[135]

In light of (or perhaps due to) the existence of such a range of types of biobanks, a recent study revealed that there is still uncertainty among biobankers themselves as to what exactly a biobank is.[136] In 2012, the European Commission described the characteristics of biobanks in their Report 'Biobanks for Europe:'[137]

> Biobanks typically: (a) collect and store biological materials that are annotated not only with medical but often also epidemiological data (e.g. environmental exposures, lifestyle/occupational information) (b) are not static 'projects', since biological materials and data are usually collected on a continuous or long-term basis; (c) are associated with current (defined) and/or future (not yet specified) research projects at the time of biospecimen collection; (d) apply coding or anonymisation to assure donor privacy but have, under specific conditions, provisions that participants remain re-identifiable in order to provide clinically relevant information back to the donor, and (e) include established governance structure (e.g. ethics review committees) and procedures (e.g. consent) that serve to protect donors' rights and stakeholder interests.

For the purpose of this thesis, biobanks are generally defined as:

> An organized collection of human biological material and associated information stored for one or more research purposes.[138]

More specifically, population biobanking is defined as:

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[134] <https://www.pxe.org/about-us> accessed 21 March 2015
[135] Gottweis H, Kaye J, Bignami F and others, *Biobanks for Europe; A Challenge for Governance* (European Commission, 2012) doi:10.2777/68942.
[136] Shaw DM, Elger BS and Colledge F, 'What is a biobank? Differing definitions among biobank stakeholders' (2014) 85 Clin Genet 223.
[137] Gottweis H, Kaye J, Bignami F and others, *Biobanks for Europe; A Challenge for Governance* (European Commission, 2012) doi:10.2777/68942.
[138] Definition of 'biobank/biorepository': P3G 'Biobank lexicon' (P3G) <http://p3g.org/biobank-lexicon> accessed 6 January 2016

> Collections of biological material and the associated data and information stored in an organized system for a population or a large subset of a population.[139]

1.3 Population biobanking: Ethical challenges

There is a wealth of literature, spanning a number of disciplines, which accepts and describes the many ethical challenges that are raised by population biobanking and an entire thesis could be dedicated to any one of them. For the purpose of this thesis and for the sake of brevity, an overview of the most prevalent challenges will be provided, including: consent and secondary research uses; privacy and confidentiality; ownership, intellectual property and commercialisation; data access and data sharing; public confidence and trust; participant engagement; and feedback of research results.

Large-scale population biobanks challenge ethical norms because they are more than individual research projects in which risk is evaluated in terms of a single research objective. They are research resources with the objective of multiple, population-wide benefits which are often described as being for the 'public good' or the 'health of future generations.' The challenge for biobank managers, therefore, is to identify ways of protecting the fundamental rights of the participants who provide their samples and access to their data, while fostering the public interest in carrying out lawful and ethical medical research that maximises access to the resource. Indeed, in order to remain operational and sustainable, biobanks depend not only on donors to participate but also on continual public, political and commercial support.

From the early stages of biobank development, the importance of trust has been recognised as having the power to considerably influence the progress and future success of biobanks.[140] Medical research scandals such as Alder Hey and more recently Care.data[141] (the centralisation of medical health records) are demonstrating that once trust is undermined it is incredibly difficult to regain. Therefore, public attitudes are of great importance and this is especially true in the constantly evolving

[139] OECD, 'Glossary of Statistical Terms' (OECD, July 23rd 2007) <https://stats.oecd.org/glossary/detail.asp?ID=7220> accessed 08th Feb 2016.
[140] Tutton R, Kaye J and Hoeyer K, 'Governing UK Biobank: the importance of ensuring public trust.' (2004) 22 Trends Biotechnol 284.
[141] Nature Editorial, 'Careless.data' (2014) 507 Nature 7.

field of genomics and biobanking.[142] Research involving human genetics has been seen as problematic by those claiming that human genetic material is exceptional, compared to other health related material. So-called 'genetic exceptionalism' is based on characteristics such as its predictability, identifiability and the implications genetic information may have for others, including family and social groups.[143] Early studies of public perceptions of biobanks demonstrated such concern.[144] However, it is notable that recent evidence shows that public attitudes recognise the value of genomic data, suggesting genetic exceptionalism is an increasingly out-dated view.[145]

Biobanks also challenge legal norms because of the combined nature of the material that is stored, which has been distinguished as 'corporeal' (donated physical samples) and 'informational' (health data). All medical data in the UK is perceived as being sensitive compared to other personal data.[146] Yet, a complex regulatory environment[147] is created in the UK by separate legislation of human tissue specimens and health information.[148] The implications of this for the regulation of population biobanks in the UK will be explored in Chapter 4 of this thesis.

1.3.1 Privacy

Different conceptions of privacy have been articulated in the context of biobanking. It has come to be accepted that biobanks raise a number of privacy concerns, including fear of misuse of personal information, stigmatisation of groups and unjustified intrusion into private life.[149] Four interrelated dimensions of privacy interests in biobanks have been articulated: (i) physical privacy (ii) informational

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[142] Gottweis H, Kaye J, Bignami F and others, *Biobanks for Europe; A Challenge for Governance* Luxembourg (European Commission, 2012) doi:10.2777/68942.
[143] Gibbons S and others, 'Governing Genetic Databases: Challenges Facing Research Regulation and Practice' (2007) 34 Journal of Law and Society 175.
[144] Nelkin D and Lindee M, *The DNA Mystique: The gene as a cultural icon* (WH Freeman 1995); cited in Levitt M and Weldon S, 'A well placed trust?: Public perceptions of DNA databases.' (2005) 15 Critical Public Health 314.
[145]'When we asked patients and families how much they want to know about their genetic information their immediate reaction was that whatever information the researchers or clinicians found out, they wanted to know too,' Alastair Kent OBE, Director of Genetic Alliance, in: Middleton A and others, 'Attitudes of nearly 7000 health professionals, genomic researchers and publics toward the return of incidental results from sequencing research' (2016) 24 European Journal Human Genetics 21.
[146] Data Protection Act 1998, s 2.
[147] Brownsword R, Yeung K, (eds) *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart 2008).
[148] Explained in Chapter 4 of this thesis
[149] Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315, 316

privacy (iii) decisional privacy and (iv) proprietary privacy.[150] Respect for privacy has led to consensus that individuals have the freedom to consent to participate as a biobank donor and not to have their samples gathered and tested without their consent at the recruitment stage (physical privacy); the right to have their specimens sufficiently anonymised to prevent unauthorised identification and to protect confidentiality (informational privacy); the right to withdraw if and when they wish;[151] an interest in controlling or influencing what is done with the resource made up of their samples and data (decisional privacy); and finally, an interest in the control of our genetic identity to protect against discrimination (proprietary privacy).[152]

It has been argued that the concept of privacy has expanded as technological innovations have made public what was previously out of the public view.[153] This has led different approaches as to where the balance should be struck between public and private interests in biobanking. As we have seen, biobanks vary according to type, size and research focus etc., and often research is conducted into diseases that affect particular groups of a population. Indeed, the assumption that privacy relates primarily to personal forms of identity is challenged in certain circumstances, and this has been argued to be the case in the context of genetics research where information about one's DNA may have implications for family members and even communities.

The concept of solidarity has been used as a moral basis to further the interests of an individual or a group that results from social cohesion. Writing in the context of bioethics, Prainsack and Buyx describe the act of solidarity as signifying:

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[150] Results from Privileged project: <http://www.privileged.group.shef.ac.uk/> cited in Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315, 316
Townend D, Taylor MJ, Wright J and Wickins-Drazilova D, 'Privacy and Access: Privacy Interests in Biobanking: A Preliminary View on a European Perspective,' in J Kaye and M Stranger (eds), *Principles and Practice in Biobank Governance* (Ashgate, 2009).

[151] Gertz R, 'Withdrawing from participating in a biobank---a comparative study' (2008) 15 Eur J Health Law 381.

[152] Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315, 316

[153] Santosuosso A, 'Should Privacy Be Abolished in Genetics and Biobanking?' in Pascuzzi G, Izzo U and Macilotti M (eds), *Comparative Issues in the Governance of Research Biobanks: Property, Privacy, Intellectual Property, and the Role of Technology* (Springer 2013).

> Shared practices reflecting a collective commitment to carry 'costs' (financial, social, emotional, or otherwise) to assist others.[154]

Solidarity has been proposed as a moral basis for biobanking; whereby solidarity 'is the default social norm from which individuals retain the entitlement to withdraw, rather than as a moral obligation from which they may be released only exceptionally'.[155] As Chapter 2 will demonstrate, this approach has been adopted in the context of population biobanking, and underpinned the Icelandic model for population biobanking.

One technical solution for biobanks to uphold individual privacy has been to enhance confidentiality by removing personal identifiers as a means of guaranteeing a high level of privacy at an individual level, while enabling sharing of data for research. Data can be de-identified on a number of levels. Anonymisation refers to the process of irreversibly de-identifying data, whereas pseudonymisation refers to the separation of identifiers from encrypted or key-coded data. Data can be made anonymous if all information capable of identifying the individual to whom the data relates is removed and destroyed, and therefore re-contact of the individual is impossible. Data can be encoded if a serial number or other code is attached to data and a key to this is held elsewhere. Encoded data might be effectively anonymous to the research team working on it because they do not hold the master list linking the serial numbers to the personal identifiers. However, the data would not be truly anonymous because someone would be able to link the two. Finally, encryption turns data into strings of numbers or letters. Only someone with the key can decipher the record itself. The latter processes pseudonymise the data.

In some cases, such as in the field of biobanking research, it is not desirable or indeed possible to fully anonymise data if the biobank is to be useful to researchers. This is true in the case of population biobanks that are designed to contain and link a number of different types of information over a long period of time, which often involves re-contact and where cross-border research is desirable. Therefore, the more practicable and commonplace threshold in biobanking is pseudonymisation, rather

[154] Prainsack B and Buyx A, 'Solidarity in Contemporary Bioethics – Towards A New Approach' (2012) 26 Bioethics 346.
[155] Ibid.

than full anonymisation.[156] This technical solution is then combined with participant consent and rules relating to data access to uphold individual privacy. Indeed, an 'either/or' approach to consent and technical data protection solutions has been argued to be insufficient to protect the privacy interests of donors' in research.[157]

1.3.2 Consent

Consent operates to protect autonomous participant's privacy interests in biobanking. However, consent alone would not ensure that all of the interests of the participants are protected and biobanks require additional policies for ethical data access to prevent misuse of an individual's data. The importance of obtaining consent of research participants able to give it is stressed at both international and national level, and is one of the fundamental principles of ethical research.[158] Typically, to be legally valid, consent must be freely given and fully informed.[159] Strict adherence to bioethical protocols would require that research participants re-consent to every individual use of their tissue sample or personal data. This is because the World Medical Association's Helsinki Declaration states:

> In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail.[160]

However, one of the most controversial aspects of population biobanking has been the use of broad consent, i.e. consenting to undefined future research uses of donations,[161] rather than the more conventional informed consent. Crucially, biobanks depend on people volunteering to give up their genetic material, but members of the public will only do this if they have confidence that their material

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[156] Briceño Moraia L, Kaye J, Tasse AM and others, 'A Comparative Analysis of the Requirements for the Use of Data in Biobanks Based in Finland, Germany, the Netherlands, Norway, and the United Kingdom' (2014) 14 Med Law Int 187.
[157] Dove T, Laurie G, 'Consent and anonymisation: beware binary constructions' (2015) 350 BMJ http://dx.doi.org/10.1136/bmj.h1139; Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315.
[158] World Medical Association, *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects* (WMA 1964, Helsinki, Latest revision Fortaleza, 2013).
[159] Mental Capacity Act 2005
[160] World Medical Association, *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects* (WMA 1964, Helsinki, Latest revision Fortaleza, 2013).
[161] Caulfield T and Kaye J, 'Broad consent in biobanking: reflections on seemingly insurmountable dilemmas' (2009) 10 Med Law Int 85.

will not be used in a manner contrary to their interests now or into the future. One way to solve this is for participants to give consent on very narrow grounds, which is common practice for small-scale, first generation biobanks. Generally, these smaller projects have a specific research purpose and participants are provided with detailed information about the uses of their donated material at the time of consent. Quite often research is conducted into conditions that the participants and/or their family are affected by, and so to an extent participants may personally benefit from their own donation. In these circumstances, consent can be classed as 'informed' because involvement is dependent upon voluntary, expressed consent based on information about the research proposal. Therefore, individual autonomy is respected.[162]

On the other hand, narrow consent in large-scale biobanking would prevent many desirable uses of collected materials, not least because many beneficial uses of population biobanks are not anticipated at the point at which material and consent is taken. Secondary research uses would be prohibited without re-consent to every use of their sample/data, which would be very time consuming, expensive, and an inefficient use of resources.[163] So the alternative is to give broad consent, in confidence that arrangements will be made to ensure that material will not be put to uses that participants would regard as improper. Such broad consent has been accepted as being ethically valid, but only if additional oversight is in place to decide on the acceptability of new propositions for study resources;[164] and to ensure the safety of personal information and uphold an individual's right to withdraw.

Re-consent has been identified as a means to enable participants to make decisions about their participation in biobanking, but generally is only required if there is a change in protocol or to confirm participant expectations in case of change. [165] There have also been proposals for more 'dynamic' consent procedures; to provide mechanisms for informing participants about the uses of their data and to allow participants to set preferences of research uses, thereby facilitating ongoing

[162] Wallace SE, Gourna EG, Laurie G, Shoush O and Wright J, 'Respecting Autonomy Over Time: Policy and Empirical Evidence on Re-Consent in Longitudinal Biomedical Reasearch' [2015] Bioethics DOI: 10.1111/bioe.12165.
[163] Greely HT, 'The Uneasy Ethical Underpinnings of Large-Scale Genomic Biobanks' (2007) 8 Annu Rev Genomics Hum Genet 343.
[164] Wallace SE, Gourna EG, Laurie G, Shoush O and Wright J, 'Respecting Autonomy Over Time: Policy and Empirical Evidence on Re-Consent in Longitudinal Biomedical Reasearch' [2015] Bioethics DOI: 10.1111/bioe.12165.
[165] Ibid.

engagement should they so choose.[166] These procedures could also facilitate feedback of research results that are pertinent to a donor's health but which are not envisaged at the time of donation and are therefore not part of the consent process. Purported 'incidental' or 'individual' 'findings' or 'results' raise difficult ethical and legal questions and will be the topic of Chapter 7 of this thesis.

Therefore, building biobank governance mechanisms that outline data access policies and procedure, communicate the purpose of the project, and describe the procedure of the day-to-day running of the resource, has been a means of further protecting individual interests.[167] This is especially the case in the UK, where there exists no specific legal framework for the regulation of biobanking, as will be described.

1.3.3 Data access

Because population biobanks are longitudinal resources often designed for unspecified research purposes, this gives rise to a number of issues associated with who gets access to the contents of the resource:

> The central question is whether access necessarily and unjustifiably compromises privacy interests or whether it can be compatible with robust privacy protection.[168]

This is especially true in the case of biobanks that contain both samples (which may be depleted) and associated data, because the risk of individual identification and possible privacy breaches are heightened when data and samples are combined.[169] Where biobanks are committed to the public interest, it is crucial that procedures are put in place that facilitate ethical and lawful access to the resource to ensure that this purpose is furthered. While consent and confidentiality processes like anonymisation

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[166] Steinsbekk KS, Myskja BK and Solberg B, 'Broad consent versus dynamic consent in biobank research: is passive participation an ethical problem?' (2013) 21 European Journal of Human Genetics 897; Williams H, Spencer K, Sanders C, Lund D, Whitley EA, Kaye J and Dixon WG, 'Dynamic consent: a possible solution to improve patient confidence and trust in how electronic patient records are used in medical research' (2015) 3 JMIR Med Inform e3; Kaye J, Whitley EA, Lund D, Morrison M, Teare H and Melham K, 'Dynamic consent: A patient interface for twenty-first century research networks' (2014) 23 Eur J Hum Genet 141.

[167] Although it has been argued that 'responsive autonomy' should be promoted: encouraging donors to take responsibility to engage in and feedback to the donor community and researchers, for genuine sharing of information and power for the duration of the project: Wallace SE, Gourna EG, Laurie G, Shoush O and Wright J, 'Respecting Autonomy Over Time: Policy and Empirical Evidence on Re-Consent in Longitudinal Biomedical Research' [2015] Bioethics, 8. DOI: 10.1111/bioe.12165.

[168] Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315, 319

[169] Malin B, Loukides G, Benitez K and Clayton EW, 'Identifiability in biobanks: models, measures, and mitigation strategies' (2011) 130 Human Genetics 383.

operate to protect privacy interests and mitigate an individual's loss of control over their information and samples, data access procedures are necessary to maximise 'bona fide' research that is in the interests of the public, the participant and the scientific community using the resource.[170] Once access is accepted to be in the public interest, the priority for biobanking is how to share data rather than whether data should be shared at all.[171]

Data access committees and data access policies have been used as mechanisms for the promotion of ethical and lawful research access to biobanks.[172] Expert data access committees may be established to review access applications in an accountable and transparent way. Data access policies can be drafted to outline the access requirements of the biobank, including criteria for researcher's proposals, affiliations and purposes. Such policies will vary between biobanks, for example depending on whether the biobank will be accessible by private commercial companies, or only non-profit researchers. If successfully granted access, researchers must then typically agree to conditions of use, which are often contained in contractual or Material Transfer Agreements (MTA). Guiding principles such as necessity and proportionality have also been put forward as a means of tempering access decisions, so for example, access should not be granted to identifiable data if appropriately anonymised access can serve just as well.[173]

Increasingly, 'open access' policies are becoming commonplace in publicly funded genomics research projects; with many funders requiring open access as a condition for funding.[174] Open access to data is believed to accelerate advances in science by making data freely available to all for the most efficient use of resources that are publicly funded. Several data generating projects now provide free access to data online, a movement arguably led by the Human Genome Project when the first

[170] Ibid.
[171] Kaye J, 'The Tension Between Data Sharing and the Protection of Privacy in Genomics Research' (2012) 13 Annu Rev Genomics Hum Genet 415.
[172] Fortin S, Pathmasiri S, Grintuch R and Deschenes M, '"Access Arrangements" for Biobanks: a fine line between facilitating and hindering collaboration' (2011) 14 Public Health Genomics 104.
[173] Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315.
[174] European Commission 'Open Services' (*European Commission, Research and Innovation*) <http://ec.europa.eu/research/swafs/index.cfm?pg=policy&lib=science> accessed 29 March 2015 Also, UK Biobank is called 'an open access resource' in: Allen NE, Sudlow C, Peakman T and Collins R, 'UK Biobank Data: Come and Get It' (2014) 6 Sci Transl Med 224ed4.

human genome sequence was uploaded for open access in 2003.[175] However, it is rarer for projects that contain identifiable personal information to be open access, with aggregate level data more readily available to all.[176]

There is also a growing acceptance that the merits of biobanking will only be fully realised if resources can 'link up and learn from each other, ideally on a global scale.'[177] In the biobanking literature there has been a shift in focus from identification of the ethical challenges raised by biobanks towards recognition of common principles for the development of best practice guidelines, to expedite effective global data-sharing.[178] This development represents a response to problems associated with cross-border sharing of data, principally the restrictions that are caused by national, uncoordinated policies.[179] As a result, a number of international networks are being established to harmonise standards and approaches to enable sharing between biobanks worldwide.[180]

The Publics Population Project (P3G) is a not-for-profit international consortium that provides the international population genomics community with easy access to the expertise, resources, innovative tools and most up-to-date information from all areas of public population genomics.[181] It aims to promote collaboration between members of the international research community to advance knowledge transfer for health of

[175] On the other hand, 'Restricted access policies' don't provide access to individual level data unless certain criteria is met, for example the Wellcome Trust Case Control Consortium have developed data release policies to control access such that researchers must establish their credentials before they are allowed access to information that could potentially identify research donors: Wellcome Trust Case Control Consortium <http://www.wtccc.org.uk/> accessed 10 May 2015

[176] Kaye J and others, 'Data Sharing in Genomics – Reshaping Scientific Practice' (2009) 10 Nat Rev Genet 331.

[177] Laurie G, 'Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law' (2011) 130 Human Genetics 347, 349; Walport M and Brest P, 'Sharing research data to improve public health' (2011) 377 The Lancet 537; Cambon-Thomsen A, Rial Sebbag E, Knoppers BM, 'Trends in ethical and legal frameworks for the use of human biobanks' (2007) 30 ERJ 373.

[178] O'Doherty and others, 'From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks.' (2011) 73 Social Science & Medicine 367; Laurie G, 'Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law' (2011) 130 Hum Genet 347; Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440; Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).

[179] Briceño Moraia L, Kaye J, Tasse AM and others, 'A Comparative Analysis of the Requirements for the Use of Data in Biobanks Based in Finland, Germany, the Netherlands, Norway, and the United Kingdom' (2014) 14 Med Law Int 187.

[180] P3G <http://www.p3g.org> accessed 15 October 2011

[181] Ibid.

populations.[182] P3G works with biobankers and other experts from around the world to 'Encourage collaboration between researchers and biobankers; Promote harmonization of information; Optimize the design, set-up and research activities of population-based biobanks; Facilitate the transfer of knowledge and provide training to those working in the field.'[183] The consortium advocates a 'Charter of Fundamental Principles' to be integrated by member biobanks, which underpin P3G activities. These include promotion of the common good, responsibility to protect the interests of affected stakeholders, mutual respect for cultural diversity and scientific specificity, accountability and proportionality.[184] There is also an international collaborative effort to establish a data sharing code of conduct for international genomic research[185] and the European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) is a collaboration of key European biobanks who are developing governance structures for biobank networks.[186]

1.3.4 Property, ownership and commercialisation

Inherent to the challenges of privacy and data access raised by biobanks are questions of ownership and commercialisation. When a sample is given for purely research purposes, the question arises as to whether the donor of the sample has any continuing interest in that sample. This process is embroiled in ethical and legal debate as to whether there is 'property' in the human body and if so, who has the 'right' to this 'property'.[187] The status and meaning of human tissue, and the relationship between the providers and users of tissues, has been the focus of ethical, legal and sociological debate and the emergence of population genetic databases has problematized this further because of its increased scientific and commercial value in this context.[188]

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[182] Ibid.
[183] Ibid.
[184] Ibid.
[185] Knoppers BM and others, 'Towards a data sharing Code of Conduct for international genomic research' (2011) 3 Genome Medicine 46, 1.
[186] BBMRI-ERIC (Biobanking and BioMolecular resources Research Infrastructure) <http://bbmri-eric.eu/> accessed 20 January 2016
[187] It is well enshrined in UK law that there is no 'property' in the human body, as will be explained in Chapter 4 of this thesis.
[188] Tutton R 'Person, property and gift: exploring languages of tissue donation to biomedical research' in Tutton R and Corrigan O (eds), Genetic Databases: Socio-ethical issues in the collection and use of DNA (Routledge 2004).

One view is to treat samples as an unconditional gift. Theoretically, this entitles the recipient to do what they wish with the sample, in the same way as the recipient of an ordinary gift may use the gift as they wish. In this view, DNA gifted to a researcher could be subjected to whatever processes the researcher chooses to employ. It has been argued that the discourse of 'gift-giving' has been a powerful means of inspiring altruism in participants to provide their samples and enrol in biobank projects.[189] In so doing, institutions seek 'to bring participants into social relationships by emphasising their common purpose in seeing improvements to human health.'[190] This language of gift giving has been used by those who resist the alternative; commodification of the human body, which is argued to be the case if property rights are recognised in the body, to represent a non-exploitative relationship between the providers and users of the tissue:

> [O]ur sense of dignity of humanity is fundamentally disturbed by the suggestion that which bears the marks of personhood can somehow be equated with property.[191]

Parts of the body that bear 'marks of personhood' are those seen to be 'central to what characterises living persons, members of the community' and these include blood or organs that 'our social traditions suggest… may be given, but not sold'. 'Gift-giving' is therefore viewed as the only acceptable way for such parts of the body to be transferred because it accords respect for the dignity of the person involved.[192] Gift-giving is also seen as altruistic in nature; expressing a sense of community or solidarity and performed to benefit the greater social good.[193] In biobanking, gift-giving is important to promote participation in the face of public

[189] Ibid.
[190] Ibid.
[191] Ibid.19
[192] Ibid. Citing Holland S, 'Contested commodities at both ends of life: buying and selling gametes, embryos, and body tissues' (2001) 11 Kennedy Institute of Ethics Journal 263.
Titmuss has contributed to this understanding of gift giving; Titmuss examined the policies of blood and viewed the donation of blood as 'one of the most sensitive social indicators which, within the limits is measurable, and one which tells us something about the quality of human relationships and of human values prevailing in society: Titmuss R, *The Gift Relationship, From Human Blood to Social Policy* (George Allen and Unwin 1970) cited in Tutton R 'Person, property and gift: exploring languages of tissue donation to biomedical research' in Tutton R and Corrigan O (eds), Genetic Databases: Socio-ethical issues in the collection and use of DNA (Routledge 2004).
[193] Nelkin D and Andrews L, 'Homo economicus: commercialisation of body tissue in the age of biotechnology' (1998) 28 Hasting's Centre Report 30. In Tutton R, 'Person, property and gift' in Tutton R, Corrigan O, (eds) *Genetic Databases: Socio-ethical issues in the collection and use of DNA* (Routledge 2004) 20.

spending on the infrastructure which relies entirely on participants being willing to volunteer.

Therefore, biobanks are 'reanimating old ethical dilemmas about the marketization of persons' and Winickoff articulates the crucial ethical challenge:

> How can societies negotiate the desire to incentivise private capital to construct mega-experimental apparatus of genomic biobanks to help drive knowledge and economy forward, even as they remain deeply concerned about the penetration of markets into the personal domains of genome and body, health, and personhood?[194]

In response, there has been a focus in legal and ethical literature on the practical solutions for biobanks; focussing on how to remedy this potential inequity of interests and ensure that biobanks are sustainable in the long term. For some, this requires recognition that participants may have limited property rights in their tissue, such that they are entitled to control how their tissue is used. Some of these solutions will be reflected upon at the end of this thesis as potential models for biobank governance. They include Winickoff's own 'Charitable Trust Model', as well as other models of benefit sharing with research donors (for example by contract, regulation, taxation and ethical standards to remedy problems of distributive justice)[195] and models for participant involvement and engagement in biobanking such as the 'Stakeholder Model' proposed by Hunter and Laurie.

Researchers are also under pressure to commercialise and translate their work and funding agencies create and reinforce this commercialisation pressure by earmarking grants of projects that aim to bring products and therapies to the market within a short amount of time. This commercialisation process creates a range of policy challenges for scientists, research participants and funders.[196] It has been argued, 'It is not unreasonable to view the overall purpose of biobanks as being to enable the development of translational outcomes which are intended to benefit patients.

[194] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440.
[195] Bovenberg J, 'Whose tissue is it anyway?' (2005) 29 Nature Biotechnology 929.
[196] Caulfield T and others, 'A review of the key issues associated with the commercialisation of biobanks' (2014) 1 Journal of Law and the Biosciences 94. The authors pose the question: What problems would introduction of private funds to publically funded biobanks cause? They argue that commercialisation will particularly and uniquely impact publicly supported biobanks, as they consider various means, including private partnerships, to ensure financial security.

Indeed, many biobanks have such an explicit aim.'[197] Since biobanks are used for research, 'it is therefore intended, and likely, that a biobank will be used by others to develop useful innovations.'[198] When research gives rise to an innovation, then that invention could potentially be patentable. A patent is a limited monopoly that is granted in return for the disclosure of technical information. For innovation to be patentable, it must satisfy a number of criteria. Patents are available for inventions in the form of products, processes or methods. The invention must be novel,[199] non-obvious or inventive[200] and susceptible to industrial application.[201]

It has been argued that the patent system reflects an implicit social contract, which balances private and public interests. Private interests are served through the grant of a limited monopoly right, which provides the incentive for further invention, investment in research and development. The public interest is served through the development of innovative products and through disclosure of technical knowledge.[202]

However, academics such as Winickoff argue a double standard currently governs the commercialisation of biological materials. This is because although intellectual property law allows researchers to capitalise on their contributions to a research enterprise, it denies donors of biological materials the right to compensation for their contributions. This is especially so given that it is arguable that value is added to the participants' human tissue as soon as it is combined, gathered, stored and used.[203] Challenges of ownership and commercialisation are therefore embroiled with how a biobank resource is set up and funded and the purpose for which the biobank was created. If a biobank is 'public' (in its funding and its purpose) then it is arguable that the benefit sharing model ought to reflect this. Alternatively, if a biobank is privately funded, private use may not necessarily be against the interests of the

[197] Hawkins N, 'Intellectual Property and Biobanks' in Mascalzoni D, *Ethics, Law and Governance of Biobanking: National, European and International Approaches* (Springer 2015), 39
[198] Ibid. 40
[199] European Patent Convention 1973, Art 54; *Synthon BV v Smithkline Beecham Plc* (No 2), [2005] UKHL 59, [2006] RPC 10.
[200]Ibid. Art 56; *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] UKHL 49, [2008] RPC 28.
[201] Hawkins N, 'Intellectual Property and Biobanks' in Mascalzoni D, *Ethics, Law and Governance of Biobanking: National, European and International Approaches* (Springer 2015), 59
[202] Hawkins N, 'Intellectual Property and Biobanks' in Mascalzoni D, *Ethics, Law and Governance of Biobanking: National, European and International Approaches* (Springer 2015), 59
[203] Which Winickoff recognises as 'biocapital': Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440.

participants or indeed, the public. In this sense, obvious support from public funding entities for population biobanks does not prevent 'concerns [which] remain about the long term financial sustainability of biobanks.' Population biobanks are expensive ventures and 'hence, 'biobankers' are looking increasingly to private funding sources and links with industry. This strategy has the potential to add further ethical and legal complexities to the many policy challenges that are associated with biobanks.[204]

1.3.5 Public and private interests in biobanking research

Population biobanks are often set up expressly to promote the public interest, which in this context has been submitted to be 'to create resources of genetic material and information and to promote access by a range of as-yet unknown parties.'[205]

There exists no single definition of 'the public interest', as recently articulated by the Nuffield Council on Bioethics.[206] Philosophers have debated how to identify the proper objects of the public interest, such as Bentham's utilitarian aggregation of individual private preferences.[207] Social contract theory advocated by Hobbes and Rawls recognises certain 'public goods' for which the State is responsible for securing, in exchange for limits to the free pursuit of individual interests.[208]

On the other hand, lawyers often focus on the procedural elements of the public interest[209] including transparency in how public interest decisions are made and clear lines of accountability for responsible decision-making.[210]

In the context of medical research the public interest has been articulated as 'securing objectives that are valued by society.'[211] As well as protecting the private interests of individuals who donate to biobanks, it has also been argued that there is a

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[204] Caulfield T and others, 'A review of the key issues associated with the commercialisation of biobanks' 2014 Journal of Law and the Biosciences.
[205] Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315, 316
[206] Nuffield Council on Bioethics, *The collection, linking and use of data in biomedical research and health care: ethical issues* (Nuffield Council 2015) < http://nuffieldbioethics.org/project/biological-health-data/> accessed 5 Feb 2016.
[207] Ibid. 54
[208] Ibid.
[209] Taylor MJ, 'Health Research, Data Protection and the Public Interest in Notification' (2011) 19 MLR 267.
[210] Daniels M, 'Accountability for reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles' (2000) 321 BMJ 1300.
[211] Ibid.

public interest in both protecting the privacy of individuals and promoting scientifically sound and ethically robust health research.[212] Arguably this means that in the context of medical research, research conducted by commercial, private actors need not necessarily be excluded to uphold the public interest in privacy protection. Therefore, the fundamental challenge for biobanks is how to uphold participant privacy while at the same time furthering the public's interest in maximising research use of the biobank resource.

While the public interest is not necessarily the opposite of a private right to privacy, the two may come into conflict with each other and the challenge will often be to reconcile the relationship between the two.[213] In the context of human rights, the public interest refers to the need for a balance of considerations rather than a substantive definition. This interaction is exemplified in Article 8 of the HRA, whereby the right to a private and family life is recognised as a fundamental human right, but this right is subject to 'proportionate and lawful restrictions'. As such, individual rights and freedoms ought to be considered first and if these are found to be engaged then the onus is on State authorities to justify any interfering actions 'as necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.'[214] Substantively, it is necessary to balance the potential for public good relative to the risks and costs for individuals and society.[215]

1.4 Global science and biobanks

Population biobanks have emerged in the context of the globalisation of scientific and genomic research. In 2002 the International Ethics Committee of the Human Genome Organisation (HUGO) stated that human genomic databases should be

[212] Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315, 316: The SHIP Principle of the public interest recognises the public interests in protecting both the privacy of individuals *and* promoting scientifically sound and ethically robust health research: Information Governance Working Group, *SHIP Guiding Principles and Best Practices* (SHIP 2010) <www.scot-ship.ac.uk/sites/default/files/Reports/Guiding_Principles_and_Best_Practices_221010.pdf> accessed 24 Jan 2014.
[213] Nuffield Council on Bioethics, *The collection, linking and use of data in biomedical research and health care: ethical issues* (Nuffield Council 2015) < http://nuffieldbioethics.org/project/biological-health-data/> accessed 05 Feb 2016.
[214] European Convention on Human Rights, Article 8(2).
[215] Ibid.

considered as global public goods,[216] the latter defined as: goods 'whose scope extends worldwide, are enjoyable by all with no groups excluded, and when consumed by one individual, are not depleted for others.'[217]

In 2011, the World Health Organisation (WHO) Regional Office for Europe commissioned a study on governance for health in the 21st Century that suggests that the main changes which are taking place in governance are also manifesting in relation to health and are crucial for achieving health gains in the decade to come.[218] The study focuses on how governance for health and wellbeing is evolving to meet these new challenges and circumstances of the 21st Century, what is driving the change in how states and society govern for health, and how governments can take steps to enact smarter governance for health through collaboration.[219] In this context, governance for health is the 'attempts of governments and others to steer communities, whole countries or groups of countries in the pursuit of health and well-being as a collective goal.'[220] The summary states that many of the challenges 'reflect the seminal shift from industrial to knowledge based societies.'[221]

Emerging academic analysis highlights that this global goal cannot be realised if diversity of practice methods and governance is too great.[222] As information overflows national boundaries, problems may arise where national positions vary. Tensions may surface between necessary diversity in ethical positions and common principles and procedures to manage these challenges to foster research[223] to the detriment of the population. The issue of governing 'new' genetic technologies such as large-scale population biobanks is inevitably approached differently at the national or societal level, according to the values and jurisprudence of the societies in question.

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[216] Human Genome Organisation (HUGO), 'Ethics Committee: Statement on human genomic databases' 2002 14 J Int Bioethique 207.
[217] Ibid. The Wellcome Trust, 'Summary of Principles Agreed Upon at the First International Strategy Meeting on Human Genome Sequencing' (Wellcome Trust 1996) <http://web.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml#1> accessed 24 Jan 2014.
[218] World Health Organisation, *Governance for Health in the 21st Century: a study conducted for the WHO Regional Office for Europe* (WHO 2011) EUR/RC61/Inf.Doc./6.
[219] Ibid. 1
[220] Ibid.
[221] Ibid. vi
[222] Kaye J, 'From single biobanks to international networks: developing e-governance' (2011) 130 Hum Genet 377.
[223] Knoppers BM and others, 'Towards a data sharing Code of Conduct for international genomic research' (2011) 3 Genome Medicine 46.

However, the regulatory regimes that govern this type of research overlap and interact at a local, regional and international level. This can give rise to problems associated with data overflowing national boundaries, causing tension between national ethical preferences and international harmonisation goals. A global understanding of science means that it may not always be appropriate to 'control' research with national or international regulation. Indeed, existing regulatory instruments are often perceived as complex hurdles obstructing progress.[224] Accordingly, 'governance'[225] regimes are challenged to move away from a strictly governmental approach to one in which a variety of regulatory activities are undertaken by numerous and differently placed actors.[226] Instead of hierarchical, detailed and compartmentalised control, governance regimes must evolve and adapt according to challenges of time, space and culture.

1.5 Conclusion

Population biobanks raise a range of ethical challenges that need to be managed if a biobank is to achieve its objectives and succeed. This chapter has provided an overview of the challenges pertinent to those involved in the biobanking process including researchers, participants and biobank managers. The crucial challenge is to manage these diverse interests in a way that is consistent with their expectations and the purpose of the biobank to inspire and maintain trust. As will be shown in the next chapter, there is no singular method and a range of models have emerged according to the type of biobank concerned.

To capitalise on the scientific promise of population biobanks and overcome the range of ethical issues that have been outlined in this chapter, the UK faced the challenge of structuring and governing a biobank resource in a lawful manner that was financially viable and inspired public trust to secure participation and ensure sustainability. Historically, the Icelandic national database was a catalyst for national and international debate of these challenges and the national biobank of Estonia has encountered and managed many of the same issues. Together, these comparative

[224] Ibid.
[225] Graham J, Amos B and Plumptre T, *Principles of good governance in the 21st Century—Policy Brief No. 15* (Institute on Governance 2003) <http://unpan1.un.org/intradoc/groups/public/documents/UNPAN/UNPAN011842.pdf> accessed 31 January 2016.
[226] Lyall C and Tait J (eds), *New Modes of Governance; developing an Integrated Policy Approach to Science, Technology, Risk and the Environment* (Ashgate 2005).

experiences show the technical, political and cultural environment in which biobanks are embedded and illustrate how ultimately, the sustainability and success of these particular biobanks depended on more than their legal frameworks; even more crucial were their business models.

Chapter 2: Governance of population biobanks: Comparative perspectives and lessons learned from public-private partnerships in Iceland and Estonia

2.1 Introduction

Population biobanks in both Iceland and Estonia were established with public and private funds between 1996 and 2000, sustained with public-private partnerships and regulated by purpose-designed national legislation.

The Act on Health Sector Database created for the Icelandic Health Sector Database granted an exclusive licence over the resource to a private, for-profit company; deCODE Genetics (deCODE). This company originally proposed the idea of a biobank and actively negotiated with the Icelandic government to set up a database to collect medical records from the entire Icelandic population. Following strong opposition from The Iceland Medical Association and later hurdles posed by the Icelandic Supreme Court and Icelandic Data Protection Commission, deCODE abandoned the national database and instead refocused on a bank of genotypic and

detailed medical data that could be obtained from a significant number of volunteers. This project is now funded (following a number of periods of bankruptcy) by US biotechnology for-profit giant Amgen.

In Estonia, while the Human Genes Research Act was passed for Gene Bank, the Estonian Ministry of Social Affairs established the Estonian Genome Project Foundation to co-ordinate and govern 'Gene Bank'. This Foundation created a private company EGeen Ltd and granted the company a 25-year exclusive commercial licence to form a public-private partnership between the Foundation and the company to finance and commercialise the results of the Estonian Genome Project. Later, the Human Genes Research Act was amended to transform the Estonian Genome Project into the Estonian Genome Centre of the University of Tartu (EGCUT) in 2007. Now, following a period of bankruptcy, the Estonian Government provides the core funding for the Estonian Biobank at the EGCUT.[227]

This chapter will discuss the evolution of these biobanks, paying attention to the differences between their institutional designs and the challenges they have encountered. The history and development of these biobanks will be outlined and discussion will focus on their mission and organisational structure. Attention will also be paid to the roles of stakeholders including funders, government, committees/review boards, participants and researchers, and how their positions are reflected in the structure and operation of the resource. Crucially, both biobanks have encountered challenges and controversies relating to their financing models. This is because population biobanks require stable and significant financial investment to establish and maintain such large-scale infrastructures.[228] Indeed, it has come to be accepted that to be sustainable, biobank governance needs to develop a strategy for

[227] Metspalu A and others, 'Cohort Profile: Estonian Biobank of the Estonian Genome Centre, University of Tartu' (2014) 1 International Journal of Epidemiology 11.

[228] Gottweis H and Lauss G, 'Biobank governance: heterogeneous modes of ordering and democratization' (2012) 3 Journal of Community Genetics (2012) 61, 66:
'To set up a biobank and to keep it, operating tends to be costly. They swallow up large amounts of money for the costs of the facility, storage expenses, and personnel alone, and these costs run over long periods of time. Such expenses do not support research as such but finance research infrastructures and tools of research; such costs are not easily carried by research funding bodies, universities, or other funding sources, such as research ministries, which tend to fund basic or applied research directly. Thus, any biobank needs to have a solid financing model that provides for both its initial setup and its operation over time. It also needs to fit into the national innovation system and its characteristics, such as the availability of venture capital, or the structure of the pharmaceutical industry. Biobank governance thus needs to develop a strategy for how to link the research network of a biobank to the worlds of potential supporters and funders.'

how to link the research of a biobank to worldwide funding and access.[229] These measures are necessary to prevent the fate of biobanks such as Singapore which closed in 2011 after failing to be used enough to be financially viable.[230]

Overall, this chapter will raise the fundamental questions faced by the UK when creating UK Biobank, in particular:

1. How to structure the resource to overcome the ethical challenges of population biobanking;
2. How to fund these expensive, national resources.

Consequently, this chapter will highlight themes of public/private interests in biobanking and public/private biobank models. These themes underpin the narrative of this thesis' investigation into the legal implications of UK Biobank's public-private model of governance. In addition, this chapter will illustrate the importance of the judiciary in the development of norms in genomics. In many ways, the Icelandic Supreme Court ruling in *Guðmundsdóttir v Iceland*[231] prompts investigation in Part 3 of this thesis into the potential jurisprudential consequences of UK Biobank legal structure.

2.2 Iceland: A global lesson for biobanks and genomics

> Iceland is a small island in the North Atlantic which was inhabited between the years 870 and 930 A.D., mostly by Norwegian entrepreneurs and Irish slaves. The year 1000 A.D. [sic], the population was around 70,000 but around the year 1410 A.D. the Plague had reduced it down to approximately 30,000. The population had again grown to about 70,000 when at 1700 A.D. Hekla, the most powerful volcano in the history of Europe, spew lava and ash all over Iceland, which led to a famine that reduced the population again down to approximately 30,000.[232]

[229] Ibid.
[230] Chan TW, 'The Closure of the National Bio-bank in Singapore' (2012) 16 Asia-Pacific Biotech News Journal 40.
[231] *Gudmundsdottir v State of Iceland* (Icelandic Supreme Court) No. 151/2003.
[232] Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80.

2.2.1 Privatising the Icelandic Health Sector Database

With a small population (270, 000) that is almost entirely derived from the original settlers, Icelanders are argued to be a genetically homogeneous people.[233] They display a strong founder effect, so by following genetic markers, it is believed to be possible to trace a common origin of a large proportion of them.[234] Partly due to this belief, which was used as an incentive by organisers, and the corresponding potential for identifying genetic factors in disease, Iceland was the first country in the world to plan a national database for population genetics research. While the Icelandic Health Sector Database is widely known in the field, this is despite the fact that the planned national database was never actually created. Instead, what operates today is a genomic biobank owned exclusively by US incorporated for-profit company deCODE Genetics. In short, what was originally intended to be a State-built database of health information on the entire population of Iceland for wide-reaching research purposes is now a smaller-scale privately run biobank established for genomic research.

The development and 'legacy' of Iceland's biobank has been well narrated by David Winickoff[235] and the story of deCODE is still evolving. deCODE has now conducted whole genome sequencing of 2,636 individuals; a little less than 1% of the Icelandic population. Indeed, on March 25 2015, deCODE Genetics published four papers in *Nature Genetics* which presented the largest set of human genomes from one population, together with findings to date.[236] In this sense, Iceland is at the forefront of genomics research, despite a history filled with ethical, legal and political controversy that has shaped consensus and informed biobank governance on an international scale.

The idea of an Icelandic Health Sector Database (HSD) was posed and led by deCODE Genetics; a US incorporated for-profit company. deCODE was founded in

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[233] Ibid.

[234] Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80.

[235] Ibid. Winickoff conducted field work in Iceland in 2000 and 2003 supported by the Programme on Science, Technology and Society at Harvard University; subsequent publications include Winickoff DE, 'A Bold Experiment: Iceland's Genomic Venture' in Mascalzoni D (ed), *Ethics, Law and Governance of Biobanking* (Springer 2015) 187.

[236] Allison Proffitt 'deCODE Publishes Largest Human Genome Population Study' (*Bio IT World*, 25 March 2015) <http://www.bio-itworld.com/2015/3/25/deCODE-publishes-largest-human-genome-population-study.html> accessed 13 June 2015

1996 by Karl Stefansson.[237] deCODE's headquarters are in Reykjavik, although 5 out of 7 Board members are from the US.[238] From 1996-1998 deCODE, led by Stefansson, actively negotiated with the Icelandic government to set up the HSD. But this was one of two of deCODE Genetics' main objectives.

Their first objective was to establish a commercial laboratory to carry out biomedical research in Iceland, with headquarters in Reykjavík, which would seek to collaborate with clinicians and pharmaceutical companies to develop new DNA diagnostic tests and drugs. At the time of the HSD lobbying, deCODE was already collaborating with local doctors to collect DNA samples from consenting individuals suffering from particular diseases. Before the HSD, medical records in Iceland were not accessible in the public domain and so access relied on hospitals and clinics to transfer their data to deCODE with independent ethics committee review. By September 1999 the company had collected samples from over 10,000 people with full written consent, and through this work the company created a large database of DNA and genealogical information. [239]

deCODE's second, more ambitious aim, was to construct the Genetics, Genealogy, Phenotype Resource database which would comprise of encrypted medical records of the entire Icelandic population and later became the Health Sector Database.[240] There was no specific legislation in operation at the time that governed such an endeavour and consequently the Icelandic government passed the Act on Health Sector Database, which gave deCODE the sole right to exploit the database commercially for a period of 12 years,[241] in return for a fee paid to the public health service sector.[242]

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[237] Iceland's model of biobanking has been articulated as an example of an 'entrepreneurial model' because of its public-private partnership led by Karl Stefansson, rather than being created by government funding: Gottweis H and Lauss G, 'Biobank governance: heterogeneous modes of ordering and democratization' (2012) 3 Journal of Community Genetics (2012) 61.

[238] Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80.

[239] Martin P and Kaye J, *The Use of Biological Sample Collections and Personal Medical Information in Human Genetics Research* (The Wellcome Trust 1999) <www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtd003283.pdf> accessed 31 January 2016.

[240] Rose H, 'The Commodification of Bioinformation: The Icelandic Health Sector Database' (The Wellcome Trust 2001) 9-10 <http://www.wellcome.ac.uk/About-us/Publications/Reports/Biomedical-ethics/WTD003280.htm> accessed 18 July 2014.

[241] Martin P and Kaye J, *The Use of Biological Sample Collections and Personal Medical Information in Human Genetics Research* (The Wellcome Trust 1999)

Throughout negotiations for the creation of the database, Stefansson painted his 'genomic vision' by emphasising Iceland's heritage, which he argued gave Iceland an advantage for discovering new genetic factors for disease:

> First and foremost was the idea that Icelanders were a genetically homogenous people because of their historic isolation… Second was the existence in Iceland of intricate and detailed genealogical records. In its early business plans, Stefansson touted the existence of a lineage database for 100 per cent of Icelanders back to 1910 and 85 per cent of Icelanders back to 1800. He explained that this record of lineage would make it 'relatively easy to determine relationships between participants or subjects in genetics studies done in Iceland.' A third foundational claim was the existence of high-quality medical records dating back to the 1920s, many of which were 'centralized and accessible.' Hence, the business plan explained, 'it is relatively easy to find a match between genotypes of Icelanders and whatever genetic traits are reflected in their diseases or health.'[243]

Stefansson argued that if all three resources: Icelanders' DNA; genealogies; and the phenotypic data could be linked together, it would create a uniquely powerful tool for conducting genetic linkage studies as well as allelic association studies.[244] This idea enticed investors and Stefansson initially raised $12 million in U.S. venture capital and $25 million from Icelandic Institutional investors. In February 1998, deCODE reached agreement with Hoffman-La Roche for rights and discoveries derived from deCODE's existing work for approximately $200 million.[245]

With financial interest secured, Stefansson could finance the creation of the database, providing the Iceland's Parliament passed legislation to realise his vision. Stefansson emphasised the economic value of the resource that had been demonstrated by US investment, in addition to arguments based on Iceland's homogenous culture and rich history:

<www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtd003283.pdf> accessed 31 Jan 2016.

[242] Gottweis H and Lauss G, 'Biobank governance: heterogeneous modes of ordering and democratization' (2012) 3 Journal of Community Genetics (2012) 61

[243] Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80, 84-85

[244] Ibid. 85

[245] Ibid. 86

> …deCODE's rhetoric addressed the central political problem of survival itself: how could such a remote island society best leverage its natural and social resources to remain a viable sovereign nation in the global order?[246]

Arguably, this was an early example of a common motivation for establishing national biobanks. For many countries including Estonia and the UK, but also non-western countries such as Singapore, population biobanks have been seen as opportunities to boost a country's economy by making them more internationally competitive.[247] To some extent, this investment has been based on the belief that population biobanks will help translate biomedical research into practice (Chapter 1). In reality, due to the expense of sustaining these large-scale projects the long-term viability of population biobanks is increasingly being questioned in light of examples of under-utilisation.[248]

2.2.2 Establishing and dismantling a legal framework: The Health Sector Database Act

In December 1998, Iceland's national Parliament (the 'Althing') passed the Health Sector Database Act (HSDA).[249] This Act provided the necessary legal framework for the operation of a centralised database containing non-personally identifiable health data from the medical records of virtually all Icelanders.[250] The Act authorised the transfer of citizen health information that was to be controlled by the state and governed by the requirements of Iceland's Data Protection Commission[251] by licence to private industry, for the creation and operation a for-profit national database.[252] Article 10 of the Act grants the licensee the right to use the data for 'purposes of financial profit.' According to Article 5(9) of the Act, the licence was to be

[246] Ibid. 88
[247] Chan TW, 'The Closure of the National Bio-bank in Singapore' (2012) 16 Asia-Pacific Biotech News Journal 40; Chang A, 'National Biobank to Close' (04th June 2011) The Straits Times S.D6-7; Fan CT, Lin JC and Lee CH, 'Taiwan Biobank: a project aiming to aid Taiwan's transition into a biomedical island' (2008) 9 Pharmacogenomics 235.
[248] Scudellari M, 'Biobank managers bemoan underuse of collected samples' (2013) Nature Medicine 19, 253; Chalmers D and Others,'Has the biobank bubble burst? Withstanding the challenges for sustainable biobanking in the digital era' (forthcoming)
[249] Act on a Health Sector Database (HSDA), No. 139/1998
[250] Arnardottir O and others, 'The Icelandic Health Sector Database' (1999) 6 European Journal of Health 307.
[251] Created by Act on the Protection of Privacy as regards the Processing of Personal Data (Data Protection Act), No. 77/2000
[252] Article 10 HSDA grants the licensee the right to use the data for 'purposes of financial profit'

temporary and would not be extended for more than 12 years.[253] deCODE Genetics were granted the licence, 'but this was *fait accompli*'[254] since deCODE had initiated the drafting of the Bill, which went through two drafts before passing.[255]

The scope of the HSDA was defined in Article 2;[256] it only applied to the collection of medical data for the HSD. The HSDA regulates data, primarily 'non personally identifiable data,'[257] in contrast to the Biobanks Act No. 110/2000,[258] which governs the collection, storage, handling and use of human biological samples[259] in all Icelandic biobanks.[260] The HSDA also stated that the health service database was not to be transported out of Iceland and that the processing of the database was also to be strictly only carried out in Iceland.[261]

Most controversially, the HSDA authorised the transfer of all medical record data to deCODE Genetics for commercial development without the express consent of individuals and relying on a rule of 'presumed consent'. Individuals had six months from the construction of the database to 'opt-out' but information on deceased individuals was to be automatically included. However, the Act did attempt to protect privacy in a number of ways compared to the first draft of the Bill, which had not included this six-month opt-out period. The Act did not allow direct access to the database or information it contained to third parties, required information to be processed in ways that could not be linked to identifiable individuals, and contained

[253] Article 5(9) HSDA
[254] Winickoff DE, 'A Bold Experiment: Iceland's Genomic Venture' in Mascalzoni D (ed), *Ethics, Law and Governance of Biobanking* (Springer 2015) 187.
[255] By a vote of 37 to 20, with 6 abstentions. The first draft of the bill was submitted in March 1998 and the second version was introduced in June of the same year with a number of changes, including the option to opt out up to 6 months after the construction of the database. The second version of the bill was enacted in December 1998. Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80, 82
[256] Article 2 states: 'This legislation extends to the creation and operation of a centralised health sector database. The legislation does not apply to the medical record systems of individual health and research institutions, data collections made in connection with scientific research into individual diseases or groups of diseases, nor to records kept by health and social security authorities on users of the health service and operation of the health service. The legislation does not apply to the storage or handling of, or access to, biological samples.
[257] Article 1 HSDA.
[258] Biobanks Act, No. 110/2000 (Iceland) As amended by Act No. 27/2008 and Act No. 48/2009; Gibbons SMC, 'Are UK genetic databases governed adequately?' (2007) 27 Leg Stud 312.
[259] Article 1 Biobanks Act, No. 110/2000.
[260] However, while the HSDA was silent on biological samples, DNA and genealogical records, deCODE's intention to link the health data with genetic information were apparently widely known: Gibbons SMC, 'Are UK genetic databases governed adequately?' (2007) 27 Leg Stud 312
[261] Article 10, HSDA.

penalties for negligent disclosure of information and violations of the act, the licence, or government regulations under the HSDA.[262]

Winickoff has analysed the legal and ethical implications of the licence, particularly the property and ownership implications of the Act which 'imposed a new regime of control of Icelandic medical records.'[263] He suggests that procedurally the licence 'sever[ed] the ability of doctors to prevent their health institutions from handing over patient medical data without their authorisation.' Instead, the directors of health institutions would be empowered to negotiate all transfer of information without review by independent ethics committees[264] (which was previously protocol). Although Notes to the Bill stated that Icelandic health records could not be subject to ownership 'in the usual sense,'[265] the government claimed power to provide access to the medical information and licence it for commercial use and 'access, use, and control are nothing but the traditional components of property.'[266] For Winickoff, the public-private model for the biobank created 'biocapital' in the collection of data and samples that was capable of being 'owned' by the state. Consequently, granting rights of ownership to deCODE, a for-profit company, gave rise to an ethical tension that ultimately undermined the database entirely.

The HSDA sparked national and international debate as to the appropriate ethical and legal framework for the collection of citizen health information and the commercial undertone of the Act, coupled with inadequate technological security measures and the 'opt-out' consent model, caused outcry amongst patient organisations. The Icelandic Medical Association publicly opposed the Act, and activist groups such as 'Mannverd' – 'Association of Icelanders for Ethics in Science

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[262] Gibbons SMC, 'Are UK genetic databases governed adequately?' (2007) 27 Leg Stud 312, 317

[263] Winickoff DE, 'A Bold Experiment: Iceland's Genomic Venture' in Mascalzoni D (ed), *Ethics, Law and Governance of Biobanking* (Springer 2015) 187.

[264] Article 7, HSDA.

[265] Bill on a Health Sector Database (Submitted to Parliament at 123rd Session, 1998-1999): '[due] to the nature of the data and their origin [Icelandic health records] cannot be subject to ownership in the usual sense. Institutions, companies or individual cannot therefore own the data [because t]hey exist primarily due to the treatment of patients.' Cited in Winickoff DE, 'A Bold Experiment: Iceland's Genomic Venture' in Mascalzoni D (ed), *Ethics, Law and Governance of Biobanking* (Springer 2015) 187, 190

[266] Winickoff argues: 'In effect, the state reduces the complex web of legal interests around the medical data by cutting off the doctors, and asserts the power to license, a property interest (Winickoff 2003)'. Citing Winickoff DE, 'Governing population genomics: law bioethics, and biopolitics in three case studies' (2003) 43 Jurimetrics 187. For more general discussion of the notion of property, see Chapter 1 of this thesis.

and Medicine'[267] argued that the Act threatened the confidentiality and human rights of Icelanders based on the Helsinki Declaration and the Nuremberg Code. Despite opposition the Act passed; 'largely because of its demonstrated ability to raise investment capital, and the power of its economic promises.'[268] However, the database was never created.

In 2003 the Supreme Court of Iceland ruled in *Guðmundsdóttir v Iceland* [269] that the HSD Act was unconstitutional. Guðmundsdóttir brought a claim to exclude her deceased father's clinical record from the database. Previously, the Medical Director of Health denied her request on the basis of the Notes on the Bill, which had stated that it was not the legislative intent to allow children to opt-out their deceased parents.[270] Guðmundsdóttir was then denied legal standing by the Icelandic District Court in 2001 on the grounds that the information in the database was not personally identifying, dismissing her assertion that she had a personal interest in preventing the transfer because it was possible to infer information from the data which could also apply to herself. The Icelandic Supreme Court reversed the decision of the lower court on the issue of standing and personal privacy interests on the grounds that the technology for the database (one way encryption) did not ensure data anonymity.[271] The Court held that:

> It is unequivocal that the provisions of Paragraph 1 of Article 71 of the Constitution – the provision that 'everyone shall enjoy freedom from interference with privacy, home, and family life'[272] – apply to information of this kind and… guarantee protection of privacy in this respect.[273]

The ruling occurred against a backdrop of emerging consensus on a national and international level that consent of patients was necessary in this context. The HSDA 'trigger[ed] a small explosion of international scrutiny and criticism' which

[267] 'Mann Vernd' <http://www.mannvernd.is/> accessed 14 June 2015
[268] Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80.
[269] *Gudmundsdottir v State of Iceland* (Icelandic Supreme Court) No. 151/2003
[270] Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80, 95
[271] Meyer M, 'Icelandic Supreme Court holds that inclusion of an individual's genetic information in a national database infringes on the privacy interests of his child' (2004) 118 Harvard Law Review 810.
[272] Constitution of The Republic of Iceland (No.33, 17 June 1944 as amended 30 May 1984, 31 May 1991, 28 June 1995 and 24June 1999), Art 71.
[273] *Gudmundsdottir v State of Iceland* (Icelandic Supreme Court) No. 151/2003

culminated in the World Medical Association declaring that it stood 'fully behind the position taken by the Icelandic Medical Association in opposing the Icelandic Healthcare Database legislation recently passed by the Icelandic Parliament,' stressing the need to safeguard the 'integrity of patient data and to have open access to all scientific data.'[274] Ultimately this debate undermined and caused the downfall of the database.[275]

2.2.3 Regulating and financing deCODE today

After the *Guðmundsdóttir* ruling, deCODE refocused their strategy on their original aim: collecting and building a research database of clinical and genetic information collected with informed consent from volunteers of the Icelandic population.[276] In addition, a number of spin-out companies have consequently been established alongside deCODE, including most recently WuXI NextCODE (discussed further in due course).

To date, deCODE Genetics has gathered genotypic and medical data from over 160,000 volunteers.[277] deCODE operates from their headquarters in Reykjavík, meaning deCODE's activities are governed by Icelandic law. Because deCODE processes personal information about participants, their activities are regulated by Law No. 77/2000 (as amended) on the Protection of Privacy, which applies to any electronic processing of personal data.[278] Under this Act, information about the health of individuals including genotype information is considered sensitive personal data[279] and the Data Protection Authority is responsible for monitoring the application of the Act.

Although deCODE Genetics continues to operate there have been significant obstacles in their path with implications for the biobank resource. In particular, deCODE has persisted through financial difficulties; in November 2009 the company

[274] Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80, 91
[275] Ibid. 81
[276] deCODE 'Research' <http://www.deCODE.com/research/> accessed 14 June 2015
[277] Although it has been noted that deCODE's approach to obtaining consent for their genetic research projects was problematic and it is not entirely clear if it is still the same: French J, 'Something is Rotten in the State of Iceland: deCODE Genetics, Population Research and Informed Consent' in Rimmer M, *Patent Law and Biological Inventions* (Elgar 2006).
[278] Act on the Protection of Privacy as regards the Processing of Personal Data (Data Protection Act), No. 77/2000.
[279] Ibid. Article 2(8)(c).

filed for bankruptcy in the US with debts of $313.9 million. deCODE had promoted and sold its shares to the public in Iceland before offering them worldwide and their bankruptcy led to large investment losses for members of the Icelandic public. In fact, deCODE's bankruptcy occurred after Iceland's own financial crisis and bankruptcy in October 2008 which resulted in a $2.1 billion loan by the International Monetary Fund in November of the same year. [280] In December 2012 US biotechnology private company Amgen purchased the company for $415 million[281] and deCODE is now an entirely private Amgen subsidiary.[282] In so doing, deCODE's biobank has 'clearly… become a 'private asset'' [283] and the sale has enabled the company to pursue various spin-off opportunities.

Prior to this sale, deCODE had been offering direct-to-consumer (DTC) genetic testing kits through their business 'deCODEme' to generate more immediate profit returns. The deCODEme Complete Scan covered 47 conditions and traits and cost around $1000. However, other DTC companies such as 23andMe seemingly out priced deCODEme and the tests are no longer available. [284] Now, deCODE's strategy will focus on using whole genome sequencing to understand common diseases and human variation:[285]

> 'One of the ways to truly realize the full value of human genetics, is to make our research synergistic with drug development efforts where target discovery, validation and prioritization efforts can be accelerated,' said Kari Stefansson, M.D., Dr. Med., founder and CEO at deCODE Genetics. 'We believe Amgen's focus and

[280] For more detail see: Winickoff DE, 'A Bold Experiment: Iceland's Genomic Venture' in Mascalzoni D (ed), *Ethics, Law and Governance of Biobanking* (Springer 2015) 187.
[281] BioSpace 'Amgen (AMGN) Bags Gene-Hunting Firm deCODE genetics, Inc. (DCGN) for $415 Million Cash' (12 October 2012) <http://www.biospace.com/News/amgen-bags-gene-hunting-firm-deCODE-genetics-inc/281726> accessed 14 June 2015
[282] Kaiser J, 'Agency Nixes deCODE's New Data Mining Plan' (2013) 340 Science 1389.
[283] Winickoff DE, 'A Bold Experiment: Iceland's Genomic Venture' in Mascalzoni D (ed), *Ethics, Law and Governance of Biobanking* (Springer 2015) 187, 188
[284]An Amgen spokesperson stated: 'Amgen does not intend to continue offering genomic screening tests to the public and healthcare providers. This is not a core part of Amgen's business interest in deCODE…' GenomeWeb 'With deCODE Purchase, Amgen Gains Genetics Expertise, Consumers Lose DTC Testing Option' (12 December 2012) <https://www.genomeweb.com/clinical-genomics/deCODE-purchase-amgen-gains-genetics-expertise-consumers-lose-dtc-testing-option> accessed 26 June 2015
[285] There are significant commercialisation advantages for Amgen having deCODE headquarters located in Iceland, including the more favourable patenting rules.

> ability to incorporate our genetic research into their research and development efforts will translate our discoveries into meaningful therapies for patients.'[286]

In October 2013 former deCODE executives launched NextCODE Health; a spin-out subsidiary private company with a five year licence with Amgen to deCODE's platform. NextCODE focusses on using deCODE's bioinformatics platform and genetic database for clinical genome analysis to develop diagnostics services in the clinical setting.[287] According to their own website, deCODE claim to have used the genotypic and medical data they have collected to put together a genealogy database covering the 'entire present day population and stretching back to the founding of the country more than 1000 years ago.'[288] NextCODE offer genome interpretation, data analysis and next-generation clinical sequencing services to enable researchers and clinicians to more quickly, accurately and cheaply decipher whole genome sequence data and diagnose conditions.[289] NextCODE have also developed the 'NextCODE Exchange'; an internet-based system that allows genomic data to be shared instantly across the globe. This year, NextCODE was sold to Chinese pharma company, WuXi PharmaTech, for 8.5 billion ISK ($65 million).[290]

In addition to financial uncertainty, deCODE has faced sustained challenges from the legal and ethical community. In May 2013, the Icelandic Data Protection Authority rejected a request from deCODE to allow it to apply computational methods to the country's genealogical records to estimate the genotypes of 280,000 Icelanders who had not previously agreed to take part in the company's research. This is an approach whereby the odds of an individual carrying a particular genetic variant are estimated without directly sequencing their DNA. deCODE had conducted whole genome sequencing of approximately 2,500 participants at the time of the challenge but wanted to use this approach to extend the data to many more, including the close relatives of the volunteers. deCODE argued that according to Article 9 of the Act, processing of sensitive personal data can be carried out in the interests of scientific

[286] BioSpace 'Amgen (AMGN) Bags Gene-Hunting Firm deCODE genetics, Inc. (DCGN) for $415 Million Cash' (12 October 2012) <http://www.biospace.com/News/amgen-bags-gene-hunting-firm-deCODE-genetics-inc/281726> accessed 14 June 2015
[287] WuxiNextCODE <http://www.nextcode.com/about-us/legacy-and-leadership/> accessed 3 July 2015
[288] deCODE genetics <http://www.deCODE.com/research/> accessed 28 June 2015
[289] Dorey E, 'NextCODE to mine Icelandic genetic wealth' (2014) 32 Nature Biotechnology 6.
[290] Xconomy Boston 'Second Exit for deCODE Investors as Spinout NextCODE Sold to WuXi' (9 January 2016) <http://www.xconomy.com/boston/2015/01/09/second-exit-for-deCODE-investors-as-spinout-nextcode-sold-to-wuxi/>accessed 3 July 2015

research without consent when the public interest of such research outweigh the privacy interests of the data subject. The Data Protection Authority refused and ruled that first deCODE had to obtain informed consent, according to Act No. 77/2000, Directive 95/46/EC (which Act No.77/2000 implements) and Article 6 European Convention on the Protection of Individuals with regard to the Automatic Processing of Personal Data.[291]

Even more recently, deCODE has attempted to recruit volunteers to give DNA samples by sending swab packs in the post together with information that couriers would collect the samples from willing participants. For every sample collected by the couriers (volunteers from Icelandic Search and Rescue (ICE-SAR)), deCODE offer a $20 donation to the charity. This has not been well received by those advocating group privacy rights, especially because of the shared nature of genetic information:

> They can fill in the missing gaps… deCODE has collected so much information that we might become the first nation to be genome sequenced. Now it becomes much more than asking questions about an individual's privacy – we are talking about group privacy… and whether we can be discriminated against as a member of that group.[292]

Despite ethical, legal and financial difficulties, it is evident that deCODE is producing significant scientific research findings and in this regard is a success.[293] On March 25 2015, deCODE announced that it had sequenced the genomes of 2,636 people from Iceland. They then culled data from genealogical records and other genetic sources to project the genetics of 101,584 more. A total of four studies were published online in Nature Genetics reporting many markers for common diseases such as Alzheimer's: 'Large-scale whole-genome sequencing of the Icelandic population;' 'Identification of a large set of rare complete human knockouts;' 'The Y-chromosome point mutation rate in humans;' and 'Loss-of-function variants in ABCA7 confer risk of Alzheimer's disease.' Stefansson has hailed deCODE as 'probably the most productive entity in human genetics in the entire world' and

[291]Which Iceland have signed and ratified (ratified on 25/3/1991): Council of Europe Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Treaty No.108); Data Protection Authority (Iceland) case no. 2012/1404.
[292] Ibid.
[293] Winickoff DE, 'A Bold Experiment: Iceland's Genomic Venture' in Mascalzoni D (ed), *Ethics, Law and Governance of Biobanking* (Springer 2015) 187, 188

maintains 'most Icelanders support our work'. [294] Stefansson even advocates this as a model for the future, including for the US Precision Medicine Initiative.[295]

Overall, the deCODE legacy demonstrates just how entrenched population biobanks are in science, technology, ethics, politics, culture and law. The downfall of the Icelandic National Database was an early and important regulatory lesson for population biobanks. Even though specific biobank legislation was enacted to govern Iceland's national database, the fact that the regulation provided an exclusive licence to a for-profit company to access individual's data using an opt-out model meant it was ultimately deemed unethical and unlawful by the national and international community. Despite starting as a 'unique blending of public and private: through an enabling statute and commercial license,' ultimately, 'this bold public-private experiment was a failure.'[296] Crucially, ethical challenges of consent, privacy and commercialisation in biobanking were illuminated, which no doubt informed the creation of Estonia's national biobank, as will now be analysed.

In particular, the themes that have emerged so far from the discussion of the Icelandic 'biobank' model, which include the choice of a regulatory mix of public and private ownership and control of the database by the Icelandic government and deCODE, as well as the public-private mixed financial model, will be explored in relation to the Estonian model. This analysis aims to identify commonalities and differences in the historical development of these international biobank examples, which may be informative for investigation into UK Biobank in the remaining chapters of this thesis.

2.3 Estonia

Much like the experience of Iceland, the historical development of the Estonian population biobank demonstrates how crucial financial models are for biobank sustainability and success. Despite a unique and forward thinking piece of biobank

[294] Karl Stefansson speaking to the BBC last year: Emma Jane Kirby, 'Iceland's DNA: The world's most precious genes?' (*BBC News*, 19 June 2014) <www.bbc.co.uk/news/magazine-27903831> accessed 31 Jan 2016. Karl Stefansson speaking to the BBC.
[295] Allison Proffitt 'deCODE Publishes Largest Human Genome Population Study' (*Bio IT World*, 25 March 2015) <http://www.bio-itworld.com/2015/3/25/deCODE-publishes-largest-human-genome-population-study.html> accessed 14 June 2015
[296] Winickoff DE, 'A Bold Experiment: Iceland's Genomic Venture' in Mascalzoni D (ed), *Ethics, Law and Governance of Biobanking* (Springer 2015) 187, 188

specific regulation, the Estonian government established the (then) Estonian Genome Project (EGP) with a public-private partnership model and predominately private funding. In December 2000, the Estonian Parliament passed the Human Genes Research Act (HGRA); a purpose built statute the primary purpose of which is to establish and govern the (then) EGP for a national population biobank. In 2007, the Estonian State funded 1.15 million euros, and 7.7 million euros were guaranteed for the years 2007-2009 to sustain the biobank, following the termination of private funding.[297] As of November 2009, the Estonian Genome Project became the Estonian Genome Centre, University of Tartu (EGCUT).[298]

Ultimately, this partnership highlighted the difference in priorities between public and private investors in genomics research and between short-term drug developments compared with research for long-term benefits for the general public. The Estonian experience also illustrates deeper ethical tensions about 'ownership' in research involving human material. Combined, these challenges led to the temporary collapse of the Project, which subsequently undermined the public trust in the Project and significantly hindered its progress. To date, the wholly public biobank has recruited only half of the 100,000 participants that it originally set out to recruit.[299] Thus, much like the Icelandic example, the evolution and organisation of the Estonian biobank is particularly interesting in terms of its choice of regulatory and financial model.

2.3.1 Organisational development of the Estonian Genome Project

The historical development of the EGP between 1999-2006 has been well narrated by Kattel and Suurna[300] and this chapter draws on the authors' analysis for this period.

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[297] Gottweis H and Lauss G, 'Biobank governance: heterogeneous modes of ordering and democratization' (2012) 3 Journal of Community Genetics (2012) 61

[298] For a recent, in depth review see Keis A, 'The Estonian Genome Centre, University of Tartu' in Mascalzoni D (ed) *Ethics, Law and Governance of Biobanking* (Springer 2015).
The Author is the Chairman of the Research Ethics Committee of the University of Tartu: <http://www.ut.ee/en/research-ethics-committee-university-tartu> accessed 05 June 2015

[299] Ibid.

[300] Research and Development Council (Estonia), 'Knowledge-based Estonia: Estonian Research and Development Strategy 2002-2006' (Research and Development Council, December 18 2001) <www.akadeemia.ee/_repository/File/ALUSDOKUD/Knowledge-basedEstonia.pdf> accessed 08th Feb 2016, cited in Keis A, 'The Estonian Genome Centre, University of Tartu' in Mascalzoni D, (ed) *Ethics, Law and Governance of Biobanking* (Springer 2015), 213.

The initiative for the EGP 'came very clearly from the scientists themselves.'[301] In January 1999, scientists from the University of Tartu and other scientists from Estonia formed the Estonian Genome Project Foundation (EGPF), which 'effectively became the organisation that started to work very actively in establishing a nationwide genetic database.'[302] The aim of the EGP was to create a database of health, genealogy and genome data from a large part of Estonia's population, to enable research into links between genes, environmental factors and common diseases and help new discoveries in genomics and epidemiology for increasing efficacy of health care in the future.[303]

Politically, though, the Project was 'positioned as a policy agenda that could play a key role in considerably strengthening the Estonian economy, creating an Estonian biotechnology industry and helping Estonia's 'return back' to Europe.'[304] According to initial plans in 2000, the EGP was intended to support existing entrepreneurship in the field of medical biotechnology, which is seen 'as one of the 'core technologies' in transforming Estonia into a knowledge-based economy'. For the public sector, the biobank combined aspirations of improving the general economic position of Estonia internationally and actively contributing to the 'reshaping of new, democratic, post-Soviet Estonia.'[305]

During the preparation phases of the Estonian Genome Project, 'two important ideas took shape: first, as the Human Genes Research Act would later state, the genetic database would, by the act of the government, be started as a foundation (a private legal entity); second, the financing of the database would come from both public and private sources.' The details of the financing of the database will be discussed in due course in this chapter, following an overview of the Act, which codified in an overriding single document the law for the governance of the (then) EGP to address

[301] Ibid.
[302] Ibid.
[303] Kattel R and Suurna M, 'The Rise and Fall of the Estonian Genome Project' (2008) 2 Studies in Ethics, Law, and Technology DOI: 10.2202/1941-6008.1050
[304] Eensaar R, 'Estonia: Ups and Downs of a biobank project' in Gottweis H and Petersen A, *Biobanks: Governance in comparative perspective* (Routledge 2008).
[305] Ibid.

the ethical challenges of biobanking that have been discussed in Chapter 1 of this thesis.[306]

2.3.2 The Human Genes Research Act

The idea of an EGP was first publicised in 1999 following a series of interviews with scientists from the EGPF. Around a year later, Parliament 'without any significant discussions internally or within the media'[307] passed the Human Genes Research Act in December 2000.[308] The HGRA established the necessary institutional and organizational framework of the EGP to regulate the establishment and maintenance of an Estonian 'Gene Bank' and to organise genetic research thereof. At the same time, the Act aimed to ensure the voluntary nature of gene donation and confidentiality of their donation and ensure protection from misuse of genetic data and genetic discrimination.[309] Today, an updated version of this same Act regulates the EGCUT, although the procedures of the EGCUT must also be in conjunction with Estonia's Data Protection Act and the Public Information Act.[310]

According to s 1(2) of the Act, the following are provided for in the HGRA:

> 1) The conditions for processing tissue samples, descriptions of DNA, descriptions of state of health and genealogies in the Gene Bank;
>
> 2) The rights and obligations of gene donors, the chief processor and authorised processors of the Gene Bank and genetic researchers relating to tissue samples, descriptions of DNA, descriptions of state of health and genealogies;
>
> 3) The conditions for the establishment and maintenance of the Gene Bank;
>
> 4) The restrictions on the use of tissue samples, descriptions of DNA, descriptions of state of health and genealogies collected in the Gene Bank;

[306] For Gibbons, 'by following such a 'hard law' approach, relying almost entirely on legislation, Estonian law makers were able to fashion an innovative, purpose-centred approach and abandon legal distinction between tissue and data in the genetic database: Gibbons S, 'Are UK genetic databases governed adequately? A comparative legal analysis.' (2007) 27 Legal Studies 317, 320
[307] Ibid.
[308] Human Genes Research Act 2000 (Estonia) RT I, 2000, 104, 685.
[309] HGRA, s.1 (1)
[310] Personal Data Protection Act 2007 (Estonia) RT I, 2007, 24, 127;
Public Information Act (Estonia) RT I, 2000, 92, 597.

5) The conditions for genetic research relating to the Gene Bank and the organisation of supervision thereof.[311]

Organisationally, the HGRA establishes a 'chief processor' to manage the Gene Bank;[312] who accordingly has the right to 'organise the taking of tissue samples… to perform research and to collect, store, destroy and issue genetic data.'[313] According to the Act, the objectives of the chief processor are to:

1) promote the development of genetic research;

2) collect information on the health of the Estonian population and genetic information concerning the Estonian population;

3) use the results of genetic research to improve public health.[314]

Originally, the chief processor that was established by the Government of the Republic of Estonia in 2001 was the EGPF, a non-profit organisation under the Ministry of Social Affairs.[315] The terms of the Act[316] allowed the EGPF to contract with authorised processors, physical or legal persons, or researchers to whom it can delegate its processing privileges.[317] This enabled them to 'retain control over the type of research undertaken as well as the macro and micro management of the authorised processor's research' such as conditions for storage, security processes and accountability mechanisms.[318]

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[311] HGRA s.1(2).
[312] Ibid. s.3(3):
'In order to achieve its objectives, the competence of the chief processor includes the establishment and maintenance of the Gene Bank. The chief processor has the right to delegate the rights of processing, except for coding and decoding, to an authorised processor on the basis of a contract in the cases and under the conditions prescribed in this Act.'
[313] Human Genes Research Act 2000: s. 3 (1) 'Chief processor of Gene Bank':
'The chief processor of the Gene Bank is a non-profit foundation founded by the Republic of Estonia on the basis of the Foundation of and Participation in Legal Persons in Private Law by the State Act (RT I 1996, 48, 942; 73, correction notice; 1998, 59, 941) within the area of government of the Ministry of Social Affairs which has the right to organise the taking of tissue samples, to prepare descriptions of state of health and genealogies, to code, deCODE, store, destroy and issue descriptions of state of health and genealogies, to perform genetic research and to collect, store, destroy and issue genetic data.'
[314] Ibid, s.3(2) HGRA
[315] Keis A, 'The Estonian Genome Centre, University of Tartu' in Mascalzoni D, (ed) *Ethics, Law and Governance of Biobanking* (Springer 2015), 213
[316] HGRA s. 3(3):
[317] HGRA, ss 5 and 18(3)
[318] Deschenes M and Sallee C, 'Accountability in Population Biobanking: Comparative Approaches' (2007) 33 JLME 46

2.3.3 Public-Private Partnership: The Estonian Genome Project Foundation and EGeen Ltd

During the preparatory phase of the EGP, representatives of the EGPF spoke about the share of public funding 'as amounting to 1/3 of the 100 million euros'. However, the public funding of the project remained 'symbolic' until 2007.[319] So, in 2001, the EGPF as chief processor founded and granted an exclusive 25 year commercial licence to use anonymous data from the biobank to a private company: EGeen Ltd, which was registered in Estonia. EGeen Ltd held exclusive and commercialisation rights of the EGP. This licence aimed to facilitate further private funding from international investors, and financed the preparation and establishment of the biobank during 2001-2002.[320] Until this point, the Estonian government had provided only initial funding of 64,000 euros for the initial costs to create the EGPF.[321] EGeen Ltd was obligated to make the annual payment of about 300 thousand euros to the EGPF; there were also additional payments depending on the financial success: unlimited annual profit payment of 0.5 % and 3% of the turnover.'[322]

Kattel and Suurna speculate as to the origin of this decision:

> [i]n 2000, the initiators foresaw that the EPG would need funding at least in the range of 100 million euros over the next 4-5 years, and it must have been clear for everybody involved that such levels of public funding would not be available. At the same time, there seemed to be quite strong enthusiasm about finding private financing, particularly from abroad. In fact, in 2001, Raim Tamm, representing LHV investment bank, which was advising the group of scientists from the Estonian Genome Foundation, spoke openly about the project as something that should be attractive to venture capitalists (Eesti Päevaleht 2001). Indeed, it is in this phase of establishing the EGP that the focus of the project seems to shift decidedly form a scientific long term endeavour to a commercial project, where innovation and venture capital become dominant.

[319] Ibid.
[320] Gottweis H and Lauss G, 'Biobank governance: heterogeneous modes of ordering and democratization' (2012) 3 Journal of Community Genetics (2012) 61
[321] Ibid.
[322] Ibid.

> Thus, setting up the database as a foundation seemed to enable the involvement of private funding without many regulatory problems.[323]

In turn, the EGPF and EGeen Ltd founded a US-based private company, EGeen Inc (EGI), which pooled funding from different venture capital firms (mostly international) and private individuals (mostly Estonians).[324] However, this public-private funding model lasted for only three years from 2001-2004, when the contract between the EGeen Ltd and the EGPF was terminated. During those three years the EGI had financed the Project, totalling 4.3 million euros. Hence, during this period, the governance structure of the EGP has been described as 'an independent foundation established by the Estonian government and almost fully financed by foreign and local private venture capital. In essence, it was a public-private partnership in science, research and development.'[325]

It has been argued that this partnership ended because of disagreement over the scientific strategy of the Foundation and the purpose of the Gene Bank. Gottweis describes that the first conflicts in the Project began in 2003 when the EGI argued that the Project should change the way the samples were gathered to have a narrower focus that concentrated on specific disease groups, rather than continuing as a broad population biobank.[326] Tension emerged between the public and private investors and it appeared that the EGI were more focussed on the short-term financial returns of the Gene Bank than the long-term research results and their impact on public health[327] to be derived from a population biobank, which the EGPF prioritised.[328]

Whereas the scientific motivation behind the Icelandic Health Sector Database focussed on the homogeneity of the Icelandic population, scientists in Estonia stressed the heterogeneity of Estonians (the result of various occupations over the

[323] Kattel R and Suurna M, 'The Rise and Fall of the Estonian Genome Project' (2008) 2 Studies in Ethics, Law, and Technology DOI: 10.2202/1941-6008.1050, 6.
[324] Ibid.
[325] Ibid.1.
[326] Ibid.
[327] Chih-Hsing H, 'Socio-legal perspectives on biobanking: the case of Taiwan' (PhD thesis, The London School of Economics and Political Science 2012) <http://etheses.lse.ac.uk/501/> accessed 04 July 2015, 61.
[328] Keis A, 'The Estonian Genome Centre, University of Tartu' in Mascalzoni D, (ed) *Ethics, Law and Governance of Biobanking* (Springer 2015), 213.

last few hundred years) as representative of the European gene pool as a whole.[329] In terms of commercialisation, this was perceived to be an advantage of a population-based model rather than a narrower disease based database.[330] The returns did not match the expectations of the US parent company, which was 'obviously interested in the short-term commercial success'[331] and eventually this disagreement led to the termination of the exclusive licence and financing contract with EGI in November 2004.

The termination of the contract meant that EGeen Ltd was no longer obligated to finance the genome project and the activity of the project, including data collection, was frozen between 2004 and 2007. During this time negotiations took place between scientists (led by Professor Metspalu) and politicians[332] as to how to finance the Project and achieve the goals set out of the HGRA. In 2007, the Estonian Parliament passed the Amendment of the Human Genes Research Act that provided a legal basis for the EGP to continue as a structural unit of the University of Tartu. The current Estonian Gene Bank is an entirely public venture funded directly by the Estonian State and accountable to the State via the HGRA. 'Essentially, the EGP was turned (back) into a basic science venture, where results will be available only in the long term.'[333]

2.3.4 Protecting participants and securing public trust

The failure of the public-private business model undermined the trust of the public despite the strength of the regulatory framework for the biobank. For the recruitment of participants and for the collection of samples and health data, a unique network of data collectors was set up consisting of General Practitioners (GPs) and other medical personnel in private practices and hospitals. Recruitment via GPs had provided several advantages, especially because of Estonian information technology infrastructure and electronic health records available for all GPs.[334] Keis has

[329] Chih-Hsing H, 'Socio-legal perspectives on biobanking: the case of Taiwan' (PhD thesis, The London School of Economics and Political Science 2012) <http://etheses.lse.ac.uk/501/> accessed 04 July 2015.
[330] Kattel R and Suurna M, 'The Rise and Fall of the Estonian Genome Project' (2008) 2 Studies in Ethics, Law, and Technology DOI: 10.2202/1941-6008.1050, 9.
[331] Ibid.
[332] Ibid.
[333] Ibid. 14
[334] Metspalu A and others, 'Cohort Profile: Estonian Biobank of the Estonian Genome Centre, University of Tartu' (2014) 1 International Journal of Epidemiology 11.

described how 'starting data collection again after a three year break was extremely difficult. The EGC had lost the trust not only of society but also of the general practitioners as well. A large number of general practitioners ceased to collect data for the biobank. The EGCUT had to establish another data collection network through participant recruitment offices.'[335] It took until 2009 for the EGCUT to collect the necessary data to move into the research phase of the biobank.[336] To date, the Gene Bank has 51,515 participants.[337]

The HGRA should now be recognised as a notably rights-based piece of biobank legislation that adopts a favourable position towards biobank participants. The HGRA was founded on UNESCO's Universal Declaration on the Human Genome and Human Rights[338] and the Council of Europe's Convention on Human Rights and Biomedicine (Oviedo Convention), which Estonia has signed and ratified.[339] This has significant implications for the content of the HGRA, including the 'Rights of Gene Donors' which are uniquely extensive:

> (1) Gene donors have the right not to know their genetic data.
>
> (2) Gene donors have the right to access personally their data stored in the Gene Bank. Gene donors do not have the right to access their genealogies.
>
> (3) Gene donors shall not be charged for accessing their data stored in the Gene Bank.
>
> (4) Gene donors have the right to genetic counselling upon accessing their data stored in the Gene Bank.[340]

By granting gene donors the right to know and not to know their genetic data, the HGRA significantly prioritises the autonomous interests of donors in the Gene Bank. The HGRA is also unique in its provision of genetic counselling. Combined these

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[335] Keis A, 'The Estonian Genome Centre, University of Tartu' in Mascalzoni D, (ed) *Ethics, Law and Governance of Biobanking* (Springer 2015), 218.
[336] Ibid.
[337] Estonian Biobank, 'About us' (*Estonian Genome Center*) <www.geenivaramu.ee/en/about-us>accessed 4 July 2015.
[338] UNESCO Universal Declaration on the Human Genome and Human Rights 1997.
[339] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine ('Oviedo Convention', opened for signature 4 March 1997, entered into force 1 December 1999) CETS No. 164.
[340] HGRA s. 11 'Other rights of gene donors'.

provisions recognise and legislate for the ethical challenge of managing results that may arise as a consequence of taking part in biobanking. This position is likely influenced by the Oviedo Convention, which upholds an individual's right to know information collected about his or her health and maintains that 'the wishes of individuals not to be so informed shall be observed.'[341] As will be seen in Chapter 4, this is distinguishable from the UK regulatory position, which does not expressly recognise a right to know or not to know one's genetic information (indeed, the UK is not a signatory to the Oviedo Convention).

According to the Act, participants are required to sign a consent form informing them of these rights. Participants provide broad consent that allows participation in a wide range of research projects without having to re-contact participants for re-consent.[342] The governance model of the biobank requires applicant research projects to be approved by the Ethics Committee on Human Research of the University of Tartu, which is an independent, multidisciplinary body with its own governing 'Statute'.[343] Once the Ethics Committee approves an application it must then be approved by the Scientific Advisory Board of the EGCUT, who evaluate the scientific validity of a project against the main objectives of the HGRA. A Material Transfer Agreement reflecting the conduct of the researcher, the EGCUT and third parties, including the return of results to the EGCUT, is also required.[344] A website based at the University of Tartu provides transparent public access to all of this information.[345]

2.4 Conclusion

To summarise, at the time of UK Biobank's development, between 1999-2004, Estonia and Iceland were two suitably comparative examples of models for the regulation and governance of a population biobank in the UK. Both countries had enacted specific legislation to regulate the collection, storage and use of samples and data and to manage the ethical challenges that are raised by such activities. As

[341] Oviedo Convention, Art 10
[342] HGRA s 12; donor consent form available here <http://vana.geenivaramu.ee/3518> accessed 5 July 2014
[343] 'Research Ethics Committee' (University of Tartu) <www.ut.ee/en/research-ethics-committee-university-tartu >accessed 5 July 2014.
[344] Keis A, 'The Estonian Genome Centre, University of Tartu' in Mascalzoni D, (ed) *Ethics, Law and Governance of Biobanking* (Springer 2015), 213, 217
[345] <http://www.geenivaramu.ee/en> accessed 5 July 2015.

previously stated, such recourse to law is arguably the natural reaction to new social challenges.[346] However, when the Icelandic Act on Biobanks[347] was declared unconstitutional this was an important lesson for biobank institutions, challenging the assumption that specific legislation would guarantee the necessary and effective protection of the range of interests at stake in biobanking.[348] Indeed, as highlighted in Chapter 1 of this thesis, population biobanks raise ongoing challenges and this makes 'biobanking and the law uneasy bedfellows.'[349]

Important lessons can also be drawn from the Estonian experience of biobanking in terms of biobank sustainability and organisational management. Crucially, the original EGP was a Foundation established and legally owned by the government of Estonia but funded almost entirely by private companies. Considerable private sector involvement resulted in a serious conflict of interests and highlighted fundamental tensions between the expectation of private investors, who prioritised short-term innovation and commercialisation, and the reality of population biobanking, which is now understood to deliver more long-term and undefined benefits for public health (Chapter 1). Private sector involvement threatened the objective of the initiative and ultimately a misalignment of expectations caused the management structure to fall apart. A complete re-organisation of the governance structure was required for the EGP to continue, and today the EGP is the EGCUT and is directly funded by the government and wholly owned by the University of Tartu.

When it came to building a population biobank in the UK, the experiences in Iceland and Estonia raised two fundamental questions: how the biobank should be established, of which funding is a key issue; and how the biobank should be regulated. Chapter 4 of this thesis will describe the UK's regulatory framework for biobanking, which notably does not include biobank specific legislation. Instead, a 'patchwork' of laws spanning a number of areas meant that there were two choices for UK Biobank's regulatory model: modify or create a new piece of legislation to

[346] Laurie G, 'Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law' (2011) 130 Human Genetics 347, 350
[347] Icelandic Act on Biobanks No. 110/2000
[348] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440.
[349] Laurie G, 'Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law' (2011) 130 Human Genetics 347.

statutorily create UK Biobank in the same way as Estonia and Iceland, or establish the biobank without a specific statutory basis.

The next chapter will describe the origins of UK Biobank to understand the motivations and pressures that were behind the choice of legal structure for the establishment of UK Biobank. UK Biobank was built with a public good mission and is often described as a 'public'[350] biobank because it is funded by a partnership between public bodies: the DH and the MRC and the WT; a private, non-for-profit research charity dedicated to promoting research that is for the public benefit.[351] As the next chapter will illustrate, such significant public investment led to an organisational model for UK Biobank that would guarantee financial security and sustainability and inspire public trust.

UK Biobank was established with a legal basis as a charitable company limited by guarantee, UK Biobank Ltd, and to a limited extent this is a similar approach to that of the Estonian Genome Foundation previously discussed. However, in contrast to the Estonian model, UK Biobank's charitable incorporation has implications for the expectations of the outputs of UK Biobank, which must be run for the public benefit (to be analysed in Chapters 4, 5 and 6). It is possible that this incorporation minimizes the potential for the conflicts of interest that were experienced in the early stages of the Estonian biobank and still persist in Iceland today. One of the aims of Chapters 5 and 6 of this thesis is to investigate how far this is the case.

[350] According to Gottweis and Lauss, UK Biobank is example of the public biobank model: '…(c) the public biobank model in which biobank networks are supported mostly through taxpayers money and nonprofit research funding organizations.' Gottweis H and Lauss G, 'Biobank governance: heterogeneous modes of ordering and democratization' (2012) 3 Journal of Community Genetics (2012) 61.

[351] By virtue of its legal basis as a charity under the Charities Act 2011.

Chapter 3: Origins and development of UK Biobank

3.1 Introduction

It is in view of the comparative experiences of biobanks in Iceland and Estonia that the origins and development of UK Biobank will now be considered. Analysis of these biobank models has illustrated the social, political and economic nexus[352] in which biobanks are entrenched; which has the power to undermine comprehensive regulatory regimes. Both Iceland and Estonia required substantial private investment to establish their biobanks and get them up and running. However, this commercial investment significantly challenged the future success of these biobanks.

This chapter will describe the origins of UK Biobank and socio-legal discussion of the development of UK Biobank will situate this thesis in the economic, social and political context of the UK at the time of the UK Biobank's creation. The first section of the chapter will show that UK Biobank was initially a governmental response to the scientific imperative for a population-based biobank following the success of the Human Genome Project in sequencing the human genome.[353] The next section will signal the key decision makers in the process, drawing on a broad range

[352] Gottweis H and Petersen A, *Biobanks: Governance in comparative perspective* (Routledge 2008).
[353] In 2001

of primary sources and empirical evidence.[354] Consequently, significant funding had to be secured to establish the biobank, whether from public or private funds. Crucially, organisers needed an institutional design to facilitate the establishment of a population biobank in the UK that was suitably regulated. While extensive Parliamentary and public debate preceded the establishment of UK Biobank, there is evidence that not all recommendations were followed, giving rise to questions as to the robustness of the eventual model.

3.2 Background

3.2.1 The UK and a 'genetic revolution'

> The United Kingdom is in a unique position to capitalise on, and derive benefit from, advances in human genetics.[355]

As discussion in the previous chapters has demonstrated, 'new generation' large-scale biobanks are ambitious and expensive ventures. One of the reasons for the development of UK Biobank was the presence of strong, expert organisations financially capable and motivated enough to drive the project forward, backed by governmental ambition to become world leaders in biomedical research. Contextually, UK Biobank was originally intended to be one of the first steps towards building a national DNA database of everyone in the NHS; an idea first proposed amidst the success of the HGP in sequencing of the human genome.[356]

The Human Genome Project (HGP)

From the beginning, the HGP and the race between the publicly funded sequence project led by John Sulston at the UK Sanger Centre and the private project led by Craig Venter in the US, illustrated a tension between innovation and commercialisation in biomedical research that has been demonstrated by the Estonian and Icelandic biobanks, and continues today.

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[354] Langan MA, 'A contemporary history of the origins and development of UK Biobank 1998-2005 (PhD thesis, University of Glasgow 2007).
[355] Department of Health, *Government response to the report from the House of Lords Select Committee on Science and Technology inquiry on human genetic databases: challenges and opportunities* (Cmd 5236, 2001), 4.
[356] Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57) para 3.17.

In the UK, the WT and MRC were key players in the UK's mission to sequence the human genome. During the course of the late 1980's to the early 1990's, John Sulston and his colleagues had been working on mapping the genome of the nematode worm at the MRC's Laboratory of Molecular Biology in Cambridge. The MRC is funded by the British taxpayer (through Parliament) and works closely with the Department of Health. The MRC receives annual 'grant-in-aid' funding from Parliament through the Department for Business, Innovation and Skills, with which the MRC bids in the Comprehensive Spending Review.[357]

In the early 1990's, the MRC approached the WT proposing a partnership to fund Sulston's worm sequencing as a pilot for the HGP.[358] The WT is a global charitable foundation established in 1936 as an independent charity[359] and with donations totalling approximately £13.9 billion it is the UK's largest non-governmental source of funds for biomedical research. The WT proposed a much larger sequencing effort in competition with the Human Genome Project in the US. This led Sulston to submit a grant application in 1992 for £40-50 million to fund the WT Sanger Centre, where the British arm of the HGP sequencing efforts would take place in pursuit of a publicly available sequence.[360] The Wellcome Trust Sanger Centre opened in 1993 after receiving an initial £46.5 million from the WT, and in March 2000 the announcement was made that the project had been a success.

Due to this heavy involvement in the HGP, the WT, MRC and UK Government were aware that in isolation the HGP findings would not create practical benefits for the UK population. The scientific imperative for a large-scale resource in the UK was voiced; to realise the potential of human genetics research, scientists wanted to access both genetic and informative data from large numbers of individuals over

[357] Medical Research Council 'Facts and figures' (*Medical Research Council*) <http://www.mrc.ac.uk/about/spending-accountability/facts/> accessed 28 July 2010

[358] Wellcome Trust Sanger Institute 'Human Genome Project and the Sanger Institute' (Wellcome Trust Sanger Institute) <http://www.sanger.ac.uk/about/who-we-are/sanger-institute/history-sanger-institute/human-genome-project-and-sanger-institute> accessed 25 July 2010

[359] Wellcome Trust 'Timeline' (Wellcome Trust) <http://www.wellcome.ac.uk/timeline/> accessed 27 July 2010

[360] Wellcome Trust Sanger Institute 'Human Genome Project and the Sanger Institute' (Wellcome Trust Sanger Institute) <http://www.sanger.ac.uk/about/who-we-are/sanger-institute/history-sanger-institute/human-genome-project-and-sanger-institute> accessed 25 July 2010 accessed 27 June 2010; The Wellcome Trust, 'Summary of Principles Agreed Upon at the First International Strategy Meeting on Human Genome Sequencing' (Wellcome Trust 1996) <http://web.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml#1> accessed 24 Jan 2014: where is was agreed that primary genomic sequence should be in the public domain.

long periods of time, to note their disease and other outcomes and look for correlations between those health outcomes, genetic make-up and other life circumstances.[361]

The UK Government conducted a comprehensive review of the regulatory and advisory framework for human genetics and biotechnology in May 1999.[362] The review concluded that in response to rapid developments in human genetics, the advisory framework for biotechnology needed to be more transparent, to gain public and professional confidence; be more streamlined, to avoid gaps, overlaps and fragmentation; ensure capacity to deal with rapid developments; and take broad social and ethical issues fully into account. To maximise the benefits from potential advances in human genetics, the Government needed advice from a variety of sources and as a result the (then) Human Genetics Commission (HGC) was established.[363]

3.2.2 NHS reform and public- private partnerships in the UK

At the same time the newly elected Labour government was leading the biggest ever Government led public-private science partnership for science in the UK, as well as reform of the NHS and importantly, medical records. This added impetus to the scientific pushes for access to informational patient data, with the aspiration to maximise the use of NHS resources that were considered by some an 'under-utilised' resource.[364]

In December 1997 the Department of Health White Paper: *The New NHS; Modern, Dependable* set out policy for the internal market to be replaced by a system called integrated care 'based on partnership and driven by performance.'[365] This marked the start of a ten year programme for the NHS and in July 1998 the then UK Chancellor, Gordon Brown announced £1.1 billion would be provided for the science base

[361] Wellcome Trust Sanger Institute 'Human Genome Project and the Sanger Institute' (Wellcome Trust) <http://www.sanger.ac.uk/about/who-we-are/sanger-institute/history-sanger-institute/human-genome-project-and-sanger-institute> accessed 27 June 2010

[362] Cabinet Office and Office of Science and Technology, *The advisory and regulatory framework for biotechnology: report from the government's review* (Stationary Office 1999).

[363]Human Genetics Commission 'Why has HGC been established?' (National Archives) <http://webarchive.nationalarchives.gov.uk/20100419143351/hgc.gov.uk/client/content.asp?contentid=80> accessed 21 November 2011

[364] Fears R and Poste G, 'Building Population Genetics Resources Using the U.K. NHS' (1999) 284 Science 267.

[365] Department of Health, *The new NHS: Modern; Dependable* (White Paper, Cm 3807, 1997).

through a public-private partnership to support innovative research programmes, with the help of £400 million from the WT.[366] This announcement signified an increasing role for charities like WT and the private sector as a whole. As will be discussed this reform goes some way to explaining subsequent funding decisions for UK Biobank.

In 1998, the Department of Health released *Information for Health; An Information Strategy for the Modern NHS 1998-2005*. Two years later, *The NHS Plan; A plan for investment, A plan for reform* followed. These strategies signalled Labour reform of the NHS: 'a 1940's system operating in a 21st century world.'[367] 'Modernising Britain' was a central theme of the Government's programme since it came to office in May 1997. Crucial to this objective was the drive to modernise the NHS; 'giving people of this country the best healthcare in the world.'[368] The aim was to update the health service by increasing funding, both public and private; enforcing far-reaching changes across the NHS to ultimately ensure patients received the best possible care. To this end, *Information for Health* envisaged the Electronic Health Record (EHR).[369] During the period of this strategy, the first versions of EHRs were developed and implemented with the aim of ensuring seamless information transfer, where authorised, across all sectors of the NHS.[370] Introducing individual patient NHS numbers to be used as an identifier throughout the health service was also seen as a means to facilitate this linkage.[371]

The NHS Plan published on 1st July 2000 made a strong commitment to 'a long-term study', emphasising that it was vital for the NHS to play an 'active and collaborative role' in realising the benefits of genetics:

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[366] Gordon Brown '1998 Speech on the Comprehensive Spending Review' (*UKpolitics.org.uk*) <http://www.ukpol.co.uk/2015/09/19/gordon-brown-1998-speech-on-the-comprehensive-spending-review/> accessed 21 November 2015

[367] Department of Health, *The NHS Plan: a plan for investment, a plan for reform* (Cm 4818-I, 2000), 2.

[368] Department of Health, *The new NHS: Modern; Dependable* (White Paper, Cm 3807, 1997).

[369] NHS Executive, *Information for Health: an information strategy for the modern NHS 1998-2005* (Department of Health 1998), 4.

[370] Department of Health, *Government response to the report from the House of Lords Select Committee on Science and Technology inquiry on human genetic databases: challenges and opportunities* (Cmd 5236, 2001), 9.

[371] Committee on Science and Technology, *Genomic Medicine* (HL 2008-09, 107-I). Chapter 6: The Role of the NHS.

> We will contribute with other government departments and medical charities to a long-term study of the interaction between genetics and the environment in common diseases of adults such as cancer, heart disease and diabetes.[372]

New genetics research partnerships between the NHS and industry were proposed in *The NHS Plan* and an extra £250 million was promised for information technology in 2003/2004.[373] The existence of the NHS meant that the UK was uniquely well positioned to generate valuable epidemiological data; 'providing the doorway to one of the largest sources of medical data and well-characterised human biological samples within Europe, consisting of 50 years of family records, ethnic diversity, access to disease (tissue) libraries and excellent clinical research frameworks.'[374] However, to do so, the NHS needed considerable investment in systems to collect standardised and comparable data on clinical history, consultations and investigations, and to allow linkage across different data sets.[375]

To date, the EHR has facilitated continued progress in NHS England. Most significantly, the Health and Social Care Act was enacted in 2012 and in late 2012 the UK Prime Minister David Cameron announced plans to sequence 100,000 genomes.[376] The project aims to establish a genomic medicine service within the NHS and support the Government Strategy for UK Life Sciences.[377] UK Biobank was envisaged during a period of widespread reform of the NHS and UK Biobank has successfully tested the methodology of data linkage to NHS medical records. Overall, the future vision is to establish England as one of the world's leading centres for innovation in digital health and care services;[378] a vision in which UK Biobank has played an early, vital role.

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[372] Department of Health, *The NHS Plan: a plan for investment, a plan for reform* (Cm 4818-I, 2000), para 11.14
[373] Ibid. Para 4.21
[374] Ibid. Para 4
[375] Committee on Science and Technology, *Genomic Medicine* (HL 2008-09, 107-I), Chapter 6: 'Role of the NHS'.
[376] UK Government 'DNA tests to revolutionise fight against cancer and help 100,000 NHS patients' (*Gov.uk*) <https://www.gov.uk/government/news/dna-tests-to-revolutionise-fight-against-cancer-and-help-100000-nhs-patients> accessed 5 February 2016
[377] Parliamentary Office of Science and Technology (POST), 'The 100,000 Genomes Project' (POSTnotes POST-PN-0504, 2015).
<http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-0504> accessed 04th Jan 2016.
[378] NHS England, *NHS Five Year Forward View* (NHS England 2014) <www.england.nhs.uk/ourwork/futurenhs/> accessed 31 Jan 2016.

3.2.3 Policy debate and consultation

During the early stages of the development of what was to become UK Biobank there was considerable debate both in and out of Parliament as to the general issues raised by biobanking, as well particular issues associated with the creation of a population biobank in the UK.

Human Genetics Commission

The original proposal for a research facility linking clinical and genetic data was planned in parallel with two reports from the HGC and progress was contingent on report findings:[379] *Whose hands on your genes?*[380] and *Inside Information.*[381]

The HGC consultation paper on the storage, protection and use of personal genetic information[382] and subsequent report *Inside Information* identified the main principle of respect for persons[383] as the basis for biobanking, and highlighted the importance of balancing the demands of autonomy with the interests of others in line with principles of genetic solidarity and altruism.[384] Four secondary principles relevant to personal genetic information were identified: privacy- a person should not be obliged to disclose information about his or her genetic characteristics; consent- genetic information about a person should generally not be obtained, held, or communicated without that person's free and informed consent; confidentiality- genetic information should generally be treated as being of a confidential nature; and non-discrimination-

[379] MRC memorandum to House of Commons Select Committee on Science and Technology 'The Work of the Medical Research Council' Session 2002-2003 Examination of Witnesses Q 133.
[380] Human Genetics Commission, *Whose hands on your genes?* (Department of Health 2000).
[381] Human Genetics Commission, *Inside Information: Balancing interests in the use of personal genetic data* (Department of Health 2002) <http://webarchive.nationalarchives.gov.uk/20061023110946/http:/www.hgc.gov.uk/UploadDocs/DocPub/Document/insideinformation_summary.pdf> accessed 31 Jan 2016.
[382] Human Genetics Commission, *Whose hands on your genes?* (Department of Health 2000).
[383] Human Genetics Commission, *Inside Information: Balancing interests in the use of personal genetic data* (Department of Health 2002), Para 2.20: 'Respect for persons affirms the equal value, dignity and moral rights of each individual. Each individual is entitled to lead a life in which genetic characteristics will not be the basis of unjust discrimination or unfair or inhuman treatment.'
[384] Human Genetics Commission, *Inside Information: Balancing interests in the use of personal genetic data* (Department of Health 2002) Para 2.10: 'We all share the same basic human genome, although there are individual variations which distinguish us from other people. Most of our genetic characteristics will be present in others. This sharing of our genetic constitution not only gives rise to opportunities to help others but it also highlights our common interest in the fruits of medically-based genetic research.'

no person shall be unfairly discriminated against on the basis of his or her genetic characteristics.[385]

Parliamentary discussion of imperative for a national database and appropriate legal framework

Human genetic databases also formed the topic of Parliamentary debate in 2000. The House of Lords Select Committee on Science and Technology launched an enquiry into the challenges and opportunities that they raised.[386] In the main, the Committee Report was geared towards the potential development of a national DNA database consisting of electronic NHS medical records linked with DNA samples, which had been proposed by George Poste in his written evidence to the report.[387] To this end, Poste had voiced the need for public/private investment in the UK (as discussed above):

> A strategy must be articulated to identify and mobilise the appropriate scientific and clinical skills, to build a large-scale computational infrastructure and to debate, and address, the ethical, legal, political and social dimensions relating to the use of clinical information... *To express this strategy and share value, we require a pre-competitive, public/private consortium, fusing technologies and encompassing NHS R&D capacity, private companies, universities and medical research funders and government.* Creation of the health resource database transcends both what the NHS is currently doing in information technology and what researchers are building with genomic databases. A consortial approach would generate a new lead for the UK in the biosciences and their application in the delivery of rational medicine. [388] [Emphasis added]

The report also expressed strong support for a large national database created to study the interactions of genetic and lifestyle factors in the occurrence of disease:[389] the 'UK Population Biomedical Collection.' In consideration of both proposals, the Report concluded that linkage of a participant's medical records with genetic lifestyle data necessitated development of both the UK's infrastructure and the

[385] Human Genetics Commission, *Whose hands on your genes?* (Department of Health 2000).
[386] Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57).
[387] SmithKline Beecham memorandum to House of Lords Select Committee on Science and Technology 4th Report: Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57).
[388] Ibid. para 8
[389] Ferriman A, 'House of Lords supports first UK genetic database' (2001) 322 BMJ 755.

methodology to obtain access to NHS records.[390] The Report stressed that the NHS needed considerable investment in systems to collect standardised and comparable data on clinical history, consultations and investigations, and to allow linkage across different data sets.[391]

The House of Lords acknowledged the primary importance of the DPA in governing genetic information in light of the definition of personal data under the DPA.[392] The Committee recommended; 'The…Government should conclude that the primary means of regulating human genetic databases should be the DPA and that, except as recommended… no additional protection is required for personal genetic data.'[393] The Report maintained that after examining the issues arising from human genetic databases and the principles that might inform regulatory arrangements, 'The more we considered the evidence received, the clearer it became that regulation of human genetic databases per se was neither necessary nor feasible…'[394] It was concluded that the provisions in the DPA are 'adequate for the purpose' and 'any regulatory framework would be impossibly cumbersome.'[395]

3.3 Building UK Biobank

Once the scientific imperative was voiced and the potential of the NHS to facilitate linkage noted, the subsequent challenge was to choose an institutional framework to enable the type of research requested by scientists effectively and securely, while at the same time inspiring and protecting the general public. The challenge for experts and stakeholders was to determine the scope and design the shape of UK Biobank.

3.3.1 Proposal

In 1998, the MRC bid to the Comprehensive Spending Review stressing the need for 'large collections of well-characterised human DNA samples for research on gene function and the interaction between genetic and environmental risk factors in multi-

[390] HC Deb, 3 July 2002, vol 388, col 365. (House of Commons adjournment debate on UK Biobank July 2002 Column 365: Dr Ian Gibson)
[391] Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57), Chapter 6: Role of the NHS.
[392] The Data Protection Act 1998: Part 1, s. 1; Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57).
[393] Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57), para 3.17
[394] Ibid.
[395] Ibid.

factorial diseases.'[396] Following this bid, a MRC Working Group on DNA sample collections and facilities for large-scale genetic typing met in May 1998 and defined three types of study needed: very large case control studies to identify disease genes or disease modifier genes; large longitudinal cohorts to study gene-environment interaction using prospectively gathered information on exposure and lifestyle; and large, well-documented case series with non-responders and responders identified from within the series to identify genes affecting treatment response.[397]

The first discussion of the proposed UK Population Biomedical Collection emerged as a result of a meeting between the MRC and WT on 14th May 1999.[398] This workshop brought together other funders and scientists involved in existing epidemiological surveys. The focus of the workshop was on multi-factorial diseases of significant public health importance. The attendees were asked to consider, in the light of collections already available in the UK, whether it would be valuable to set up one or more large new collections in the UK, and, if so, what form it/they should take.[399] There was general agreement that existing cohorts established for other purposes would not be suitable for a number of reasons, including the appropriateness of existing consent and the technical limitations of existing resources, whose size were considered insufficient to provide the necessary number of incidents of disease to be statistically valid and capable of being linked to environmental factors:[400]

> In the UK and world-wide, most existing collections are too small to allow statistically meaningful research, do not have enough high quality health information, have too little DNA left, or are not based on full consent for this sort of research.[401]

The workshop established an Expert Working Committee to develop the outline for the resource and the Group produced a report and recommendations in March 2000. The report proposed the establishment of a cohort; 500,000 adults aged 45-64 for the

[396] Committee on Science and Technology, *Human Genetic Databases: written evidence received up to 31 October 2000* (HL 1999-2000, 115).
[397] Ibid. para 8
[398] WT memorandum to Committee on Science and Technology Fourth Report: 'Human Genetic Databases: Challenges and Opportunities' (HL 2000-2001, 57).
[399] Ibid. para 24
[400] Ibid. para 25-26
[401] MRC memorandum to Committee on Science and Technology Fourth Report: 'Human Genetic Databases: Challenges and Opportunities' (HL 2000-2001, 57) para 23.

study of interaction between genetic and environmental risk factors for common multi-factorial diseases. It also recommended the creation of a birth cohort of approximately 20,000-50,000 to construct a population profile of exposure and immunological responses to the prevailing infections in the UK.[402] However, the Group stressed the higher priority of the former, which was predicted to have more of an impact on public health in the medium term since disease would develop faster in this age range and because it was at a more developed stage of planning.[403] The report was approved by the MRC Council and WT Governors and circulated to the MRC Research Boards, WT Panels and individual experts for comment on the ethical, legal and management issues involved prior to further protocol development.

3.3.2 Public-private funding for UK Biobank

The project envisaged by the Expert Working Committee required substantial funding, both in the short term to build the resource, and in the long term when industry would be invited to join the research later on for specific projects that they would fund.[404] UK Biobank was to be an exceptionally large-scale resource. A suitably large amount of funding was needed for its creation; potentially outside the scope of the private sector capabilities. In other words, for UK Biobank to succeed it needed to be backed and financed by the Government. The MRC and the WT committed funds to Biobank as early as June 2000, when the proposal for the UK Population Biomedical Collection was agreed in principle.[405] Despite representation on the Expert Working Committee, the Department of Health had not at this stage dedicated funding. The MRC expressed their desire for Governmental involvement and funding for the project:

> It is currently assumed that the MRC and WT will be partners in funding the setting up of the resource, and will provide the majority of the necessary funding, although

[402] Langan MA, 'A contemporary history of the origins and development of UK Biobank 1998-2005 (PhD thesis, University of Glasgow 2007), 124.
[403] Barbour V, 'UK Biobank: a project in search of a protocol?' (2003) 361 The Lancet 1734.
[404] Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57), Para 4.18.
[405] Langan MA, 'A contemporary history of the origins and development of UK Biobank 1998-2005 (PhD thesis, University of Glasgow 2007), 124.

> it is hoped that the Department of Health, the Scottish Executive and other charities may also contribute.[406]

The need for Government involvement was also raised in the House of Lords 4th Select Committee on Science and Technology 4th Report on Human Genetic Databases.[407] Written evidence noted the 'obligation' of the NHS to act as a research resource for the development of initiatives that would improve the quality of care, for which new public-private partnerships were vital. Indeed, the challenge of high cost new technologies had led other industry sectors to explore the value of precompetitive public-private consortia to generate innovation.[408] In the same way, 'the time has come when the escalating cost of life sciences research requires analogous activities in healthcare.'

> We envisage a precompetitive public-private consortium requiring a fusion of technologies (particularly biomedical, informatics, and communications disciplines), involving multiple companies, universities, medical research charities and government… The challenge now lies in forging the relationships for this partnership, for improved training, and for consideration of the ethical and social issues, in order to ensure that the potential value of epidemiology is realised to produce better health and quality of life.[409]

Thus, UK Biobank was an opportunity for the UK Government to put the UK at the forefront of genomics research. Funders were keen to facilitate the type of research required and initial funding for the project of £45 million was announced by the MRC, WT (£20 million each) and Department of Health (DH £5 million) in April 2002.[410] Active involvement from the DH was confirmed in 2002 in a House of Commons Select Committee on Science and Technology Report.[411] Here, it was

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[406] MRC memorandum to Committee on Science and Technology Fourth Report: 'Human Genetic Databases: Challenges and Opportunities' (HL 2000-2001, 57) para 44.
[407] Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57).
[408] 'Prominent examples of this trend are computing, automobile, aerospace, and materials science sectors' Representing pharmaceutical company SmithKline Beecham memorandum to House of Lords Select Committee on Science and Technology 4th Report: Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57), 2
[409] Ibid.
[410] UK Biobank <http://www.ukbiobank.ac.uk/> accessed 4 April 2012.
[411] Committee on Science and Technology, *The Work of the Medical Research Council* (HC 2002-3, 132).

explained[412] that the WT, MRC and DH would be continually committed to UK Biobank and it was expected that the biobank would in time generate income; from industrial organisations that would use the information.[413] Questioning the enthusiasm of industry about Biobank, the Select Committee asked; 'Are the industry jumping up and down with this idea and saying 'we would love to put millions into this?' Are you hearing from them at all?'[414]

> What we are hearing from industry is it is important that something like this is set up, in the first instance, without industrial funds so that it clearly belongs to the public domain. Once you have it set up, yes, we would very much want to be part of it and we would come in.[415]

It has also been argued that the decision to fund the UK Biobank from a variety of public and private resources was informed by the Icelandic database, which was suffering huge criticism for its approach at the same time as UK Biobank was developing in the UK (Chapter 2).[416] High costs, coupled with a Governmental push for public-private partnership and lessons from Iceland and public outcry over their privately owned population biobank, ultimately resulted in £62 million initial funding from the UK Government and the WT to create UK Biobank. In turn, there was a pressing need to justify the use of public funds for a project like UK Biobank.

3.3.3 Consulting with stakeholders[417]

It was important that the ethical issues of biobanking were given proper consideration by UK Biobank developers and were shown to be given such consideration, to be deemed legitimate and ensure overall success (Chapters 1 and 2). In a bid for openness and transparency, a number of consultations were conducted and commissioned by the funding bodies with a variety of groups including: industry, interest groups, scientists, health workers, general practitioners

[412] House of Commons adjournment debate Q 107: House of Commons Select Committee on Science and Technology 'The Work of the Medical Research Council' Session 2002-2003 Para 24.
[413] Ibid.
[414] Examination of Witnesses Q111: House of Commons Select Committee on Science and Technology 'The Work of the Medical Research Council' Session 2002-2003.
[415] Ibid.
[416] Adalsteinsson R, 'The Constitutionality of the Icelandic Act on a Health Sector Database' in Sandor J, *Society and Genetic Information: Codes and Laws in the Genetic Era* (CEU Press 2003) 203.
[417] For the purpose of this Chapter 'stakeholder' generally refers to interested parties, and is distinguished from specific stakeholder approaches to corporate governance that are discussed in Chapter 5.

and the public to inspire confidence in the endeavour.[418] Initiatives such as the WT Biomedical Ethics Programme,[419] and numerous workshops organised by UK Biobank funders, considered the ethical challenges of human biological sample collections. Cragg Ross Dawson undertook public consultation in 2000, funded by the MRC and WT to investigate public perceptions of the collection of human biological samples.[420]

In opposition, GeneWatch UK, a not-for-profit policy research and public interest group that 'aims to ensure that genetic technologies are developed and used in the public interest'[421] critiqued the scientific rationale of UK Biobank; namely the inadequacy of medical records and quality of data; the scope and age of the cohort used; and the likelihood of UK Biobank delivering meaningful results.[422]

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[418] UK Biobank, 'Public Consultation' (UK Biobank) http://www.ukbiobank.ac.uk/public-consultation/ accessed 5 February 2016.

[419] Set up in June 1997 for research into the social, ethical and public policy implications of advances in biomedicine: Wellcome Trust Policy Unit 'Review of the Wellcome Trust Biomedical Ethics Programme' (Wellcome Trust, 2001) <http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/WTD003263.pdf> accessed 5 February 2016.
Workshop on Human Biological Sample Collections took place on 5th Nov 1999. The workshop was organised so that interested researchers could familiarise themselves with the scientific developments, and identify areas of social, ethics and public policy research which needed to be done. The workshop produced policy pointers (as well as themes for further social, ethics and policy research) even though this was not the main purpose of the meeting. Policy points raised were reciprocal altruism, consent and unanticipated use of stored material, confidentiality, public trust, social outcome, commodification of human body and personal information: Martin P and Kaye J, *The Use of Biological Sample Collections and Personal Medical Information in Human Genetics Research* (The Wellcome Trust 1999) <www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtd003283.pdf> accessed 31 Jan 2016.

[420] Cragg Ross Dawson Ltd, *Public Perceptions of the Collection of Human Biological Samples—Report Prepared for the Wellcome Trust and Medical Research Council* (Wellcome and MRC 2000) <www.ukbiobank.ac.uk/wp-content/uploads/2011/07/Public-Perceptions-Collection-Human-Biological-Samples.pdf> accessed 26 January 2016.

[421] GeneWatch UK 'About GeneWatch' (*GeneWatch UK*) <http://www.genewatch.org/sub-396416> accessed 4 April 2012

[422] GeneWatch UK, Memorandum submitted by Gene Watch UK (Appendix 2 to The Minutes of Evidence) in Select Committee on Science and Technology, *The Work of the Medical Research Council* (HC 2002-3, 132). One of the group's main concerns is that UK Biobank will produce 'spurious links' between genes and environment. GeneWatch argues that most statistical links between genes and environment will later turn out to be wrong, because of the multiple factors involved. Furthermore, the Group states that environmental factors will be poorly measured in Biobank because people will find it impossible to provide fully reliable information; GeneWatch PR: UK Biobank based on false assumptions and a waste of public money, says GeneWatch' (GeneWatch 15 March 2006) <http://www.genewatch.org/article.shtml?als[cid]=507674&als[itemid]=537742> accessed 12 April 2012.

Indeed, the consultations have been criticised as being 'too politically tailored by biobank planners';[423] for avoiding contentious issues (such as the establishment of a UK-wide biobank in the first place);[424] for 'the validity of the science for which the database is being created';[425] and for 'ignoring public concerns.'[426] Hunter and Laurie have argued that 'the consultations may be criticised for having adopted an expectation of a 'passive public' rather than one which would be more involved in UK Biobank's governance and decision making.'[427] This has led to academic debate as to 'how to include people well in biobank governance', including calls for greater participant involvement on decision making bodies such as the Ethics and Governance Council and the Board of Directors. This is an issue that goes to the heart of this thesis and will be explored in the chapters that follow.

3.3.4 Protocol development

A Protocol Development Committee was established in May 2001 to 'steer and oversee' the production of a detailed draft protocol for a proposed cohort study (size, age-range etc.) and to endorse it in time for international peer review and for passing on to the funding bodies. It was asked to consider the financial constraints involved in UK Biobank and the consultations undertaken with the scientific community, the public, health professionals, industry, and charities that would 'inform' the protocol. The Committee was comprised of experts and representatives of the funders, including a representative of the DH following the first meeting. The first draft of the Protocol was produced on 12 October 2001 and was sent out for international peer review in November 2001. The protocols were sent to a MRC board (the document

[423] Wallace H,'The development of U.K. Biobank: excluding scientific controversy from ethical debate' (2005) 15 Critical Public Health 323.
[424] Wakeford T and Hale F, Generation Scotland: Towards Participatory Models of Consultation (University of Newcastle, Policy Ethics and Life Sciences Research Institute (PEALS) 2004) <www.generationscotland.org/images/stories/GS_-_towards_participatory_models_of_Consultation.pdf> accessed 06 Feb 2016.
[425] Godard B, Marshall J, Laberge C and Knoppers BM, 'Stategies for consulting with the community: the case of four large-scale genetic databases' (2004) 10 Science and Engineering Ethics 468.
[426] Ibid.
[427] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C, *The Governance of Genetic Information: Who Decides?* (CUP 2009),155.

does not specify which board) on 22 Feb 2002 in preparation for the aforementioned funding decision meeting in March 2002. [428]

Between 2000 and 2003, representatives from the DH, WT and the MRC formed a 'Joint Funders Action Team' (JFAT). The group addressed key issues including the funding decision, the development of the organisational model ('hub and spoke model') and the role of various committees that would continue the development of UK Biobank.[429] The eventual model will be discussed in detail in the next chapter.

3.4 Conclusion

This chapter has contextualised the formation of UK Biobank, which was influenced by a number of historical developments in the UK and worldwide. The establishment of a population biobank in the UK was driven by the MRC and WT following heavy involvement in the success of the HGP in the late 1990's, and in response to pressure from the scientific community for a large-scale epidemiological resource to combine patient medical information with human tissue samples to investigate the linkages between lifestyle, genes and environment. Around the same time (late 1990's) the NHS was undergoing considerable reform including the development of the electronic health record, as well as governmental investment in new genetics research partnerships between the NHS and industry. This infrastructure and investment meant that the UK was in a unique position to be able to fund and facilitate a world-leading resource comprised of 500,000 participants' human tissue and medical records.

Early consultations and Parliamentary and public debate identified the corresponding question of how to structure the biobank in a way that lawfully facilitated scientific research while at the same time protecting the interests of the individuals who would eventually donate to the biobank (Chapter 1). The question was whether the UK ought to specifically regulate the biobank via legislation, as had been the case in Iceland (Chapter 2) or whether the existing regulatory framework for medical research in the UK would be sufficient. The next chapter will analyse this framework, as well as the discussions that led to the eventual decision to embed UK Biobank within the existing regulatory environment. Significantly, there is no single,

[428] Langan MA, 'A contemporary history of the origins and development of UK Biobank 1998-2005 (PhD thesis, University of Glasgow 2007).
[429] Ibid.

biobank specific piece of legislation in the UK and instead, the law that governs biobanking spans a number of fields of law including data protection law, the regulation of human tissue and human rights. Therefore, the way in which the wider legal framework of UK Biobank and its own policy the 'Ethics and Governance Framework' protects the private interests of the UK Biobank donors will be outlined.

Part 2

Understanding the legal parameters of UK Biobank Ltd

Chapter 4: Governance of UK Biobank

4.1 Introduction

The previous chapter has highlighted how international experiences of the ethical challenges of biobanking, as discussed in Chapters 1 and 2 of this thesis, were clearly influential in the debate and design of UK Biobank. Lessons learned from comparable population biobanks such as the Icelandic biobank (Chapter 2), demonstrated the importance of managing the ethical challenges raised by population biobanking (Chapter 1) and crucially, the need to strike an appropriate balance between the protection of the private interests of the individuals who would ultimately donate their human tissue (and data therein) to the biobank, with the perceived potential benefits for the population as a whole.

In both Iceland and Estonia, specific legislation was enacted in an attempt to realise this equilibrium. However, the Icelandic experience was an early warning of the

difficulties associated with building a biobank on a statutory footing that is reliant on a private funding model. Ultimately, an exclusive licence granted to the private company deCODE, coupled with an ethically controversial and unpopular 'opt-out' statutory provision for participation, undermined the success of the national database. On this basis, both the regulatory and funding model for the Icelandic biobank seem to be equally culpable for the demise of the resource.

On the other hand, while the sustainability of private funding used to establish the Estonian population biobank threatened the survival of the biobank, once subsequent public funding was secured, the statutory framework of the biobank provided a stable environment for the continuance of the biobank. This experience suggests that the legal framework in Estonia successfully balanced, and continues to balance, the private interests of the individual participants (including most notably a right to feedback of research results) with the public interest in the research taking place. Therefore, comparative analysis suggests that while there is a crucial relationship between funding and regulatory models, a critical challenge for a successful and sustainable biobank model is to design a legally accountable governance framework that adequately manages the ethical challenges associated with population biobanking and strikes an appropriate balance between public and private interests.

With Chapters 1-3 in mind, the purpose of this chapter is to contextualise UK Biobank in the 'regulatory environment' for biobanking in the UK and consider the ways in which this environment has evolved to protect public and private interests in biobanking. Unlike the Estonian and Icelandic model, UK Biobank was not created by Parliament and a specific statute. If UK Biobank had been established on statutory basis, the result would be that it would be clearly subject to public law duties and Parliamentary oversight of its legal basis. Instead, UK Biobank was built with private law model that sits in the existing nexus of regulatory instruments and legislation relating to biobanking, including: data protection law, the regulation of human tissue and human rights, UK common law jurisprudence, EU directives, regulations and international directives, and 'soft-law' policy guidance, as well as a number of oversight bodies and research ethics committees (RECs).

Chapter 3's discussion of the origins of UK Biobank has highlighted the integral role of the WT and the MRC in driving the decision to build a population biobank in the

UK, which was partly motivated by the anticipated scientific benefits voiced following the success of the HGP. In addition, the WT, the MRC and DH recognised the perceived opportunity for the UK to lead the innovation agenda by capitalising on the potential of the NHS to facilitate linkage to the UK population's medical records. The dominant role of the WT and MRC in the development of UK Biobank is ultimately reflected in the legal structure of UK Biobank as a charity company with representatives of the WT and the MRC as the signatory Members of UK Biobank Ltd.

The choice of legal structure for UK Biobank has implications for the accountability of the resource. Briefly, the most significant consequence of establishing UK Biobank as an independent charity company is that it falls to management within the corporation to run the resource and manage the inherent ethical challenges that have been described in Chapter 1. As will be illustrated in more detail in Chapters 5 and 6, the use of a private law structure to facilitate the public mission of UK Biobank raises tensions between the interests promoted and protected by a combination of (potentially conflicting) legal frameworks. This chapter sets out the reasons for the choice of this dual legal structure, including the creation of Ethics Governance Council as a collateral advisory body, and identifies the inherent legal complexities of the structure before the implications of these complexities are critically analysed in Chapter 6.[430]

Overall, this chapter aims to highlight the difficulties raised by the choice of a private law model and associated multiple layers of law to address the public dimensions of UK Biobank as well as the interests of the individual donors.

4.2 The 'Regulatory environment'[431] for biobanking in the UK

4.2.1 Statutory framework

In the UK there is no specific statute for the regulation of population biobanks. In fact, there is no single piece of legislation for medical research on human beings.[432]

[430] And the way in which the common law may interact with this legal structure in the future will be investigated in Chapters 7 and 8, in order to consider the extent to which public and private interests in the running of UK Biobank are balanced in this model.
[431] Brownsword R, Yeung K, (eds) *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart 2008).
[432] Kaye J, 'The Regulation of Human Genomics Research' in Kumar D and Eng C (eds) *Genomic Medicine: Principles and Practice* (2nd Edn, OUP 2014).

This has led to widespread criticism of what has been described as 'a fragmented patchwork of law'[433] for biobanking:

> …[T]here exists a bewildering array of statutes, legislative provisions, regulations and common law doctrines, together with well over 30 codes of practice… statements of ethical principles, plus numerous binding or non-binding but influential international conventions, directives, declarations, recommendations, statements, resolutions , decisions and guidelines, all have some obvious or potential bearing on genetic databases or the professionals involved with them.[434]

Fundamentally, a distinction is maintained across UK legislation between human material (samples) and information relating to individuals (data) and this distinction determines the appropriate regulatory framework for each.[435] The Human Tissue Act 2004 (HTA) regulates and requires a licence for the storage and use of human tissue,[436] whereas the Data Protection Act 1998 (DPA) requires the fair and lawful processing of personal data including the sensitive personal information that may be derived from genetic information.[437] Since human tissue samples contain genetic material standardly assumed to contain genetic information including sensitive personal information[438] about the source of the tissue and their current and future health,[439] the DPA and the HTA are the primary sources of legislation for the

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[433] Kaye J, Bell J, Briceno LM and Mitchell C, 'Biobank Report: United Kingdom' (forthcoming) JLME

[434] Gibbons SMC, 'Are UK genetic databases governed adequately?' (2007) 27 Leg Stud 312, 319.

[435] Briceño Moraia L, Kaye J, Tasse AM and others, 'A Comparative Analysis of the Requirements for the Use of Data in Biobanks Based in Finland, Germany, the Netherlands, Norway, and the United Kingdom' (2014) 14 Med Law Int 187, 191

[436] The Human Tissue Act 2004 is the implementation into UK law of European Parliament and Directive of the European Parliament and of the Council 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L102/48.

[437] As a Member State of the European Union, the Data Protection Act implements the Directive of the European Parliament and of the Council 95/46/EC of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data [1995] OJ L281/31 ('EU Data Protection Directive') due to be replaced by a General EU Data Protection Regulation by 2018. It is noted that genetic information is explicitly recognised as 'personal data' in the final draft of General Data Protection Regulation: draft available: <http://www.haerting.de/sites/default/files/pdfs/proposal-eudatap-regulation-final-compromise-151216.pdf> accessed 20 January 2016

[438] The European Commission Data Protection Working Party considers that genetic information is sensitive personal data under Article 2(a) of the EU Data Protection Directive: Article 29 Data Protection Working Party, 'Working Document on Genetic Data' (European Commission 12178/03/EN, WP 91, 2004).

[439] Manson N, 'The medium and the message: tissue samples, genetic information and data protection legislation' in Widdows H and Mullen C *The Governance of Genetic Information: Who Decides?* (CUP 2009), 15.

regulation of UK Biobank. As such, the establishment of UK Biobank in Manchester, where the physical samples are stored, was licensed in accordance with the HTA 2004.

Beyond the DPA and the HTA, legal principles relevant to biobanks built for the collection, storage and use of tissue samples[440] and data, are enshrined in several statutes including: the Human Rights Act 1998,[441] specifically the Right to respect for private and family life;[442] the Mental Capacity Act 2005, which dictates who will be legally able to consent to participation in biobanking;[443] the Freedom of Information Act 2000;[444] and the National Health Service Act 2006, the Health and Social Care Act 2012 and the Care Act 2014, which combined, and for certain purposes that include research, allow the supply of identifiable NHS patient information without consent.[445] European and International Human Rights law such as the UNESCO Declaration on the Human Genome and Human Rights (1997) and the Council of Europe Oviedo Convention[446] may also shape how biobanking is regulated in UK law. Unlike Estonia and Iceland, the latter is not binding in the UK because it has not been signed and ratified.[447]

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[440] Excluding gametes and embryos, which are regulated separately by the Human Fertilisation and Embryology Act 1990 as amended, implementing the Directive of the European Parliament and of the Council 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L102/48.

[441] Implementing into UK law the Convention for the Protection of Human Rights and Fundamental Freedoms ('European Convention on Human Rights', as amended, opened for signature 11 November 1950, entered into force 03rd September 1953) CETS No. 005.

[442] European Convention on Human Rights Art 8

[443] Mental Capacity Act 2005, s. 3(1) (a)-(d)

[444] Which covers any recorded information that is held by a public authority in England, Wales, and Northern Ireland, and by UK-wide public authorities based in Scotland.

[445] National Health Service Act 2006, s. 251-252; which requires the approval of the Confidentiality Advisory Committee under s.158 of the Health and Social Care Act 2008. The Health and Social Care Act was amended by the Care Act 2014 to allow the discretionary dissemination of data by the Health and Social Care Information Centre only for: (a) the provision of health care or adult social care, or (b) the promotion of health (s. 261(1A) Health and Social Care Act 2008)

[446] Convention for the Protection of Human Rights and Fundamental Freedoms ('European Convention on Human Rights', as amended, opened for signature 11 November 1950, entered into force 03rd September 1953) CETS No. 005.

[447] Within the legal framework for biobanking in the UK, there are a number of organisations that have a role in the governance of biobanks in order to ensure their compliance with ethical and legal requirements. Some bodies are statutorily created to administer legislation, such as the Human Tissue Authority (under the Human Tissue Act 2004). The Authority is the regulator for human tissue and organs and is responsible for licensing collections of samples (excluding gametes and embryos, which is the remit of the Human Fertilisation and Embryology Authority: <http://www.hfea.gov.uk/> accessed 8 July 2015) and administering Codes of Practice as guidance for professionals and researchers, as well as guidance for the public: <https://www.hta.gov.uk/> accessed 8 July 2015.

4.2.2 Case law

In addition, and because the English legal system is founded on common law, a number of judicial decisions have been made relating to the ethical challenges that are associated with biobanking including consent, privacy and property rights, and ownership of human tissue. These decisions are precedents that may be applied in the future, although to date there have been no reported cases in UK or EU courts that have applied these decisions specifically to biobanking.

Privacy and consent

It has been argued that the doctrine of consent operates to protect privacy interests in a number of ways within UK law.[448] Broadly speaking, appropriate consent is required to legitimize any interference with one's physical integrity and autonomy. Unlawful touching i.e. intentional interference without such consent may amount to a tort of battery[449] or assault[450] under English tort law.[451] Other remedies are also available where the individual has suffered physical harm or psychological harm as a result of the negligence of the defendant.[452] The Mental Capacity Act codified the common law position that to be legally valid, consent must be freely given and fully informed.[453] But what counts as 'informed' consent will vary according to context. In the context of medical treatment, consent may be express (in the form of a

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Under the Data Protection Act, the Information Commissioner has powers to enforce the Data Protection Act via audits, fines and investigations: <https://ico.org.uk/> accessed 8 July 2015.
In the specific context of research, in 2011 the Human Research Authority (HRA) became the first single government body in the UK responsible for the oversight of the research process in the UK, to protect and promote the interests of patients and the public in health research (NHS Health Research Authority, *HRA Approval*: <http://www.hra.nhs.uk/> accessed 20 January 2016). The National Research Ethics Service now comes under the ambit of the HRA and is responsible for providing guidance and the system of accreditation for research ethics committees (RECs).
At the time of creation, UK Biobank was granted research ethics approval from the North West Multi-centre Research Ethics Committee (MREC). Instead of requiring each applicant to obtain separate ethics approval to use the resource, UK Biobank has generic Research Tissue Bank (RTB) approval: UK Biobank, *Access Procedures: Application and review procedures for Access to the UK Biobank Resource Version 1.0* (UK Biobank, 2011 <www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Access-Procedures-2011.pdf> accessed 24 Jan 2014. B.7: 'Legal and ethics approval'

[448] Kaye J, Bell J, Briceno LM and Mitchell C, 'Biobank Report: United Kingdom' (forthcoming) JLME.

[449] *Re T (Adult: Refusal of Treatment)* [1992] 4 All ER 649

[450] Ibid. *Re B (Adult, refusal of medical treatment)* [2002] 2 All ER 449

[451] Despite Scotland's separate legal regime, the applicable principles are Scottish tort law: Mason JK and Mason K and Laurie GT, *Mason and McCall Smith's Law and Medical Ethics* (9th edn OUP 2013) Ch 5.

[452] See for instance, *Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37, [2010] QB 1.

[453] Mental Capacity Act 2005 s 3(1)(a-d).

signature in a consent form)[454] or implied (i.e. via one's actions of allowing a blood sample to be taken). The deference accorded to medical opinion in the leading House of Lords cases over the past three decades in setting standards of disclosure to secure 'informed consent' has been recently eroded in the 2015 Supreme Court decision in *Montgomery v Lanarkshire Health Board.*[455] *Montgomery* took a significantly patient orientated approach in its robust analysis of informed consent by setting a high standard of care owed to patients in respect of disclosure of small yet material risks prior to medical intervention.[456]

The importance of obtaining the consent of research participants is stressed at both international and national level and is one of the fundamental principles of ethical research.[457] It is thus accepted that consent is required for the taking of samples from biobank participants, as a means of protecting their right to make autonomous decisions about their body. However, whether and to what extent biobank donors fall within the category of research participants is far from clear and has certainly been doubted by leading scholars.[458] This could potentially raise difficulties in the application of established principles in the medical and research context and will be returned to in Chapter 7.

In addition, as discussed in Chapter 1, another significant challenge in securing 'informed' consent for the use of samples is that it is often not possible to predict all

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[454] *Re T (Adult: Refusal of Treatment)* [1992] 4 All ER 649

[455] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [2015] 2 WLR 768

[456] Ibid.
The new test is a test of '*material risk*', which may involve asking whether a risk is one that the particular patient would regard as significant. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that
the particular patient would be likely to attach significance to it. '….patients are now widely regarded persons holding rights, rather than as the passive recipients of the care of the medical profession.' [75]

[457] Plomer A, *Law and Ethics of Medical Research: International Bioethics & Human Rights* (Routledge 2005).
At the international level, relevant documents include the Oviedo Convention, Art 16 states the need for express and specific consent to participation in research. At the national level, ethics committees enforce the ethical requirement of consent, and all statements of professional bodies and funding bodies such as the MRC stipulate the need for informed consent of the research subject, of the subject is capable of giving such consent. Issues have been covered in depth by the MRC in their operational and ethical guidelines: Medical Research Council, Guidelines on Human Tissue and Biological Samples for Use in Research (Medical Research Council 2001).

[458] For this reason, this thesis will refer to UK Biobank 'donors' rather than participants, except when citing references to 'participants'. Luther L and Lemmens T, 'Human Genetic Data Banks: From Consent to Commercialization – An Overview of Current Concerns and Conundrums' in Doelle WH and DaSilva EJ (ed) *Biotechnology, Encyclopedia of Life Support Systems* (EOLSS 2007).

future applications for which a biobank might be used at the time consent is obtained. This is problematic because interpreted strictly, the doctrine of informed consent would appear to require that consent be re-obtained for any use other than that explicitly anticipated when consent was originally obtained.

Finally, the use of individual's 'health data' is also regulated separately under the Data Protection Act. When research is based on identifiable personal health data, it may take the form of a 'broad consent' to multiple uses of a person's health data. As long as the consent is 'explicit,'[459] this may be to a range of potential future uses.

In practice, but only to a limited extent, the (de) identification of an individual's data may be secured by technical measures to protect the individual's confidentiality[460] in biobanking.[461] It is recalled from Chapter 1 that generally, technical fixes can be employed to enhance confidentiality of information collected and stored. Because one scientific benefit of population biobanks is their longevity, biobank organisers will typically reversibly anonymise data samples for their storage and use, so that individuals may be re-identified for research purposes, and to honour participant's right to withdrawal (Chapter 1). In reliance on these practical measures, UK Biobank has been set up on a broad consent basis. Individual samples and data are being donated and released on the understanding that systems will be in place for secure data flow, including (reversibly) anonymising data and samples, and enforcing confidentiality.[462]

However, it has recently been proven that it is impossible to absolutely anonymise genetic data.[463] Arguably, this calls into question the appropriateness of the 'consent or anonymise' approach that has prevailed in biobanking to date and in UK

[459] Data Protection Act 1998, Sch. 3, Para 1
[460] Although this has been argued to lead to a 'consent or anonymise' dichotomy, which Dove and Laurie have argued inappropriately conflates the protection of ethical interests with technical standards: Dove T, Laurie G, 'Consent and anonymisation: beware binary constructions' (2015) 350 BMJ http://dx.doi.org/10.1136/bmj.h1139.
[461] Taylor MJ and Townend D, 'Issues in protecting privacy in medical research using genetic information and biobanking: the PRIVILEGED project' (2010) 10 Med Law Int 253; Townend D, Taylor MJ, Wright J and Wickins-Drazilova D, 'Privacy and Access: Privacy Interests in Biobanking: A Preliminary View on a European Perspective,' in J Kaye and M Stranger (eds), *Principles and Practice in Biobank Governance* (Ashgate, 2009).
[462] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016.
[463] Hayden EC, 'Privacy protections: The genome hacker' Nature: Vol 497: Issue 7448: 2013

Biobank,[464] and potentially gives rise to heightened risks of personal harm as a consequence of participating in biobanking, which may or may not have been appreciated at the time of consent.

In fact, in 2015 a tort of misuse of private information was expressly recognized in the Court of Appeal's ruling of *Google v Vidal Hall*, which held that damages will be awarded for misuse of private information which causes 'mere distress' under the Data Protection Act.[465] This is in contrast to the previous position, which required proof of financial damage for distress to be compensated. The threshold test is whether the person publishing information knows or ought to know that the information in question should be kept confidential.[466] Awarding such damages for mere distress provides significant 'teeth' to privacy and data protection regulation.

Property and ownership

A key ethical challenge inherent in biobanking is the question of whether there exist ownership rights to samples once they have been donated for the purpose of research (Chapter 1).

The HTA 2004 avoids the complex question of ownership of tissue samples and instead upholds consent as the main tool for regulating the competing interests of individuals, researchers and potentially corporations.[467] Jurisprudence in the UK and internationally has maintained that there are no property rights in the human body. In the US, this was the principle established in the landmark case of *Moore v Regents of the University of California*[468] and subsequently in *Greenberg v Miami Children's Research Hospital Institute.*[469] This ruling has subsequently been cited with approval by English courts in cases such as *R v Kelly*,[470] which qualified that ownership rights may arise in respect of body parts where sufficient 'work or skill' has been exercised over them. Since these decisions, it is notable that *Yearworth v North Bristol NHS*

[464] UK Biobank, *Ethics and Governance Framework* (Version 3.0, UK Biobank 2007) < http://www.ukbiobank.ac.uk/resources/> accessed 26 January 2016.
[465] *Google Inc v Vidal-Hall & Others* [2015] EWCA Civ 311, [2015] 3 WLR 409
[466] In the *Google* case, 'personal' and 'private' information are considered separate 'types' of information.
[467] Human Tissue Authority, *Code of Practice 1: Consent* (Version 14.0, HTA July 2014) < www.hta.gov.uk/sites/default/files/Code_of_practice_1_-_Consent.pdf> accessed 31 Jan 2016.
[468] *Moore v Regents of the University of California* 51 Cal. 3d 120, 271 Cal. Rptr. 146, 793 P.2d 479 (1990)
[469] *Greenberg v Miami Children's Research Hospital Institute* 264 F. Supp. 2d 1064 (S.D. Fla. 2003)
[470] *R v Kelly* [1999] Q.B. 621 (CA), [630] held that amending the rule would require legislative intervention.

Trust[471] broke new ground by holding that sperm was the property of the six men from which it was derived and that this would have been the case even if it had not been subjected to any kind of work or skill in the light of the background statutory framework of the HFE Act. This landmark ruling potentially signals a move towards increased recognition of property rights in human samples.[472]

However, in the absence of a legislative framework clearly asserting the continuing rights of veto over use of the tissue samples it is not clear how far rights of ownership may be extended in biobanking and specifically in the case of UK Biobank. The powers of Directors of the biobank in respect of such uses and ownership are discussed below in connection with the governance structure of UK Biobank.

4.3 The legal structure for UK Biobank: Private corporation with a public mission

> Biobank… will help us to increase knowledge and we, as politicians, must make sure that the framework is right for the use of this knowledge… We have to make sure that 'evil people'… cannot use it for 'evil ends'… The debate should be about a framework to safeguard the proper and secure use of all the new knowledge that Biobank generates… The insights that scientists have, and even more so their application, depend on the institutional framework and the regulatory regime under which science takes place. We need to get the framework right to achieve the benefits from Biobank that we all hope for and to prevent abuses and negative consequences.[473]

4.3.1 Rationale for the legal structure

The rationale behind the choice of legal structure as a charity company for UK Biobank was informed by the regulatory experiences in Iceland and Estonia

[471] *Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37, [2010] QB 1

[472] In *Yearworth*, the Court of Appeal rested its decision that the sperm supplied by the men amounted to property that belonged to those men, on the facts that 'By their bodies, they alone generated and ejaculated the sperm... The sole object of their ejaculation of the sperm was that, in certain events, it might later be used for their benefit...[the] sperm [could not] be stored or continue to be stored without their subsisting consent [under the terms of the Human Fertilisation and Embryology Act 1990]...no person, whether human or corporate, other than each man [who supplied the sperm had] any rights in relation to the sperm which he...produced': *Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37, [2010] QB 1 [45](f).

[473] House of Commons Select Committee on Science and Technology 'The Work of the Medical Research Council' Session 2002-2003: Adjournment debate

(Chapters 2 and 3) as well as consultations and policy debate which highlighted the need to inspire public confidence and trust in the biobank to secure participation (Chapter 3). Most likely though, the legal structure was chosen by the MRC, the WT and latterly the DH because it appropriately safeguarded the significant financial investment that they dedicated to the establishment and maintenance of UK Biobank. Crucially, the private model as a charity company empowers the funders who are the Members of the Company.

Evidence of the decision to incorporate UK Biobank as a company can be traced back to the Medical Research Council's Memorandum to the House of Lords Select Committee on Science and Technology in 2002.[474] Speaking on behalf of the DH, the Minister of State revealed that the current thinking of the funders of UK Biobank (WT and MRC) was that funding would be provided through the creation of an independent limited company, owned by its Members (the WT and the MRC as the main funders of UK Biobank) and consisting of a Board of Directors (with representatives of the Funders), a Steering Committee (led by a Chief Executive Officer) and an International Scientific Advisory Board. Upon advice from the specifically created Interim Advisory Group (IAG) for UK Biobank (Chapter 3), the funders established UK Biobank without specific statutory footing, despite the absence of formal specifically tailored biobanking regulation in the UK:[475]

> Consideration was given to whether it would make sense to seek a statutory basis, guaranteeing the independence of the Council, for instance… But the view came to be that in the current parliamentary climate such legislation was unlikely to be obtainable, certainly within the time frame of UK Biobank's development.[476]

[474] MRC memorandum to House of Commons Select Committee on Science and Technology 'The Work of the Medical Research Council' Session 2002-2003 Examination of Witnesses Q 133.
[475] Although, around the same time the Human Genetics Commission advised the UK Government that while there was not a need for additional, tailored legislation to ensure the ethical oversight of genetic research, 'genetic research databases established for health research should not be used for any purpose other than such research and that this be put beyond any doubt, by legislation if necessary': Human Genetics Commission, *Inside Information: Balancing interests in the use of personal genetic data* (Department of Health 2002) <http://webarchive.nationalarchives.gov.uk/20061023110946/http:/www.hgc.gov.uk/UploadDocs/DocPub/Document/insideinformation_summary.pdf> accessed 31 Jan 2016, para 5.50
[476] Interim Advisory Group on Ethics and Governance, 'UK Biobank Ethics and Governance Framework Background Document' (Wellcome Trust, 10th October 2003) <www.wellcome.ac.uk/about-us/publications/reports/biomedical-ethics/wtd003284.htm> accessed 06 Jan 2016.

Interestingly, empirical and archival research undertaken by Langan into the origins of UK Biobank between 1998 and 2005[477] suggests that historically, it was not always anticipated that UK Biobank would take this form and at least one of the motivations behind the model was security of significant investment of public and charity funding. Indeed, this model was perceived to depart from 'standard academic practice' in science research, which can ordinarily be typified into two funding models:

> 'It is a strange set up as usually funding takes two forms: the idea is approved and people are given the money to do it or (mostly in the private sector) funders give people the money to manage the project but it is still their project. UK Biobank is trying to do both. It invited investigators to take part but the funders have not allowed them the authority to take care of the science.' [030, p.42; p. 3].[478]

Langan's thesis was based on evidence from MRC archived documentation, within which there was no record of any debate regarding the selection of the model. In fact, to date there is still very little concrete, accessible evidence as to whom selected the model, why it was chosen, and what alternatives were considered.[479] However, based on Langan's empirical findings, it is possible to deduce that establishing UK Biobank as a separate legal identity was seen as a means of providing protection for people taking part in the study; gaining the public's trust in the project, as well as securing the considerable investment of public and charitable funds.

Langan conducted interviews with the academic scientific community involved (directly and indirectly) in UK Biobank, representatives of the funding bodies and representatives of UK Biobank Ltd between 2004- 2005 (i.e. after UK Biobank's establishment).[480] Answers from those interviewed suggest that representatives of the funding bodies (DH/MRC/WT) established the 'hub' as a company to ensure that it was free from any particular individual or groups' control. Representatives of the funding bodies argued that the hub should be established as an entity separate from the funding bodies, the Government and any single organisation, including

[477] Langan MA, 'A contemporary history of the origins and development of UK Biobank 1998-2005 (PhD thesis, University of Glasgow 2007). Langan's research was conducted until 2005 when significant organisational changes meant that the 'hub and spoke' model was significantly altered and Professor Sir Rory Collins was appointed CEO and PI of UK Biobank.
[478] Ibid.
[479] Ibid.
[480] Ibid. 85: Langan refers to interviewing 'four funders' though these are not specified and interview responses are of course confidential.

universities, to ensure its independence. Establishing the 'hub' of UK Biobank as a charitable company was a means to prevent any organisation from exerting undue influence and to grant it a strong separate identity 'that would gain a life of its own.'[481] A 'spoke'[482] representative commented:

> They chose it [the establishment of the hub as a charitable company] to sort of remove it from them [the funding bodies] the power of control of it [UK Biobank], so its separate, it's not the MRC's project, it's not Wellcome's project, it's not the Department of Health's - it's Biobank's project.[483]

A representative of the funding bodies stated:

> We believe it [the establishment of the hub as a company] gives, especially with this type of database, patients who consent to be part of the study reassurance that this is not a company that's going to make profit out of it, it's not a Government sponsored organisation that they might begin to feel a little bit, in the future anyway, not happy with, some kind of Government sponsored thing for patients is a fear that they are not giving it to a truly independent body and use it in the best interests, not simply to them but of the other people in the UK.[484]

Another funding body representative remarked:

> It wasn't easy to see how you could create the kind of resource that you wanted while simply giving a grant to one of the organisations in the field. You'd have ended up with something that belonged more to a university than it did to the national research enterprise but then we also needed a model through which a set of funders could operate and feel comfortable with.[485]

Thus, independence emerged as the key reason for establishing UK Biobank as a charitable company. However, the interviews also highlighted a fundamental tension between the views of academic scientists and the funding bodies (MRC and WT) regarding such independence and the reality of those actually in control. In particular, academic scientists criticised the project as being politically rather than scientifically driven and expressed dissatisfaction at the control exerted by the

[481] Ibid. 212
[482] 'Spokes' are the regional collaborating universities: described in Ibid.
[483] Langan MA, 'A contemporary history of the origins and development of UK Biobank 1998-2005 (PhD thesis, University of Glasgow 2007), 211
[484] Ibid.
[485] Ibid. 212

funding bodies over the resource, which was allegedly 'driven from the top.'[486] Academic scientists from the collaborating Universities ('spokes') argued that it was in fact the funding bodies, and not the Company (UK Biobank Ltd - or the 'hub') who were in control of UK Biobank. One spoke member reflected:

> Whenever we've raised something that we think should be questioned and we are given back the message that the funders won't countenance it, it gives us the impression that the funders are keeping a very tight rein on the project.[487]

The interviews highlighted dissatisfaction of scientists and collaborating Universities with the chosen organisational structure. In particular, criticism focussed on the role of the funding bodies (the MRC, WT and the DH) in the organisation and running of the resource. One spoke member commented:

> The funders are particularly concerned with the scale and in discussions of having fewer participants and more detailed information the funders have always stuck to the scale of the project… the project is not scientifically driven, it is driven from a marketing point of view, political with a small p. They do not want a better study with smaller, they want to be the 'largest', they are just not interested in anything smaller.[488]

Academic scientists also accused the funding bodies of taking organisational decisions, such as those regarding the chosen model and the Board of Directors. They argued that the funding bodies, rather than the scientists, were responsible for the model. A member of the Expert Working Group remarked:

> In terms of the way the project was set up, I can't really comment except that it went into the offices of the Wellcome Trust and the MRC and to my knowledge, the model for how it was to be set-up did not arrive out of a consensus view offered by the study proponents but by the organisers and the funders, so it was driven by the funders, not by the scientists.[489]

Criticism focussed on the role of the funding bodies within the organisational structure, specifically in the Board of Directors. Given the involvement of representatives of the funding bodies, academic scientists questioned the

[486] Ibid.197
[487] Ibid.
[488] Ibid.198
[489] Ibid. 199

independence of the Board. For example, a clinical academic involved in UK Biobank commented:

> It's not a truly independent company because there are three directors who come from the funding agencies, of course, very properly, their interest in coming from the funding agencies is declared but it means that the Board is looking over its should all the time, what the funding agencies would want.[490]

One spoke member stated: 'the Board is largely, not necessarily governed, but largely influenced by the views of the funders.'[491] Acknowledging the role of the funding bodies on the Board, one member of the Board commented 'the Board has to be aware of the need to meet the requirements of the funders at all times.' Justifying this involvement, academic scientists acknowledged the funding bodies' financial obligations and their importance in getting the project up and running. A clinical academic involved in UK Biobank stated:

> It's an awful lot of money and it is their money, they're responsible publicly for it... they've got to retain a delicate, light touch but very clear understanding of what's going on so that they're guarding their money but not slowing things down.[492]

Representatives of the funding bodies also justified their role based on their obligations to ensure the security of financial investment. For example, one representative commented:

> It's not something that the Medical Research Council or even the Wellcome Trust would probably feel comfortable simply delegating to a group of scientific champions... in the after analysis the Wellcome Trust has its trustees, and the MRC has its council and government to whom they are accountable.[493]

They also referred to their legal obligations as members UK Biobank Ltd (the company itself) as justification for their continued involvement following the set-up of UK Biobank Ltd;

> There is still some need I think to be involved in stakeholder engagement, ensuring that we get the best value for money from Biobank and that Biobank's providing

[490] Ibid
[491] Ibid.
[492] Ibid. 200
[493] Ibid. 202

> what the scientific community wants and that can't solely be down to Biobank and its objectives.[494]

Overall, it seems that Langan's empirical research is evidence that the decision to structure UK Biobank as a charity company was made by the funders, who saw the model as a means of securing the independence of the biobank while guaranteeing their significant financial investment and retaining long-term control of the organisation and maintenance of the resource. As will be briefly explained, the funders went on to be key stakeholders in the legal structure of UK Biobank.

Constituting UK Biobank in this way raises a number of risks for the accountability of UK Biobank to both the individual donors and the public good mission of the resource. Some of these risks are hinted at in Langan's empirical findings, such as the seemingly dominant control of the funders, potentially at the expense of advice of scientific experts who questioned the merit and justifications for a population biobank in the UK. Moreover, despite justifying the choice of a private legal structure on the grounds of its separation from any one funder, the remains of this chapter will highlight that in fact the companies' Board of Directors who are responsible for running the resource are accountable to the WT and the MRC as the signatory Members of the company. Furthermore, the Ethics and Governance Council, which alternatively could have been set up on a statutory footing to secure public accountability to Parliament, is also in fact accountable to those behind the creation of the EGC and the EGF: the WT and the MRC.

Therefore, to investigate the potential risks raised by this framework, the next section of this chapter will introduce the dual legal structure of UK Biobank Ltd as a charity company, before Chapters 5 and 6 critically analyse the constitution of this private model, the interests that are protected and promoted in the running of UK Biobank, and the extent to which it is publically accountable.

4.3.2 Legal structure

UK Biobank was incorporated as a charity company, 'UK Biobank Ltd', on 28 November 2003[495] and consequently is registered with Companies House[496] and the

[494] Ibid. 202

Charity Commission.[497] Acknowledging the need to command the public's full confidence and trust, it was planned that the Chairman (CEO) and all other Board members of the company would be appointed in a transparent way using the 'Nolan Principles for Public Life'.[498]

It is important to deconstruct exactly what this legal structure entails, because in conjunction with the public-private mix of funding from the WT, MRC and DH, the private model that was chosen has significant implications for mechanisms of oversight for UK Biobank activities. Fundamentally, by virtue of this legal structure and the timing of its incorporation, UK Biobank is subject to a dual regulatory regime of both UK charity law via the Charities Act 2011 and UK company law and the Companies Act 2006.[499] This legal basis will be briefly explained before more critical analysis of the implications of this regime in Chapters 5 and 6. Overall, incorporation as a charity company adds a further layer of complexity and accountability to the multi-faceted legal framework of UK Biobank, in addition to the wider legal framework for biobanking outlined in the first section of this chapter.

4.3.3 Incorporation as a charity

A critical aspect of the legal position of UK Biobank is its charitable status; a choice that allowed the founders to advocate the new body as an organisation that was not driven by a profit motive and would act in the public interest.

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[495] Company number 04978912: <https://betACompanieshouse.gov.uk/company/04978912> accessed 19 January 2016

[496] Ibid.

[497] Charity Commission 'UK Biobank' <http://betACharitycommission.gov.uk/charity-details/?regid=1101332&subid=0> accessed 19 January 2016

[498] House of Commons Select Committee on Science and Technology 'The Work of the Medical Research Council' Session 2002-2003 adjournment debate: Column 370;
Committee on Standards in Public Life, 'The 7 principles of public life' (the 'Nolan principles', Cabinet Office 1995) <www.gov.uk/government/publications/the-7-principles-of-public-life/the-7-principles-of-public-life—2> accessed 17 September 2014.

[499] The Charities Act 2006 introduced the Charitable Incorporated Organisation as new legal structure for charity companies, now incorporated in the Charities Act 2011 Part II 'Charitable Incorporated Organisations'. Amongst other benefits simplifies the regulatory regime such that only the Charity Commission regulates charity companies with this structure. This will be discussed further in this Chapter. For now, it is important to note that this legal structure was not available to UK Biobank Ltd at the time of its establishment, although it is possible for them convert to this legal structure in the future: Charity Commission 'Change your charity structure' (*Gov.uk*) <https://www.gov.uk/guidance/change-your-charity-structure> 2 January 2016

For the purpose of the Charities Act 2011, 'charity' means an institution that is established for charitable purposes only,[500] and falls to be subject to the control of the High Court in the exercise of its jurisdiction with respect to charities.[501] The main advantages of charitable status include: significant tax exemptions and reliefs;[502] enhanced public standing;[503] advice and support from the Charity Commission;[504] and consent requirements for charity proceedings.[505] All of these benefits match the proclaimed purposes of the model chosen for UK Biobank.

On the other hand, there are a number of perceived disadvantages of charitable status, from the perspective of company law. Primarily, charities are subject to a certain degree of public control by the Attorney-General (A-G) and the Charity Commission. The Charities Act also imposes specific duties on persons having general control and management of the administration of the charity.[506] This oversight means charity companies are subject to a dual administrative burden and must register and report to both Companies House and the Charity Commission.

Registration as a charity also places considerable limitations on the scope of a company's objects and powers. The default provision in respect of private companies is that such a company's objects are unlimited.[507] On the other hand, the objects of a charitable company must be wholly and exclusively charitable[508] and its benefits must be made available to a sufficient section of the community for the company to fulfil its charitable purpose.[509] Satisfying the requirements for charitable

[500] Charities Act 2011 s.1(1)(a)
[501] Ibid s.1(1)(b)
[502] Specific tax exemptions can be claimed by a charity by virtue of s.505(1) of the Income and Corporation Taxes Act 1988.
[503] There is argument that possession by an institution of a charity registration number continues to inspire confidence in the public mind, and may elicit a better response in appeals for funds: Luxton P, *The Law of Charities* (OUP 2001), 62
[504] One of the Charity Commissions' general functions is to promote the effective use of charitable resources by giving information or advice to charity trustees on any matter affecting the charity: Charities Act 2011 s 15.
[505] Legal proceedings brought under the court's jurisdiction with respect to charities including charitable companies are 'charitable proceedings' for the purpose of Charities Act 2011 s.115. As a general rule, charity proceedings may only be brought by a specified class of persons and only with the consent of the Charity Commission. These restrictions can be seen as a form of protection for charities: *R v National Trust, ex p Scott* [1988] JPL 465, 467. This matter will be described in detail later in the chapter.
[506] Charities Act 2011 s.177 *Charity Trustees (*The meaning of which will be discussed later in this chapter)
[507] Companies Act 2006 s.31(1)
[508] Charities Act 2011 s.1(1)(a)
[509] Ibid. s.4

incorporation, UK Biobank's mission is to advance the health and welfare of human beings, and promote knowledge and education,[510] and was designed to fall within the list of charitable purposes found in the Charities Act, under 'the advancement of health or the saving of lives.'[511] As will be argued later in this thesis (Chapter 6), incorporation as a charity adds an additional layer of accountability that ensures UK Biobank is run in accordance with its public good mission. This accountability arises because charities must be run for a recognised charitable 'purpose' to enjoy the benefits of charitable status and a (broadened) non-exclusive list of these purposes is found in s.3(1) of the Charities Act 2011.

The choice of charity company status for UK Biobank needs to be viewed in the context of more general ongoing debates about this model of organisation, which will be discussed in detail in the next Chapter of this thesis. In brief, only institutions with a recognised legal structure can enjoy charitable status. Prior to the Companies Act 2006, these were the trust, unincorporated association or corporation.[512] The drawbacks of these legal structures for charitable institutions have been noted:[513] the trust is seen to lack legal personality distinct from its trustees and the unincorporated association falls at the same hurdle.[514] Consequently, this leaves trustees vulnerable to potentially unlimited liability; [515] for example, when an unincorporated association is sued or incurs liabilities the trustees are jointly and severally liable. On the other hand, the most commonly used corporate form, the company limited by guarantee, enjoys separate legal personality so that it may enter into contracts, hold title to land, sue and be sued in its own name. Trustees and Directors of an incorporated charity are therefore better insulated from individual financial liability;[516] and any liability

[510] <www.ukbiobank.ac.uk> accessed 20 October 2012
[511] Charities Act 2011 s.3(d)
[512] Charities Act 2011
[513] Cabinet Office Strategy Unit, 'Private Action, Public Benefit: Charitable Incorporated Organisation' (Background Paper, Cabinet Office, September 2002) Pg 4 <http://webarchive.nationalarchives.gov.uk/+/http://www.cabinetoffice.gov.uk/media/cabinetoffice/strategy/assets/inc.pdf> accessed on 22nd October 2012
[514] Cross SR, 'New legal forms for charities in the United Kingdom' [2008] Journal of Business Law 662.
[515] Warburton comments that '[I]t is probably no longer realistic to expect charity officers to accept potential open-ended liability.' Warburton J, 'Charity corporations: the framework for the future' [1990] Conveyancer and Property Lawyer (March-April) 95. Cited in Cross SR, 'New legal forms for charities in the United Kingdom' [2008] Journal of Business Law 662.
[516] Although, trustees remain liable for breaches of trust and in the case of a charitable company for fraudulent or wrongful trading. Fraudulent trading is when a person acts dishonestly with the intent to defraud creditors. Wrongful trading is where the director knew or ought to have known that there was no reasonable prospect of the company avoiding insolvency: Cabinet Office Strategy Unit, 'Private

will be on the part of the Company as a separate entity.[517] Incorporation can also facilitate a membership structure without shareholders, where there is no share capital.[518]

However, the charitable company structure is not without drawbacks. Charity companies are subject to dual registration at Companies House and the Charity Commission, thereby doubling the administrative burden of preparing and submitting accounts and annual returns.[519] The result is that some charitable institutions may be subject to two sets of laws: those that relate to status (charity law) and those that relate to structure (company law).[520] As we will see all of these issues are relevant to, and evident in, the UK Biobank model.

4.3.4 Ownership of UK Biobank Ltd

As will be analysed in more detail in Chapter 6 of this thesis, another fundamental implication of the creation of UK Biobank Ltd as a charitable company limited by guarantee is that UK Biobank Ltd is a separate entity with its own legal personality that is 'independent' of the resource itself. This means that any liability will be on the part of the Company as a separate entity, rather than the individual members or directors. This independence also facilitates ownership rights over the biobank to the charitable company, who in turn have powers to pursue its charitable objects. In brief these objects are:

- The power to undertake the project;[521]

Action, Public Benefit: Charitable Incorporated Organisation' (Background Paper, Cabinet Office, September 2002) Pg 4 <http://webarchive.nationalarchives.gov.uk/+/http://www.cabinetoffice.gov.uk/media/cabinetoffice/strategy/assets/inc.pdf> accessed on 22nd October 2012

[517] *Salomon v Salomon & Co Ltd* [1897] AC 22, HL. This case established the following fundamental principle of company law: on incorporation, a company becomes a separate legal entity distinct and separate from its shareholders and is not the agent of those shareholders. As a separate legal entity, the company must be treated like any other independent person with rights and liabilities appropriate to itself. Hannigan B, *Company Law* (2nd ed, OUP 2009) 53. Unless, in exceptional circumstances the 'veil of incorporation' is lifted so as to hold individual actors liable for their actions. For example, to prevent a fraud from being perpetrated: *Guildford Motors v Horne* [1933] Ch 935.

[518] A company limited by guarantee is a company having the liability of its Members limited by the Memorandum to such an amount as the Members may respectively thereby undertake to contribute to the assets of the company in the event of it being wound up: Companies Act 2006 s.3(3)

[519] For example most charitable companies must make annual filings with both Companies House and the Charity Commission.

[520] Charities Act 2011; Companies Act 2006 respectively.

[521] Memorandum of Association Para. 4(A): UK Biobank Ltd., 'Memorandum and Articles of Association of UK Biobank Limited' (Incorporated 28 November 2003) available at Companies

- To collect, gather in, label, store and anonymise information and blood and samples;[522]
- To develop and operate policies governing and encouraging access and use of the resource and data samples and to grant licenses inside and outside the UK;[523]
- To receive, investigate and resolve complaints;[524]
- To hold, grant licenses, sell, lease and deal with or dispose of rights or interest in, the undertaking, property, rights and assets held by the Company, including the Resource;[525]
- To invest capital held by the Company not immediately required for the objects of the Company in any part of the world in investments;[526] and
- To acquire any copyright, patent, publication or other intellectual property right in or arising out of the resource, data samples and any other research or research results.[527]

Significantly, the Board of Directors, who are charity trustees for the purpose of UK charity law[528] and Company Directors for the purpose of UK company law,[529] 'may exercise all the powers of the Company.'[530] The purpose of the next chapters (Chapters 5 and 6) will be to critically analyse the implications of this dual legal framework for the range of stakeholders involved in UK Biobank. For now, it is clear that this apparent 'ownership' gives rise to an ethical tension between the no property rule and rights of access, use, and control that are all traditionally accepted to be property interests.[531]

House, company no. 04978912 <https://beta.companieshouse.gov.uk/company/04978912/filing-history> accessed 8 Feb 2016.

[522] Ibid. Para 4(B)

[523] Ibid. Para 4(E)

[524] Ibid. Para 4(G)

[525] Ibid. Para 4(J)

[526] Ibid. Para 4(K)

[527] Ibid. Para 4(Q)

[528] Charities Act 2011 s 177.

[529] Companies Act 2006.

[530] Articles of Association, Para 13.1: UK Biobank Ltd., 'Memorandum and Articles of Association of UK Biobank Limited' (Incorporated 28 November 2003) available at Companies House, company no. 04978912 <https://beta.companieshouse.gov.uk/company/04978912/filing-history> accessed 8 Feb 2016.

[531] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440.

Significantly, this chapter has identified a number of key risks that may arise from the choice of this structure, informed by both Langan's empirical analysis and Chapters 1 and 4's discussion of the ethical and legal challenges of biobanking in the UK. For example, the public good mission of UK Biobank may compete with the aims and objectives of the funders of the corporation and its managers. Furthermore, the rights of individual donors (Chapters 1 and 4), such as protection from breach of privacy or personal harm, may not be as effectively protected as would be the case under English public law or via Parliamentary scrutiny, which may have been the case if UK Biobank had been established on a statutory footing. However, the dual legal basis of UK Biobank does go some way to addressing certain risks, as will be shown in the remaining chapters. To investigate the potential risks that arise by virtue of this dual legal structure in terms of the interests that are protected and promoted within this model, Chapter 6 will critically analyse the constitution of this private model to highlight the extent to which it is publically accountable. The remains of this thesis will be dedicated to investigating the extent to which these risks are mitigated by the potential for legal remedies outwith the model, in negligence or judicial review.

First, though, the question arises as to how the UK Biobank design addresses the risks that derive from its legal structure. In direct response to these risks the core funders (the WT and the MRC) built core institutional safeguards in the form of a self-regulatory governance policy; the UK Biobank 'Ethics and Governance Framework'. This Framework details the ways in which UK Biobank Ltd manages the ethical challenges associated with population biobanking and their relationship with 'participants', 'research users', and 'society'. Furthermore, an accompanying independent 'Ethics and Governance Council' has been established, accountable to the WT and the MRC, to monitor UK Biobank's conformance with this Framework, and mandated with a purely advisory role to advise on the interests of participants and the general public in relation to UK Biobank. The final part of this chapter will outline some of the ways in which this governance framework addresses the ethical challenges described in Chapter 1 and will begin to consider the remit of the EGC, before the wider legal standing of the EGC in the running of UK Biobank Ltd as a charity company is evaluated in Chapter 6.

4.4 UK Biobank Ethics and Governance Council and Ethics and Governance Framework

4.4.1 Interim Advisory Group on UK Biobank Ethics and Governance

The first draft Ethics and Governance Framework (EGF) was prepared by the UK Biobank funders the DH, MRC and the WT, with the advice of an Interim Advisory Group on Ethics and Governance (IAG).[532] In view of the regulatory framework for biobanking in the UK and bearing in mind the choice of legal structure for UK Biobank as a charity company, the IAG ultimately recommended that the UK Biobank should adopt and be subject to an 'Ethics and Governance Framework' (EGF), which was to be overseen by an independent, 'Ethics and Governance Council' (EGC).[533]

The IAG included experts in research ethics, philosophy, law, science and social science, and lay representation and was chaired by a consultant in health policy and ethics. The Group met during early 2003 and their deliberations were informed by the aforementioned consultations, an ethics consultation workshop held in April 2002 and two consultation exercises; undertaken in May 2003 on an early draft of the EGF, in which members of the public, health-care professionals, and a wide-ranging group of experts and stakeholders participated. The IAG also recruited People Science & Policy Ltd (PSP) to establish a panel of 64 lay people aged between 45 and 69 (the age group of UK Biobank participants) to consult on the draft EGF before finalising their report to the funders. Version 1.0 of the EGF was published in September 2003 and copies of the Framework were made publically available for comment and sent to over 100 stakeholders between 24 September 2003 and 24 October 2003.

Evidently, UK Biobank's funders perceived the need to establish internal governance arrangements and independent oversight as an extra layer of scrutiny of the management and day-to-day running of UK Biobank, in the hope that this inspired trust in participants and the general public. It is arguable that their decision was

[532] Interim Advisory Group on Ethics and Governance, 'UK Biobank Ethics and Governance Framework Background Document' (Wellcome Trust, 10th October 2003) <www.wellcome.ac.uk/about-us/publications/reports/biomedical-ethics/wtd003284.htm> accessed 06 Jan 2016.
[533] Ibid.

informed by the concerns expressed in reports of the House of Lords Select Committee and Human Genetics Commission, previously mentioned, as well as the controversy that had led to the demise of the Icelandic national database (Chapter 2). The EGF was an opportunity to communicate in a transparent way exactly how the project intended to handle these ethical challenges. The contents of the Framework and the remit of the Council will now be outlined.

4.4.2 The Ethics and Governance Council

During the IAG discussions the need for the establishment of an oversight body widely perceived to be critically important[534] and this oversight body became the Ethics and Governance Council. The EGC was established in 2004 as an independent advisor to the Board and the Funders and according to the EGC modus operandi,[535] the remit of the EGC includes the publishing of public reports on the conformance of UK Biobank with the EGF and with the interests of the participants and the public.[536]

The EGC does not have the power of veto over the use of data or samples. This power, as we have seen, belongs to the Board of Directors. However, no member of the EGC is present on the Board of Directors. In fact, if the EGC feels that a particular application is not in the public interest or is unethical, they have three forms of redress: lodge a complaint, report publically on their views and ultimately, if dissatisfied with the Board's response, they could resign. Influential media coverage could mean, 'if the EGC did 'go public' no doubt there would be extensive

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[534] People Science and Policy Ltd, *UK Biobank Consultation on the Ethical and Governance Framework—Report prepared for the Wellcome Trust and The Medical Research Council* (People Science & Policy Ltd 2003) <www.ukbiobank.ac.uk/wp-content/uploads/2011/07/EGF-Consultation.pdf?> accessed 5 February 2016

[535] UK Biobank Ethics and Governance Council 'Terms of Reference and Modus Operandi' <http://egcukbiobank.org.uk/sites/default/files/terms%20of%20reference%20and%20modus%20operandi.pdf> accessed 5 February 2016

[536] It is noted that the remit of the EGC was modified as of 1 January 2015 and consequently, the EGC will no longer review every application made to the UK Biobank. Instead, the UK Biobank Board of Directors will 'Alert' the EGC to applications that raise ethics or governance issues that merit the Council's attention: 'Under this arrangement, the EGC will rely on UK Biobank to advise it that a significant application is in the system. An application will be significant where it involves: a request for re-contact; or; a novel and/or important ethical issue; or; a novel and/or important governance issue; or making a decision that will set a major precedent; or; some other matter that, in the judgment of UK Biobank, merits the attention of the EGC.'
UK Biobank Ethics and Governance Council 'The Ethics and Governance Council's Oversight in Relation to UK Biobank's Administration of the Access Process' (2014): <http://egcukbiobank.org.uk/sites/default/files/Final%20EGC%20Oversight%20131114.pdf > accessed 5 February 2015

media coverage and a subsequent effect on recruitment/retention of donors.'[537] Significantly, this falls short of the promise made in the Government White Paper *Our Inheritance, Our Future* (previously mentioned) that stated there would be an 'independent monitoring body with the power of veto.'[538]

In fact, the remit and powers of the EGC were 'the most difficult issue for the IAG – suggestions ranged from monitoring and advising, to regulatory oversight, even to veto power over UK Biobank's actions.'[539] Some members, 'sceptical of what they saw as being merely rhetorical power' thought that the EGC should have the veto powers envisaged in the aforementioned White Paper, as well as independence, to give it authority to exert over UK Biobank's actions if necessary and foster public perception of its protective status. The Group also noted that veto powers could conflict with the legal authority and responsibility of the Board of Directors and probably would not be acceptable to the Funders or the Board. The IAG examined a number of possibilities and obtained legal advice on the matter, and concluded that the most appropriate status for the Council was a committee established by the MRC and the WT: 'On practical legal grounds the Council's being established as a company limited by guarantee was judged not to be appropriate'.[540]

As a committee established by the MRC and the WT the EGC is accountable to the Funders for acting within its remit, carrying out its functions and acting in accordance with their modus operandi. The EGC may be required by the Funders to provide information to demonstrate this.[541] Importantly, to fulfil this remit, the EGC have the right to require from parties involved in UK Biobank 'whatever information and discussion are necessary.'[542] Chapter 5 will investigate how far this is a satisfactory position from the perspective of corporate governance theory, or whether the EGC should be more adequately represented on the Board of Directors, to better

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[537] Ibid.
[538]Department of Health, *Our Inheritance, Our Future: Realising the Potential of Genetics in the NHS* (White Paper, CM 5791-II, 2003).
[539] Interim Advisory Group on Ethics and Governance, 'UK Biobank Ethics and Governance Framework Background Document' (Wellcome Trust, 10th October 2003) <www.wellcome.ac.uk/about-us/publications/reports/biomedical-ethics/wtd003284.htm> accessed 06 Jan 2016.
[540] Ibid.
[541] UK Biobank Ethics and Governance Council 'Terms of Reference and Modus Operandi' <http://egcukbiobank.org.uk/sites/default/files/terms%20of%20reference%20and%20modus%20operandi.pdf> accessed 5 January 2016
[542] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016.

protect donors and facilitate accountability. Subsequently, Chapter 6 of this thesis will demonstrate that despite a lack of legal 'teeth', there may nonetheless be avenues available within the legal structure of UK Biobank as a charity company for the Ethics and Governance Council to hold UK Biobank to account.[543]

Before this detailed legal analysis, the final part of the current chapter will examine UK Biobank's EGF and the extent to which this policy instrument strives to balance the public and private interests involved in UK Biobank.

4.4.3 The Ethics and Governance Framework

The Ethics and Governance Framework was drafted by the WT and the MRC for UK Biobank in view of the regulatory framework for biobanking in the UK. While the EGF is not legally binding, it is a statement of principle that communicates how the ethical challenges of biobanking will be managed as per the UK's regulatory position. As a living document it will be revised as necessary to adapt to changing social attitudes or unanticipated challenges. A series of vital statements as to UK Biobank's constitution are enshrined in the EGF. The Framework communicates the UK Biobank's relationship with, and commitment to, participants,[544] researchers,[545] and society at large[546] and in so doing, 'it identifies a very full range of stakeholders and the interests considered to be at stake…'[547] (to be explored in Chapter 5 and 6.)

Purpose

The Biobank's purpose is articulated in the Framework as:

> UK Biobank aims to build a major resource that can support a diverse range of research intended to improve the prevention, diagnosis, and treatment of illness and the promotion of health throughout society.[548]

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[543] In charity law, as a 'person interested', the EGC is potentially able to challenge the BoD decision making via UK Biobank's legal structure as a charity company limited; analysed in depth in the next two Chapters of this thesis.
[544] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016
[545] Ibid. II. 'Relationship with Research Users'
[546] Ibid. III. 'Relationship with Society'
[547] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).
[548] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016; 'Purpose and Overview'

Their website expands;

> UK Biobank will ensure that only those who are bona fide researchers working on health related research in the *public interest* get access to the valuable information and data.[549] (Emphasis added)

Consent

As Chapter 1 has illustrated traditional, informed consent is problematic in the biobanking context, where it is not possible (or desirable) to predict all future applications for which the biobank will be used. Therefore, two options were available to UK Biobank: specific or broad consent. With specific consent, any use of data other than that explicitly outlined in the consent process would require contacting donors to re-consent each time a new research proposal came up for consideration. UK Biobank aims to encourage as many legitimate uses of the material stored as possible, consistent with its stated purpose of the public interest. To enable this, and informed by guidance from the (then) Human Genetics Commission that consent in this context cannot be fully specific,[550] UK Biobank adopted a broad consent model.[551] This general consent was deemed to be acceptable by the HGC where confidentiality is protected, data is anonymised and there is provision for the right to withdrawal.[552]

UK Biobank's EGF reflects this and states:

> Consent will be sought to participate in UK Biobank. Participation will be presented as an opportunity to contribute to a resource that may, in the long term, enhance other people's health. Because it will be impossible to anticipate all future research

[549] UK Biobank 'UK Biobank in the news' (*UK Biobank*) <http://www.ukbiobank.ac.uk/2012/04/uk-biobank-in-the-news-2/> accessed 9 April 2012
[550] Human Genetics Commission, *Inside Information: Balancing interests in the use of personal genetic data* (Department of Health 2002) <http://webarchive.nationalarchives.gov.uk/20061023110946/http:/www.hgc.gov.uk/UploadDocs/DocPub/Document/insideinformation_summary.pdf> accessed 31 January 2016.
[551] At the time, interest groups such as GeneWatch UK argued that participants should be given more specific information so they had the option to be informed of when and where their genetic information was being used, and whether to consent to use of their data in research funded by certain organisations: GeneWatch UK, Memorandum submitted by Gene Watch UK (Appendix 2 to The Minutes of Evidence) in Select Committee on Science and Technology, *The Work of the Medical Research Council* (HC 2002-3, 132).
[552] Ibid.

> uses, consent will be sought for research in general that is consistent with UK Biobank's stated purpose (rather than for specific research.)[553]

This consent is based on an explanation of the following: the purpose of the biobank and its longitudinal nature; the participation process; the fact that there will be a link to the full record of medical and health relevant information; the fact that UK Biobank is the legal owner of the database and the samples therein; the safeguards that will be in place including reversible anonymisation; the research access requirements, including that commercial entities will apply; re-contact; the right to withdrawal at any time; and UK Biobank's commitment to engage with participants and society.[554] Participants have a three-tiered right to withdrawal: 'No further contact' maintains permission to use information and samples and allows UK Biobank to obtain further information from participant's health records, but prohibits further direct contact with the participant. 'No further access' prohibits UK Biobank obtaining further information from participant's health records in the future, but is otherwise the same as 'no further contact.' 'No further use' is the most comprehensive withdrawal option and prohibits further contact or obtaining further information and requires any information or samples collected previously to be no longer available to researchers and destroyed.[555]

Safeguarding confidentiality

UK Biobank organisers concluded that general consent was acceptable since there was to be anonymity of data samples;[556] Biobank data will be stored and routinely used in this format:

> UK Biobank is committed to protecting the confidentiality of data and samples. Systems will be in place for secure data flow and for protecting confidentiality, (reversibly) anonymising data and samples, and enforcing confidentiality.[557]

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[553] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 4 April 2012; I.B.1: 'Consent'

[554] Ibid.

[555] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 4 April 2012; I.B.6: 'Right to withdraw'

[556] Human Genetics Commission, *Inside Information: Balancing interests in the use of personal genetic data* (Department of Health 2002) <http://webarchive.nationalarchives.gov.uk/20061023110946/http:/www.hgc.gov.uk/UploadDocs/DocPub/Document/insideinformation_summary.pdf> accessed 31 Jan 2016.

No information will be released in any form that allows individuals to be identified. That said the anonymisation process has to be reversible to allow individuals to be re-identified for research purposes and to honour participants right to withdrawal.[558] Participants are made aware at the time of consent that UK Biobank has the facilities in place for re-contact and consent accordingly. The consent form states:

> I understand that I may be re-contacted by UK Biobank (e.g. to answer some more questions and/or attend another assessment visit), but this is optional.[559]

Since UK Biobank reached its target for recruitment in 2010, 20,000 participants from Manchester, Sheffield, Liverpool and Leeds have returned for a second assessment.[560]

Access and Ownership

Access will be granted to UK Biobank if research purposes are deemed to be in the public interest. But data held in UK Biobank is potentially of interest to a number of parties other than researchers. For instance: the police;[561] insurers;[562] employers; commercial companies outside of medical research; and the participants themselves. In response to the controversy surrounding the Icelandic population database, which granted an exclusive licence to private company deCODE Genetics, UK Biobank is

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[557] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 4 April 2012; I.B: 'Understandings and Consent'

[558] Therefore there is some potential for misuse of data: 'ultimately there will remain a remote possibility that the identifiable information will be released from the UK Biobank and that this must be clearly explained when seeking consent': Human Genetics Commission written evidence to House of Commons Select Committee on Science and Technology Third Report: 'The Work of the Medical Research Council' Session 2002-2003 Ev. 55

[559] UK Biobank, Consent Form: UK Biobank (UK Biobank 2006) <www.ukbiobank.ac.uk/wp-content/uploads/2011/06/Consent_form.pdf?phpMyAdmin=trmKQlYdjjnQIgJ%2CfAzikMhEnx6> accessed 31 Jan 2013

[560] Re-contact will become available to more UK Biobank donors in other parts of the country in due course: UK Biobank 'Have you been invited to a repeat assessment?' <http://www.ukbiobank.ac.uk/2012/06/repeat-assessments-adding-value-to-this-exciting-resource/> accessed 1 August 2013

[561] Currently the DPA contains exemptions allowing police access to personal data to prevent or detect crime or to apprehend or prosecute offenders: Data Protection Act 1998 s.29(1)

[562] Prohibited use of genetic information by insurers is currently subject to a voluntary moratorium agreed with the Association of British Insurers (ABI): HM Government and Association of British Insurers, *The Concordat and Moratorium on Genetics and Insurance* (ABI 2014) <www.abi.org.uk/Insurance-and-savings/Topics-and-issues/Genetics/Genetic-testing> accessed 19 March 2015.

the ‘legal owner’ of the samples for benefits to be directed towards the ‘public good’ and held in the public domain.[563]

According to its specifically drafted ‘Access Procedures’[564] UK Biobank will seek payment for granting access to the resource with a fixed charge for managing the application review process and a variable charge depending on how many samples, tests and/or data are required for the approved research project.[565]

Feedback of results

UK Biobank will generally not provide health information to participants and a clear explanation of this policy (and the few exceptions) will be provided in the participant information material:

> UK Biobank will aim to ensure that participants understand that enrolment does not provide them with a health check. In principle, it would be possible to provide participants with the results of some measurements or observations at any of the three stages; at the initial assessment visit (e.g. blood pressure or incidental findings), in the initial stage before the samples are stored (e.g. white cell count) and much later as results arise from research studies (e.g. genetic or biochemical studies).[566]

Under existing arrangements, the only information that individual UK Biobank participants receive are ‘baseline measures’ at the assessment visit.[567] These are

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[563] UK Biobank, ‘UK Biobank Ethics and Governance Framework’ (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 1 August 2013 II. A: ‘Stewardship Of Data And Samples’

[564] UK Biobank, *Access Procedures: Application and review procedures for Access to the UK Biobank Resource Version 1.0* (UK Biobank, 2011 <www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Access-Procedures-2011.pdf> accessed 24 Jan 2014.

[565] UK Biobank ‘Principles of Access’ <http://www.ukbiobank.ac.uk/principles-of-access/> accessed on 7 April 2012

[566] UK Biobank, ‘UK Biobank Ethics and Governance Framework’ (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 1 August 2013, B. 3: ‘Provision of health information to participants’

[567] Ibid. B.3 states:

‘At the initial assessment visit: It would be impractical and inappropriate to conceal from participants some of the measurements taken in their enrolment visit (i.e. blood pressure, height, weight, estimated amount of fat). Consequently, a printed report will be provided at the end of their visit as a means of feeding back such measurements. By reporting standard ranges, the participant should be provided with sufficient information to give meaning to the measurements taken, so that they may act on the results if necessary and arrange to see their general practitioner or other relevant health professional. The legal duty of care for staff conducting enrolment will be determined by the research context, and will apply mainly to safe and competent collection of questionnaire data, baseline measurements, and blood or other samples. They will not have the same duty of care that they would have in a clinical setting. However, even in this research context, there may be occasions when staff consider there to

communicated in the form of a printed report which participants may act upon as necessary.[568] Measurements include blood pressure, lung function, bone density, weight, and estimated amount of fat.[569] They are compared to population standard ranges so participants have some indication of whether their results fall outside the 'normal' range. Results are considered 'abnormal' where they deviate significantly from reference values. They are considered critical when they will cause a patient to suffer a life-threatening event if not communicated immediately, in which instance participants are advised by UK Biobank (via the data collector) to visit their GP.[570]

This is also the approach adopted in UK Biobank's enhanced imaging study; for which participants were contacted to re-consent. Imaging scans conducted by trained radiographers present an important opportunity for feedback at the collection site, before researchers for subsequent studies use data. Incidental findings in the course of imaging research are reported to be common, around 3-12% in neuroimaging and up to 30% in body imaging depending on the population being studied.[571] Therefore, UK Biobank's provisional approach will be to provide limited feedback as part of their 'baseline assessment'[572] for incidental findings considered to be potentially 'serious' (defined in this context as 'likely to threaten life span, quality of life or major body functions'[573]) that are observed during the data acquisition or quality control stage. The feedback loop provides for review by the radiologist performing the assessment, and then, if appropriate, feedback will be provided to the participant

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be a professional or ethical obligation to draw attention to abnormal measurements (such as elevated blood pressure) or incidental findings (such as possible melanoma). In such circumstances, participants will be encouraged to contact a relevant health professional.'

[568] Though donors are reminded that this is not to be considered a 'health check': UK Biobank 'Invite to repeat assessment visit' <http://www.ukbiobank.ac.uk/repeat-assessment/> accessed 18 December 2013

[569] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> 18 December 2013

[570] Knoppers BM and Kharaboyan L, '"Deconstructing" Biobank Communication of Results' (2009) 6 SCRIPTed 677, 680

[571] The Royal College of Radiologists (RCR) and the Scottish Imaging Network: A Platform for Scientific Excellence (SINAPSE), *Management of Incidental Findings Detected During Research Imaging* (The Royal College of Radiologists 2011) <www.rcr.ac.uk/docs/radiology/pdf/BFCR(11)8_Ethics.pdf> accessed 19 Dec 2015.

[572] UK Biobank's Principle Investigator Rory Collins argues that this approach is 'consistent with- but more detailed than- the standard operating procedure on incidental findings in the baseline UK Biobank assessment visit.' Peterson SE and others, 'Imaging in population science: cardiovascular magnetic resonance in 100, 000 participants of UK Biobank- rationale, challenges and approaches' (2013) 15 Journal of Cardiovascular Magnetic Resonance 46, 54

[573] Ibid.

and his/her GP.[574] This feedback mechanism raises the question of whether UK Biobank should feedback other incidental findings and the extent to which this would be in the interests of the participants and the public. This will be the topic of Chapter 7 and part of Chapter 8 of this thesis.

4.5 Conclusion

This chapter has attempted to contextualise the choice of a private legal structure for UK Biobank within the wider context of the regulatory framework for biobanking in the UK, to begin to illustrate the multiple layers of laws that are applicable to the running of the resource to secure public objectives and protect the interests of individual donors. This legal structure raises risks relating to the protection of the 'public' and 'private' interests in UK Biobank.[575] For example, it is debatable how far donors are protected from personal harm by this legal structure (Chapters 1 and 7). Furthermore, the private legal structure (as defined in the introduction of this thesis) as a charity company arguably diminishes the 'public' accountability of UK Biobank. However, the remaining chapters of this thesis will analyse the legal framework in more detail to show the extent to which such risks are avoided or mitigated.

In summary, UK Biobank was incorporated as a charity company with a mix of public and private funding from the WT, the MRC, and latterly the DH. This choice of legal structure potentially reduces the public accountability of the resource because UK Biobank Ltd is a separate legal entity independent of the public funds used to create it rather than a public body established on a statutory footing. Although comparative experiences of Iceland and Estonia suggest that the specific statutory frameworks for population biobanks do not necessarily guarantee a successfully operating biobank, it is arguable that public accountability goes some way to ensuring that a biobank is held to their stated aims. Thus, while the legal structure of UK Biobank as a charity company undoubtedly brings with it a number of benefits for the funders (for example, investment security, tax advantages and liability implications) whether accountability has been lost or maintained is questionable. Additionally, it is necessary to consider the extent to which this

[574] Ibid.
[575] It is recalled from the Introduction that these are not easily separated, as will be shown in the remaining chapters of this thesis.

structure benefits the interests of the individual donors of UK Biobank. While incorporation as a charity at least means that UK Biobank Ltd is held to its charitable purpose to benefit the health of future generations, had the biobank or the EGC been established on a statutory footing this would have facilitated more straightforward public accountability via Parliament. Instead, this choice of private model has created risks for the public accountability of UK Biobank Ltd.

Considering an 'extensive consultation process' to gauge public interest, inspire confidence and ultimately engender participation in the ambitious project[576] (Chapter 3) UK Biobank might be considered a 'model for public involvement'.[577] However, UK Biobank has since been criticised for failing to invite the public and other consultees to consider more fundamental questions prior to the project's creation, such as 'the priorities of commercial users versus the public interest, the likelihood of benefits set against other possible uses of those resources, the content of regulations and who would be enforcing them.'[578] Instead, such concerns are supposedly addressed by the general reassurance made in the EGF (and on the UK Biobank website) that as a charitable company, UK Biobank will serve the public interest and will only act in the public good, monitored by the EGC. While it is arguable that the EGC and EGF have been created with donors and wider stakeholders in mind and to cover the ethical challenges associated with biobanking, there are a number of potential shortcomings if this Framework is relied upon for the protection of public and private interests in the running of the resource in and of itself.

For example, there are currently no members of the EGC on the Board of Directors (although the Chair of the EGC is able to sit in on Board meetings[579]) and the EGC does not have the legal standing to veto applications made to UK Biobank should they deem this necessary. Furthermore, there are no donor or public representatives on the Ethics and Governance Council. As identified in this chapter, other risks flow

[576] Jones M and Salter B, 'The governance of human genetics: policy discourse and constructions of public trust' (2003) 22 New Genetics and Society 21.
[577] Levitt M, 'UK Biobank: a model for public engagement?' (2005) 1 Genomics Society and Policy 78.
[578] Ibid.
[579] UK Biobank Ethics and Governance Council 'The Ethics and Governance Council's Oversight in Relation to UK Biobank's Administration of the Access Process' (2014): <http://egcukbiobank.org.uk/sites/default/files/Final%20EGC%20Oversight%20131114.pdf > accessed 19 January 2016

from this choice of legal structure. These include the potentially dominant role of the funders as Members of the Company and the potential for the public good mission of UK Biobank to come into conflict with the aims and objectives of these Members (as the principal funders of UK Biobank); the lack of statutory independence for the EGC; and the potentially diminished protection of individual donors within this private legal structure, which may not have been the case if UK Biobank was more clearly accountable under English public law (via Parliamentary scrutiny) and established on a statutory footing. This has led to criticism that the UK Biobank model fails to adequately represent the full range of interests that are associated with the project[580] and proposals for improved donor representation in the future,[581] to which the next chapter will now turn.

[580] Papaioannou T, 'Democratic governance of genomics: the case of UK Biobank' (2012) 31 New Genetics and Society 111.
[581] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 449; Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).

Chapter 5: Exploring the theoretical underpinnings of UK Biobank Ltd

5.1 Introduction

The previous chapters (Chapters 2, 3 and 4) have shown that there existed a range of organisational and legal models for a population biobank in the UK, including establishing the biobank on a public, statutory footing. Instead, UK Biobank was established with a private legal structure and a complicated dual legal basis as a charity and a company.[582] Chapter 4 has identified that both UK charity and company law[583] regulate the legal status and structure of UK Biobank Ltd as a charitable company limited and highlighted some of the potential difficulties in protecting the public mission of UK Biobank and the private interests of the individual donors in a private model. This would not necessarily have been the case if UK Biobank had been set up on a statutory basis as a public body and directly accountable to Parliament (to be considered in Chapter 8 of this thesis).

The previous chapter has begun to identify some of the key stakeholders[584] of UK Biobank Ltd, including the MRC and WT as Members of the Company, the Board of Directors, the EGC and the general public. Correspondingly, Chapters 3 and 4 have

[582] As identified in Chapter 4.
[583] Charities Act 2011; Companies Act 2006.
[584] It is remembered from Chapter 3 that the general use of the term 'stakeholder' refers to anyone with an interest or concern in a matter. This is distinguished from the more specific definition within corporate governance, the leading of which is Freeman's popular definition: 'any group or individual who can affect or be affected by the achievement of the organization's 'objective': Freeman RE, *Strategic Management: A Stakeholder Approach* (CUP 1984).

highlighted the criticism that UK Biobank faced during its development stages, on the grounds that donors and other interested stakeholders were not given adequate opportunity to be involved in early decisions or consultations about the eventual UK Biobank governance model.[585] The purpose of this chapter is to explore the theoretical underpinnings of corporations in the UK to better understand the ways in which interests are prioritised and promoted in the governance of profit and not-for-profit organisations. As will be seen, different conceptions of corporate governance have implications for the ways in which companies are run, the range of interests that are taken into account, and the mechanisms in place for accountability to these interests in the running of the organisation. Responding to criticism that UK Biobank fails to adequately involve donors in it's governance model (Chapter 3), theories of corporate governance have been applied in the context of biobanking, in an attempt to better understand what it means to govern biobanks well and the extent to which donors and the public ought to be involved in the running of UK Biobank.[586] These proposals will be discussed after the relevant perspectives of corporate governance have been outlined, namely; 'shareholder', 'stakeholder' and 'social institutions'.

5.2 Corporate governance in profit and not-for-profit organisations

Other than to facilitate their establishment as separate legal entities and distinct legal forms, the law in the UK has historically played an arms-length role in the regulation of corporations.[587] The courts are reluctant to enter into the merits of commercial decisions and will usually not interfere with the internal management of companies acting within their powers.[588] Rather, it is left to the shareholders and the directors of

[585] Levitt M, 'UK Biobank: a model for public engagement?' (2005) 1 Genomics Society and Policy 78.
[586] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440; Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).
[587] Statutorily regulated by the Companies Act 2006.
[588] This principle is often referred to as the 'business judgement rule', which emphasises that a director is 'employed to take risks' and that sometimes those risks result in losses to the company. There is a danger that courts might apply hindsight and conclude that directors acted without due care and skill, and so 'the assessment of commercial matters and the making of business decisions is a matter for managers… That other managers might have taken a different course and made different decisions is beside the point.' *IBM United Kingdom Holdings Ltd v Dalgleish* [2014] EWHC 980 (Ch).

the company to manage company affairs,[589] and it is for the shareholder majority to enforce issues relating to the running of the company; for example the performance of director's duties.[590] In the event of wrongdoing to the corporation (itself a legally recognised 'person') it will be for the company to bring an action in court to redress matters that cannot be decided by the majority of a company's shareholders.[591] It is said that without these principles, which have been upheld for over one hundred years, futile actions,[592] oppressive litigation,[593] and multiplicity of suits[594] would ensue and companies would be 'torn to pieces' by litigation.[595]

Given the relative freedom of companies in their operation,[596] it is best practice for companies to develop 'corporate governance' strategies to facilitate effective management for a successful company;[597] detailing the composition and scope of the company, and to guide assessment of what the purpose of the company should be, in whose interests the company should be run, and the particular forms of accountability that are in place for the protection of the company and its objectives.

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[589] 'It is not the business of the court to manage the affairs of the company. That is for the shareholders and the directors:' Scrutton LJ, in *Shuttleworth v Cox Bros. & Co.* [1927] 2 KB 9 [23]. Cited in Wedderburn KW, 'Shareholders' Rights and the Rule in Foss v. Harbottle' (1957) 15 Cambridge Law Journal 194.

[590] Which must be exercised their subjective good faith judgment: *Smith and Fawcett Ltd, Re* [1942] Ch 304; Upheld in Companies Act 2006 s.172, as will later be discussed in more detail.

[591] *Foss v Harbottle* [1843] 67 ER 189 (1843) 2 Ha 461 and *Mozley v Alston* (1847) 1 Ph. 790. Together, these principles – majority shareholder control and the role of the court in the running of a company are widely referred to as 'the Rule in *Foss v Harbottle': Burland v Earle* [1902] AC. 83, 93 (P.C.) *per* Lord Davey. Cited in Wedderburn KW, 'Shareholders' Rights and the Rule in Foss v. Harbottle' (1957) 15 Cambridge Law Journal 194.

[592] *Foss v Harbottle* [1843] 67 ER 189 (1843) 2 Ha 461 [494]; Bagshaw v E. Union Ry. Co. (1849) 7 Hare 130.

[593] *Gray v Lewie* (1873) 8 Ch App 1035, [1050-1051]

[594] *Mozley v Alston* (1847) 1 Ph 790, [799]; *Lord v Copper Miners Co.* (1848) 2 Ph. 740, [752]; *MacDougall v Gardiner (No. 2)* (1875) 1 Ch.D. 13, [25].

[595] *La Cie. de Mayville v Whitley* [1896] 1 Ch 788 [807], Kay LJ cited in Wedderburn KW, 'Shareholders' Rights and the Rule in Foss v. Harbottle' (1957) 15 Cambridge Law Journal 194.

[596] Sjafjell B, Johnston A, Anker-Sorensen L, and Millon D 'Shareholder primacy: the main barrier to sustainable companies' in Sjafjell B and Richardson BJ (eds), *Company Law and Sustainability: Legal Barriers and Opportunities* (CUP 2015). The authors argue:
'Organising the firm through a corporate legal structure has – or is meant to have – implications for the decision making process of the firm. Those implications include constituting the shareholders as the general meeting within which certain important decision are made; vesting in the board a strategy-setting, supervisory, and in some jurisdictions executive role; protecting creditors; and, in some jurisdictions, also regulating employee participation through codetermination rules.'
This is notable in terms of the motivations behind choosing the corporate legal structure for UK Biobank over alternatives such as the trust, as will be explored later in this chapter and in Chapter 6.

[597] The UK Corporate Governance Code describes the purpose of corporate governance is to 'facilitate effective, entrepreneurial and prudent management that can deliver the long-term success of the company': Financial Reporting Council, *The UK Corporate Governance Code* (FRC 2014) <www.frc.org.uk/Our-Work/Publications/Corporate-Governance/UK-Corporate-Governance-Code-2014.pdf> accessed 6 Jan 2016

Generally then, 'corporate governance' is the way in which companies are directed and controlled.[598] In the narrow sense, corporate governance relates to the composition of the Board of Directors who are responsible for the running of the company.[599] More broadly corporate governance encompasses both the set of relationships of those who depend on, or contribute to, the organisation, as well as the structure of a corporation, its purpose, and the role of those exercising control.[600]

To safeguard the running of charities for the public benefit, the Charity Commission was statutorily created by the Charities Act 2011 to regulate the running of charities in the UK. Therefore, the operation of corporations that are incorporated as charitable will be subject to external oversight, which, as will be demonstrated in this Chapter, gives rise to an inherent legal tension between the primacy of shareholders under company law[601] versus the priority of the general public as the beneficiaries of charitable organisations under charity law.[602] Consequently, this gives rise to uncertainty as to who director's duties are owed, how they are enforced, and by whom.

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[598] Ibid: 'Corporate governance is the system by which companies are directed and controlled. Boards of directors are responsible for the governance of their companies. The shareholders' role in governance is to appoint the directors and the auditors and to satisfy themselves that an appropriate governance structure is in place. The responsibilities of the board include setting the company's strategic aims, providing the leadership to put them into effect, supervising the management of the business and reporting to shareholders on their stewardship. The board's actions are subject to laws, regulations and the shareholders in general meeting.' Citing the Cadbury Committee definition produced for the first UK Corporate Governance Code in 1992: Committee on the Financial Aspects of Corporate Governance (the Cadbury Committee), *Report of the Committee on the Financial Aspects of Corporate Governance* (Gee 1992).

[599] Taylor PN, 'Enlightened Shareholder Value and the Companies Act 2006' (PhD thesis, Birkbeck College, University of London 2010), 13

[600] Most recently, the OECD have reviewed their Principles of Corporate Governance and adopt a broad definition encompassing both the relationships and the structure of a corporation and its governance:
'Corporate governance involves a set of relationships between a company's management, its board, its shareholders and other stakeholders. Corporate governance also provides the structure through which the objectives of the company are set, and the means of attaining those objectives and monitoring performance are determined.'
OECD Corporate Governance Committee, *Principles of Corporate Governance* (OECD 2015) <www.oecd.org/daf/ca/Corporate-Governance-Principles-ENG.pdf> accessed 30 Jan 2016.

[601] It is noted that whether such primacy is still appropriate today is the subject of comprehensive academic debate. See: Ireland P, 'Company Law and the Myth of Shareholder Ownership' (1999) 62 MLR 32; Sjafjell B, Johnston A, Anker-Sorensen L, and Millon D 'Shareholder primacy: the main barrier to sustainable companies' in Sjafjell B and Richardson BJ (eds), *Company Law and Sustainability: Legal Barriers and Opportunities* (CUP 2015).

[602] Charities Act 2011

Furthermore, the lack of share capital[603] raises deeper theoretical questions as to the appropriate conceptual basis of a charitable company.[604] In short, because charities are created for the benefit of the public, it is more appropriate to refer to 'membership' rather than 'shareholding' in companies that are incorporated as charitable. On this matter, corporate governance research has produced a number of theories that seek to explain how interests within an organisation ought to be safeguarded and prioritised.[605] Fundamentally, perspectives of corporate governance vary according to the particular organisation under consideration and this is usually dictated by the particular 'asset' that is owned and managed by the company. Traditionally, profit making organisations have been conceptualised as based on either property or as a nexus of contracts.[606] According to these perspectives, shareholders are prioritised in the corporation. Shareholder models of governance are based on the principle that the role of the Board of Directors is to act as 'agents' of the shareholders in the day-to-day management of the company.[607] Therefore, directors are typically elected to the Board by virtue of their expertise and ability to inspire trust and to maximise profit for shareholders.[608]

More recently a third way of viewing organisations has emerged; as a social institution.[609] This view is argued to be more appropriate for non-profit

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[603] Though, it is noted that there has been a reluctance to define what constitutes a 'share': Ireland P, 'Company Law and the Myth of Shareholder Ownership' (1999) 62 MLR 32

[604] Which will be explored in Chapter 8 and the Conclusion of this thesis.

[605] Mason C, Kirkbride J and Bryde DJ, 'From stakeholders to institutions: the changing face of social enterprise governance theory' (2007) 45 Management Decision 284.

[606] Historically this was because shareholders were treated as the legal 'owners' of the corporate assets, or the firm was the base for contracting with the aim of to maximising benefits for shareholders via optimal contracting and increased residual income. According to the property view the shareholders have a property interest in the company, akin to ownership. On the other hand, the nexus of contracts model conceptualises the firm as the base for contracting. The ultimate aim is to maximise benefits for shareholders via optimal contracting and increased residual income. This is not necessarily still the case, because of the widespread recognition of companies as separate legal personalities and as such, it is the company that 'owns' the company's assets.
For an in depth overview of the historical development of (the 'myth' of) shareholder primacy, see: Ireland P, 'Company Law and the Myth of Shareholder Ownership' (1999) 62 MLR 32.
For views on social enterprise theory, see: Mason C, Kirkbride J and Bryde DJ, 'From stakeholders to institutions: the changing face of social enterprise governance theory' (2007) 45 Management Decision 284.

[607] Taylor PN, 'Enlightened Shareholder Value and the Companies Act 2006' (PhD thesis, Birkbeck College, University of London 2010).

[608] Low C, 'A framework for the governance of social enterprise' (2006) 33 International Journal of Social Economics 376; citing: Iecovich E, 'The profile of board membership in Israeli voluntary organisations' (2005) 16 Voluntas 161.

[609] Low C, 'A framework for the governance of social enterprise' (2006) 33 International Journal of Social Economics 376

organisations, whose assets are held in trust and locked-in for public benefit[610] and so are theoretically owned by the public rather than by shareholders.[611] In contrast to profit making organisations, it is arguable that stakeholder models of governance are appropriate for not-for-profit organisations or social institutions. This is because stakeholder approaches to governance prioritise the importance of wider interests beyond those of company shareholders.[612]

Stakeholder theory has been motivated by a 'changing business scene', which is characterised by 'the emergence of numerous stakeholder groups and new strategic issues [that] requires rethinking of our traditional picture of the firm.'[613] Stakeholder approaches seek to emphasise corporate social responsibility of businesses and business managers' moral obligations to all the interests at stake.[614] This is founded on the assumption that giving prominence to shareholders is problematic and that corporate governance should in fact be the arena for attending to the legitimate interests of all stakeholders, through mechanisms such as giving board positions to stakeholder representatives.[615] 'Stakeholders need to communicate with the board of directors, and managers need to be given the scope to pursue stakeholders' interests most effectively.'[616] Therefore, members of the board of directors are typically democratically elected to represent the full range of stakeholders associated with the corporation, as opposed to election based on their expertise.[617] According to Freeman's most widely cited definition, a stakeholder is 'any group or individual who can affect or be affected by the achievement of the organisation's 'objective'.[618] Commonly identified stakeholders in the corporate context include: shareholders and

[610] Dunn A, Riley CA, 'Supporting the not-for-profit sector: the government's review of charitable and social enterprise' (2004) 67 MLR 632.
[611] Ibid.
[612] Mason C, Kirkbride J and Bryde DJ, 'From stakeholders to institutions: the changing face of social enterprise governance theory' (2007) 45 Management Decision 284, 288
[613] Freeman RE, *Strategic Management: A Stakeholder Approach* (CUP 1984).
[614] Ibid.
[615] Goodpaster K, 'Business ethics and stakeholder analysis' in Winkler E and Coombs J (eds), *Applied Ethics: A Reader* (Blackwell 1993) 229; Donaldson L and Preston M, 'The stakeholder theory of the corporation: concepts, evidence, and implications' (1995) 20 Academy of Management Review 85 cited in Low C, 'A framework for the governance of social enterprise' (2006) 33 International Journal of Social Economics 376
[616] Mason C, Kirkbride J and Bryde DJ, 'From stakeholders to institutions: the changing face of social enterprise governance theory' (2007) 45 Management Decision 284, 289
[617] Taylor PN, 'Enlightened Shareholder Value and the Companies Act 2006' (PhD thesis, Birkbeck College, University of London 2010).
[618] Ibid.

investors, employees, customers and suppliers, special interest groups, competitors, the natural environment, the state, local communities and society at large.[619]

Before the reform of the Companies Act in 2006, company law in the UK was arguably founded on the traditional shareholder approach to corporate governance.[620] To a limited extent, this approach has been 'reformed' by the introduction of s.172 into the Companies Act 2006.[621] This provision represents a move towards 'enlightened shareholder value.' which means directors owe a statutory duty to have regard for non-shareholder interests.[622] Enlightened shareholder value is intended to promote inclusiveness among stakeholders and encourage directors to consider long-term sustainability in terms of what is good for society at large, in recognition of the increasing role that companies play in wider society.[623] For some, this provision is akin to stakeholder approaches to governance because it explicitly recognises the importance of taking into consideration wider interests for the success of the company.

5.2.1 UK Biobank: shareholder or stakeholder approach?

As a charity company it might be assumed that UK Biobank Ltd is most appropriately conceptualised by a stakeholder model of governance, because of its public mission and the lack of share capital. In fact, it is not immediately appropriate to talk of UK Biobank Ltd in terms of 'shareholding' but rather 'membership'. As will be discussed in this chapter, part of the Board's functional responsibility is to negotiate access to the resource; to maximise use of the resource and optimise public benefit outputs. In pursuit of this objective it is arguable that expertise, rather than

[619] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009), 169; citing Hillman AJ and Keim GD 'Shareholder value, stakeholder management, and social issues: what's the bottom line?' (2001) 22 Strategic Management Journal 126.
[620] Although, for commentary on the extent to which this is true, see Ireland P, 'Company Law and the Myth of Shareholder Ownership' (1999) 62 MLR 32.
[621] Which will be analysed in the context of UK Biobank Ltd in Chapter 6 of this thesis.
[622] This followed an overwhelmingly positive response to consultation and consequential recommendation by the Company Law Review Steering Group, alongside the Charity Commission's Advisory Group, who saw the advantage in having a separate vehicle for charitable companies: Cross SR, 'New legal forms for charities in the United Kingdom' [2008] Journal of Business Law 662, 665.
[623] Historically, public-private partnerships became more popular under New Labour Government (Chapter 3) and in the last decade UK company law (via the Companies Act 2006) has recognised new legal structures for companies including the Charitable Incorporated Organisation, and the Community Interest Company; recognising the increasing public service delivery role of private corporations. This transition from private to public will be explored in more detail in Chapter 8 of this thesis (which analyses the role of public law in UK Biobank).

democratic representation, fuelled the election of the UK Biobank Board of Directors, and this approach corresponds with a traditional shareholder approach to corporate governance.[624]

On the other hand, analysis will also reveal that the Board is under a statutory duty to consider wider stakeholders by virtue of the previously mentioned 'enlightened shareholder value' provision of the Companies Act 2006 and in this regard it may be more fitting to view UK Biobank governance as being underpinned by a stakeholder perspective of governance. However, analysis will demonstrate that this is not necessarily fully realised because the Board of Director's are not democratically elected to represent this full range of stakeholders. Donors are 'conspicuously absent'[625] from the governance model and members of the EGC, who are supposedly responsible for safeguarding the interests of the public in the running of UK Biobank,[626] are also absent from the Board.

In view of these perceived shortcomings, and evaluating the UK Biobank governance model, Winickoff and Hunter and Laurie have put forward solutions founded on a wider debate between stakeholder and shareholder perspectives of corporate governance.[627] Winickoff has expressed dissatisfaction regarding the 'critical distance remaining between the rhetoric of partnership and the actual structure of entitlements within UK Biobank… donors possess little control share,

[624] Low C, 'A framework for the governance of social enterprise' (2006) 33 International Journal of Social Economics 376.
[625] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 449.
[626] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016
[627] Because of this thesis' investigation into the legal structure of UK Biobank Ltd as a charitable company limited by guarantee, this discussion will focus on two particular proposals from David Winickoff in Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440; and Hunter and Laurie in Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009). Although it is acknowledged that there are many other proposals for good biobank governance such as: Haddow G and others, 'Tackling community concerns about commercialisation and genetic research: A modest interdisciplinary proposal' (2007) 67 Social Science & Medicine 272; Fortun M, 'Towards Genomic Solidarity: Lessons from Iceland and Estonia.' (OpenDemocracy, 9 June 2003) <www.opendemocracy.net/theme_9-genes/article_1344.jsp> accessed 30 Jan 2016; Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315; O'Doherty and others, 'From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks.' (2011) 73 Social Science & Medicine 367.

and no equity share, in the common pool resource.'[628] Winickoff therefore proposes solutions inspired by a traditional shareholder model, whereby donors are recognised as shareholders for their contribution of 'biocapital' to the company without which UK Biobank would not exist. Hunter and Laurie have argued against Winickoff's call for direct donor representation on the Board of Directors to bridge this gap, and instead favour mechanisms for ongoing dialogue and communication between the wide range of UK Biobank stakeholders, including donors and those responsible for the administration and management of the resource.[629]

The next section of this chapter will briefly consider this debate, because it casts important light on the range of interests within the governance framework of UK Biobank and the extent to which the approach of UK Biobank is considered appropriate. The debate also further explains some of the key risks which may arise if interests are not adequately protected and it is important to bear these risks in mind for the analysis of the legal structure in the next chapter. In brief, the authors put forward solutions for more direct engagement between donors, the EGC, and the Board of Directors as managers of UK Biobank. However, the limits of the proposals made by Winickoff and Hunter & Laurie are notable because they presuppose critical legal analysis of the legal structure of UK Biobank Ltd. Such investigation is crucial to an appreciation of the range of interests protected by the private legal structure and the range of accountability mechanisms that are available to these stakeholders within the dual model as both a charity and company. In fact, there are a number of means within the structure that arise by virtue of both charity and company law, although these are limited in both their scope and application. The next chapter of this thesis will investigate these avenues and propose options for reform informed by the theoretical underpinnings of UK Biobank, which will now be discussed.

[628] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440.
[629] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).

5.2.2 Shareholding in UK Biobank Ltd: Reconciling the 'agency gap' between biobank managers and the expectations of donors and the public

Winickoff argues that the core problem underlying UK Biobank Ltd governance is 'agency',[630] and more specifically how to represent the interests of the donor collective to ensure alignment with management aims.[631] Winickoff contends that membership of the Board of Directors evinces a clear logic of representing important UK Biobank constituencies, including the WT, MRC, DH, academic research community and experienced members of the field, who are all 'well represented' (as Chapter 4 and 5 have illustrated).[632] Yet, on the matter of representing important UK Biobank constituencies, 'one thing is clear about Board membership: donor representation is conspicuously absent...' and for Winickoff, this is a missed opportunity.

Winickoff argues that this lack of representation gives rise to the risk that 'if certain commercial deals are struck or if public access is somehow limited, there may be a real or perceived sense in which managers have reneged on an implied promise to advance 'public good.'' The adoption of a 'controversial policy might operate as a triggering event, eliciting withdrawals of donations and a decrease in the value of the resource'. For Winickoff: '… [If] donors had some form of real representative power then project goals would be better achieved.'[633] Moreover, mechanisms of meaningful representation of the donor collective 'could greatly enhance both participation rate, participation trust, and by extension, project sustainability.'[634]

To address this risk, Winickoff argues:

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[630] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 450.

[631] Agency theory is based on the traditional separation of ownership and control and the principle that managers in corporate governance are in a relationship as 'agents' of the companies' shareholders. An agency gap is the risk that the expectations of the shareholders are not in line with the managers and corporate governance is therefore designed to minimize this risk: Ireland P, 'Company Law and the Myth of Shareholder Ownership' (1999) 62 MLR 32.

[632] As you would expect according to shareholder perspectives of corporate governance where management is elected on the grounds of expertise: Low C, 'A framework for the governance of social enterprise' (2006) 33 International Journal of Social Economics 376; Iecovich E, 'The profile of board membership in Israeli voluntary organisations' (2005) 16 Voluntas 161.

[633] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 449.

[634] Ibid.

> Project planners and potential research participants ought to consider new forms of 'partnership governance' that draw upon the logic of corporate governance to solve the agency problems involved in the management of collective genomic assets.[635]

Applying a shareholder partnership[636] approach to accountability in corporate governance, he suggests, may be 'less strange' than it may seem, given UK Biobank's legal structure as a corporation (Chapter 4):

> The idea that shareholders will be represented in corporate decision making is one of the pillars of the corporate concept. Why should the same not apply in the realm of biobanks?[637]

How then, does Winickoff propose to move from rhetoric to practice?[638] By enacting a committee of direct representatives of the research participant group who would play a formal role within the governance structure.[639] Accordingly, use of the resource would be contingent on review of two bodies; the typical ethics review board and a 'Donor Approval Committee.' This latter committee would function as a 'conduit between the donor group, the board of trustees, and the researchers to address controversial projects or issues as they arise.'[640] During the consent process potential donors could voluntarily sign on to a donor association. Association members would elect leadership to sit on UK Biobank's Board of Directors 'akin to how a major institutional investor would sit on such a corporate board.'[641] Furthermore, the donor association would be responsible for filling a number of seats on the EGC.[642] Public meetings would be held annually to address attitudes and preferences and deliberate policy choices regarding resource distribution,[643] and leadership would be bound to represent any collective decisions reached on the

[635] Ibid.
[636] For an overview of the historical development of how corporations moved from laws of usury (broadly concerned with monetary loans) to laws of partnership see: Ireland P, 'Company Law and the Myth of Shareholder Ownership' (1999) 62 MLR 32.
[637] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 451.
[638] Ibid.
[639] Winickoff DE and Neumann L, 'Towards a Social Contract for Genomics: Property and the Public in the 'Biotrust' Model' (2005) 1 Genomics Society and Policy 8. Cited in Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440.
[640] Ibid. 450
[641] Ibid. 451
[642] Ibid. 449
[643] Ibid. 451

Board and EGC.[644] Donors would thereby possess a 'share' in determining how a collective public resource is charitably allocated. Winickoff submits that this form of empowerment could address the 'agency gap' between public expectations and values and those of biobank managers,[645] and could enhance the spirit of public giving to ensure that the project moves forward 'fairly and sustainably.'[646]

From the outset, Winickoff acknowledges a number of potential criticisms of this proposal. First, putting donors into an interest group modality might mean the group merely advances their self-interests. In turn this might undermine the altruism that motivates people to participate.[647] However, Winickoff reiterates that the organisation is obliged to act in accordance with its charitable mission and as such, neither donor representatives nor the Board as a whole could act in a way that would benefit themselves or their groups in a direct financial way without jeopardising the project's mission and legal status,[648] as Chapter 4 of this thesis has illustrated. There is also potential for the donor association and its process of electing representatives on the BOD and EGC to reproduce the same issues of agency and representation because the large donor collective is unlikely to agree on their preferences, and representation itself entails problems of bias and self-interest. Therefore, the consequential challenge is to come to an acceptable form of representation that minimises this risk.[649]

Practical and conceptual issues with the shareholder model

Responding to this shareholder reform proposal, Hunter and Laurie criticise the theoretical underpinnings of the shareholder model on the basis of UK Biobank's legal structure as a charity company.[650] As this chapter has previously mentioned, this structure means there is no share capital and therefore no shareholders. Moreover, a crucial consequence of UK Biobank's charity status is that the powers of the company can only be exercised in pursuance of the charity's objectives and 'public good' mission (as identified in Chapter 4). Here lies the basis of Hunter and

[644] Ibid. 452
[645] Ibid.
[646] Ibid.
[647] Ibid
[648] Ibid
[649] Ibid.
[650] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009),158

Laurie's first practical issue: the shareholder model only accommodates the donor collective; 'the wider public is conspicuously absent.'[651] For these reasons, Hunter and Laurie criticise the shareholder model for its failure to 'take adequate account of the central question any system of governance must answer: 'What is the objective of the corporation and for whose benefit is it to be run?''[652] On this basis, Winickoff's proposal is unsatisfactorily narrow; UK Biobank has an extremely wide constituency of concern, which includes not only its participants and their interests, but extends to the wider public and health of future generations.[653]

Next, Hunter and Laurie comment on the dangers of 'democratic representation.' Winickoff also acknowledges this issue and questions 'whether a body could adequately represent the donor collective of UK Biobank... a collection of 500,000 heterogeneous donors without a clearly shared goal.'[654] The representative body would need to reflect the diverse interests and views of the collective, and it would be very difficult to ensure that this included a broad range of voices that avoided the domination of vocal minorities.'[655] This leads the authors to question whether Winickoff's proposal successfully addresses the aforementioned agency gap and trust problem, and argue that in fact it may even 'widen that gap by placing additional actors within governance mechanisms and do little more than provide a pastiche of participation.'[656]

Conceptually, Hunter and Laurie raise the distinction between notions of 'partnership' and 'shareholders.' Winickoff's articulation of 'partnership', which 'connotes a form of cooperative human relations with respect to shared conditions

[651] Ibid
[652] Ibid.
[653] Ibid.159
[654] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 452.
[655] The authors use the GM crops experience, which found vocal minorities exerting disproportionate influence on 'representative' processes. This has been described as 'the replacement of one vested interest (the agro-biotechnology industry) by another more recently influential group...(public interest advocacy groups), with equally negative outcomes for democratic decision making on risk issues: Tait J, 'Risk governance of genetically modified crops: European and American perspectives' in Renn O and Walker KD (eds) *Global Risk Governance* (Springer 2008). Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009), 159
[656] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009), 161

and aims'[657] is distinguished from the analogy of 'shareholding' which 'suggests an interest-based form of relations, moving the discourse-and any resultant model-away from charity towards economics and private (property) rights.'[658] Drawing upon traditional Anglo-American corporate governance[659] they evaluate: 'The 'shareholder' analogy envisions not 'partnership' or 'co-operation' but, rather, self-interest and control. There is something inherently antagonistic about the relationship between shareholders and managers, which neither embodies nor reflects an 'ethos of trust' of 'goodwill.''[660] Ultimately, whereas the objective of a shareholder model is to 'maximise profits for its shareholders,' UK Biobank aims to 'maximise benefits' for public health. '[T]his language and conceptualisation therefore clearly sit awkwardly with… UK Biobank'[661] in view of its charitable objectives.

Nevertheless, Hunter and Laurie do not entirely dismiss Winickoff's proposal and note that it may be adequately robust for a private biobank[662] with one overriding research goal (Chapter 1). In this case it is more feasible to conceptualise donors as

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[657] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 443.

[658] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009), 162

[659] Kairie S, 'At crossroads: shareholder value, stakeholder value and enlightened shareholder value: which road should the United Kingdom take?' (2007) 17 International Company and Commercial Law 329.

Anglo-American corporate governance, which has traditionally been based on a shareholder approach, can be contrasted with approaches in Germany or Japan for example, where stakeholders principles are predominant in governance: Ireland P, 'Company Law and the Myth of Shareholder Ownership' (1999) 62 MLR 32.

Arguably, UK corporate governance is moving towards an increasingly stakeholder orientated approach to corporate governance in light of the reformed Companies Act 2006 and the most recent UK Corporate Governance Code: Financial Reporting Council, *The UK Corporate Governance Code* (FRC 2014) <www.frc.org.uk/Our-Work/Publications/Corporate-Governance/UK-Corporate-Governance-Code-2014.pdf> accessed 06 Jan 2016.

[660] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009), 164

[661] Ibid.

[662] Ibid. Hunter and Laurie illustrate that the shareholder model might be adequate for private companies such as PXE International. This company has negotiated a contract with researchers, in which the foundation retains ownership rights in any patent application arising from the research, thereby enabling the foundation to share any revenues, to influence future licensing agreements and to ensure widespread and affordable genetic tests. They note that PXE International has an overriding research goal- to encourage researchers to study the genetic basis of PXE to develop therapies. Since donors to the PXE biobank are those affected by the rare disease and their families, it is easier to conceptualise them as 'shareholders.' Citing Gitter D, 'Ownership of human tissue: a proposal for federal recognition of human research participants' property rights in their biological material' (2004) 61 Washington & Lee Law Review 262.

shareholders, since they are likely to have a direct and tangible interest in the research and its benefits. However, 'the analogy breaks down in the context of large-public orientated resources such as UK Biobank' since 'the participants… will have varied and potentially conflicting goals, will be unlikely to benefit directly from the any research conducted using the resource and have contributed to the resource explicitly for the benefit of others.'[663] For these reasons, Hunter and Laurie conclude that the shareholder model is neither 'necessary nor sufficient' to address concerns of an agency gap and maintenance of trust.

Overall, Hunter and Laurie critique that the very idea of shareholders implies a privileged position for participants, when the purpose of UK Biobank is known to be benefit for all.[664] For this reason, the authors take issue with Winickoff's contention that the main problem with biobank governance is agency and donor representation. It is their belief that giving donors a 'voice' would be contrary to UK Biobank's charitable purpose to benefit the public and would be unlikely to address the 'trust problem,' where past experiences have shown dominating vocal minorities undermining democratic participation.[665] Furthermore, the authors submit that Winickoff's model of representation does not ensure that 'the right sort of deliberations take place' within either the Board or the EGC, with the donor collective as a whole, or wider constituencies.[666]

Instead, Hunter and Laurie believe the fundamental challenge is to engage with and take into account the views of all UK Biobank 'stakeholders' via transparent processes throughout the life of the project. To this end, aside from the notion of shareholding but still in the corporate sphere, the alternative 'stakeholder' framework is proposed.

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[663] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009), 165

[664] Ibid.

[665] Ibid. The authors use the example of the GMO 'scandal'.

[666] Ibid 166. On this point, the authors note developments in political democratic theory, which have given rise to an increase in the use of 'Deliberative and Inclusive Processes' in a variety of different fields, including policy, which has influenced the design of engagement processes in emerging areas of science and biotechnology as well as biobanking. Deliberative democratic mechanisms focus upstream and inform the questions that are consulted upon, as well as providing an evidence base for decision-making. However, as the authors note, deliberations say little about how the process might be translated into policy or concrete decisions, and it remains arms-length to management, so the practical impact is unclear: M Burgess, O'Doherty K and Secko D, 'Biobanking in British Columbia: discussions of personalized medicine through deliberative public engagement' (2008) 5 Personalized Medicine 285.

5.2.3 Stakeholders of UK Biobank Ltd: Where to draw the line?

Stakeholder theory is based on communitarian philosophy which strives for a society based on 'fairness and a move towards social responsibility and respect for others.'[667] The theory maintains that a firm should be 'run for the benefit of, and be accountable to, all their stakeholders'[668] rather than just the shareholders. Compared with shareholder approaches to corporate governance, stakeholder approaches are more democratic.[669] As such, managers are more likely to be appointed to be representative of the full range of interests that are inherent in the corporation, rather than on the basis of their expertise. Stakeholder approaches to governance are therefore argued to be more appropriate for non-profit corporations that are established to benefit the public.

The most widely cited definition of a stakeholder is Freeman's definition: 'any group or individual who can affect or be affected by the achievement of the organisation's 'objective.'[670] Employing this definition, Hunter and Laurie acknowledge the vast number of stakeholders who might have a legitimate 'stake' in UK Biobank: participants; Board of Directors; EGC; funders and Members of the company; researchers; communities; the wider public or society; and, arguably, future generations whose health the resource is intended to improve.[671] While inclusion of potential beneficiaries and future generations as potential stakeholders is unusual, Hunter and Laurie justify that in the context of UK Biobank its longitudinal nature means that wider groups such as this are crucial to success of the project and are therefore easily identified as stakeholders. It has also been argued that the British taxpaying public enjoys a form of indirect representation on the Board of Directors via the DH and the MRC.[672] Hunter and Laurie concede that it is 'undeniable' that the British public has a stake in UK Biobank, on the grounds that it is publicly funded and the public is explicitly identified as a beneficiary in the EGF.

[667] Metcalf C, 'The stakeholder corporation' (1998) 7 Business Ethics 30, 34
[668] Ibid. Citing Hutton W, *The State We're In* (Jonathan Cape 1995).
[669] Low C, 'A framework for the governance of social enterprise' (2006) 33 International Journal of Social Economics 376.
[670] Freeman RE, *Strategic Management: A Stakeholder Approach* (CUP 1984) cited in Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009), 167
[671] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009), 170
[672] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 444.

Furthermore, the public enjoys an element of control over the success of the project, by choosing to participate or not and later whether to withdraw from it. This reinforces the need for UK Biobank policies to reflect social and ethical values and take into account public concern (Chapter 1).

The authors acknowledge that while there is a good argument for identifying donors, the general public and future generations as stakeholders, it is more difficult to imagine how such a wide group can be involved in practice. It appears that 'everyone' could theoretically be a stakeholder; 'accountability becomes valueless because it is too broadly set and useless from a managerial point of view.'[673] Hunter and Laurie argue that while direct participation in decision-making is unrealistic, it is the role of management to ensure that the expectations of organisational constituents and wider society are aligned. They therefore favour 'the stakeholder involvement strategy' over a 'stakeholder participation strategy' for the governance of UK Biobank.

i) The stakeholder participation strategy

This strategy is most commonly achieved through representation on Boards or other management bodies. The fundamental issue is determining which stakeholder groups should be included, and to overcome this, proposals have been made for large numbers of stakeholders to form 'stakeholder council[s].'[674] Such councils would not strictly be part of the management Board, but may have an elected representative who is.[675] Arguably proposals such as this are similar to Winickoff's shareholder model, however there are key differences. For example, representatives would be drawn from a larger constituency (not just the donor collective), participation would not be conditional on representatives donating 'biocapital' to the resource, and representatives would be 'recruited' rather than self-selected.[676] However Hunter and Laurie argue that the key problems with Winickoff's shareholder model could also

[673] Kakabase NK, Rozeul C and Lee-Davies L, 'Corporate responsibility and stakeholder approach: a conceptual review (2005) 1 International Journal of Business Governance and Ethics 277.
[674] Low C and Cowton C, 'Beyond stakeholder engagement: the challenges of stakeholder participation in corporate governance' (2004) 1 International Journal of Business Governance and Ethics 45, 48, cited in Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).
[675] Ibid.
[676] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009), 173

undermine this model, including difficulties ensuring truly representative individuals, openness and accountability. Because the authors are not persuaded by the merits of representation, the alternative 'stakeholder involvement strategy' is chosen for application to UK Biobank.

ii) The stakeholder involvement strategy

This governance strategy envisages 'long term interactive, mutually engaged and responsive relationships' between companies and stakeholders to 'create the groundwork for transparency and accountability.'[677] This form of interaction[678] requires organisational commitment both to put in place mechanisms for ongoing dialogue with multiple stakeholders and to respond and adapt to their concerns. As a result,'in contrast to the shareholder model, a stakeholder model genuinely resonates with democratic notions of participation, involvement and inclusion.'[679]

For Hunter and Laurie, this strategy already resonates with UK Biobank governance, especially given the EGC's commitment to actively engage with a variety of stakeholders, including 'participants, research users and society in general over the lifetime of the resource.'[680] Moreover, UK Biobank's EGF demonstrates a commitment to ethics that reflects the stakeholder involvement model that is underpinned by a 'strong normative core, which recognises that ethics cannot be separated from an organisation's activities.'[681] The authors argue that the EGF is ideally placed to facilitate such ethical responsibilities, since it is a living document it can evolve in response to changes in stakeholder expectations. To fully realise this

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[677] Andriof J, Waddock S, Husted B and Rahman R, *Unfolding Stakeholder Thinking: Theory, Responsibility and Engagement* (Greenleaf 2002), cited in Hunter, K., Laurie, G. 'Involving publics in biobank governance: moving beyond existing approaches.' Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).

[678] Morsing M and Shultz M, 'Corporate social responsibility communication: shareholder information, response and involvement strategies' (2006) 15 Business Ethics: A European Review 323, cited in Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).

[679] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C, *The Governance of Genetic Information: Who Decides?* (CUP 2009)

[680] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016.

[681] Freeman RE, 'The politics of stakeholder theory: some future directions' (1994) 4 Business Ethics Quarterly 409, 412, cited in Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).

strategy, the authors recommend that it is reasonable and appropriate for stakeholders to expect that their views and perspectives will be taken into account in decision-making and governance, and that these processes are transparent with clear explanations and justifications for decisions reached or advice given.[682] The extent to which this has happened to date is debatable.

As the authors note, UK Biobank and the EGC have demonstrated openness and transparency via their respective websites by publishing information as to successful research grants, minutes of EGC meetings, and releasing annual reports on biobank activities. On the other hand, significant developments have taken place in UK Biobank since the time of participation, which have not been consulted upon and have instead progressed under the broad consent of the donor's. For example, UK Biobank is currently genotyping all 500,000 participants and the genotype data on 150,000 participants has recently been released.[683] While participants have the option to withdraw from UK Biobank if they are unhappy with such genotyping (Chapter 3), they have been given no option to opt out of this particular development alone. It is questionable how far UK Biobank Ltd (because it can be assumed that it was the company managers and Principal Investigator who made the decision to genotype data) considered the views of participants when making this decision. Admittedly, there has not been a surge in participant withdrawal since, which in itself may demonstrate agreement. It remains to be seen whether risks associated with genotyping (Chapter 1) will manifest in the future, and if they do UK Biobank may well be criticised for failing to engage their participants in upstream decision making.

5.3 Conclusion

A number of important lessons may be drawn from Winickoff and Hunter & Laurie's theoretical debate, which aid understanding of the kinds of risks that may ensue should UK Biobank Ltd's legal structure fail to adequately protect and be accountable to the full range of interests that are at stake in its activity (in addition to those identified in Chapter 1 - 4).

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[682] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009)175

[683] Released in June 2015: UK Biobank 'Genetic data' (UK Biobank) <http://www.ukbiobank.ac.uk/scientists-3/genetic-data/> accessed 5 February 2016

For example, Winickoff argues that the adoption of a controversial policy by the Board could lead to the mass withdrawal of participants, which would in turn affect the value of the resource, and therefore contends that direct donor representation in the legal structure would help prevent this eventuality and go some way to ensuring the sustainability of UK Biobank. However, both Winickoff and Hunter and Laurie acknowledge the difficulties associated with securing truly 'representative' individuals, both in terms of the range of interests that individuals would be representing, and the legitimacy of 'representing' other donors who may or may not share the same view. Even though Hunter & Laurie's adaptation of stakeholder governance aims to overcome this shortcoming by involving a wider range of constituencies via a number of engagement strategies, the authors acknowledge that it falls to management to ensure that a genuine commitment is made to involve stakeholders. Thus, such reliance gives rise to the additional problem of how to hold UK Biobank managers to such promises.

Therefore, the debate between Winickoff and Hunter & Laurie raises a series of important corollary legal questions as to which interests are prioritised and protected in the legal structure of UK Biobank, and to what extent those with an interest in the running of UK Biobank may utilise the legal structure to hold UK Biobank accountable to its stated aims. To answer these questions, Chapter 6 will now analyse the range of interests empowered by the legal structure, who might be framed as those with a 'share' in the company i.e. the funders as Members of the Company and the Board of Directors. On the other hand, and contrary to what might be expected of a charitable organisation, the donors, members of the public or members of the EGC are not directly represented in the legal structure. Chapter 6 will identify the range of interests that might be indirectly represented in the model beyond those with a 'share' in the company and including more widely the EGC, researchers, the general public, and potentially future generations intended to benefit from the resource.[684] In this sense, UK Biobank is arguably more representative of the stakeholder model, as articulated by Hunter and Laurie.

[684] Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).

In fact, irrespective of the murky theoretical underpinnings of UK Biobank there are a number of irreducible legal conflicts that arise by virtue of the dual regulation of charitable organisations in UK charity and company law, which are arguably not fully captured by the stakeholder/shareholder conception and have motivated the introduction of new legal forms for corporations in the UK.[685] Because the corporate regime is tailored to meet the practicalities of the for-profit commercial sector, the model sits uncomfortably with the conception of charities, as the next chapter will now show.

Given these conflicts, the next chapter is a critical legal analysis of UK Biobank's legal structure as a charity company, to more fully understand and establish the avenues of accountability that are available within the charity company structure to further the public and private interests at stake and hold UK Biobank to its stated aims. Investigation will focus on the legal implications of a charity company structure for the operation of UK Biobank to identify the range of interests that arise by virtue of the model and evaluate the extent to which donors are, if at all, represented in the legal structure of UK Biobank Ltd. The investigation goes to the heart of how companies are run, and the procedural and governance requirements imposed by both charity and company law in light of dual regulatory status as a charitable company. The analysis focuses on those actors responsible for the management and administration of the company, the Board of Directors and the Members of the Company, and the stakeholders who are affected by their discretionary power and decision-making. In particular, how truly independent is UK Biobank Ltd? What influences do the main funders, the MRC and the WT as Members have over the running of the project? What are the rights and duties that arise from this role? What duties do the Board of Directors owe, and to whom? As a charity company limited by guarantee what mechanisms of oversight are in place? Who has standing to enforce such oversight? The next chapter will investigate the legal reasons for, and implications for stakeholders of, the chosen structure for UK Biobank, which is: 'not a body that's completely at arm's-length; legally it's a company limited by guarantee with members and the members are the Wellcome

[685] Which will be discussed in the next chapter.

Trust and the MRC, and the structure of it, the corporate structure of it means that there are required to agree all sorts of major decisions.'[686]

[686] Langan MA, 'A contemporary history of the origins and development of UK Biobank 1998-2005 (PhD thesis, University of Glasgow 2007), 211 (Citing interviewee).

Chapter 6: UK Biobank Ltd: Investigating the limits of a private law model to secure public objectives

6.1 Introduction

The previous chapter has shown the criticism that UK Biobank has faced from leading scholars who have opted for stakeholder and shareholder models of governance to reform the lack of direct representation or involvement of donors or members of the public in the governance model of UK Biobank, as well as the lack of representation of the EGC on the company's Board of Directors.[687] However, to date there has been no sustained legal analysis of how UK Biobank Ltd operates as a charity and a company when, arguably, the inherent legal tensions between charity and company status cut across the criticisms in the socio-legal literature regarding the engagement of donors within the governance model.[688]

To contribute to this debate, the aim of this chapter is to consider the mechanisms which are in place within this private legal structure to hold UK Biobank to account to its public objectives and critically analyse the dual legal basis of UK Biobank Ltd in company and charity law; highlighting the legal tension between UK Biobank's company objects and charitable purpose. This chapter will undertake a detailed analysis of the legal avenues open to donors and the EGC within the dual legal structure of UK Biobank to secure public accountability and protect donor's interests.[689] This dual legal basis has implications for the role played by the Members and Directors, based on the underlying assumption that they have a financial interest in the company, which is not always the case.[690] As has previously been raised, there is legal tension as to exactly how the duties imposed on directors by company law overlap with the duties imposed by charity law on trustees and,

[687] Levitt M, 'UK Biobank: a model for public engagement?' (2005) 1 Genomics Society and Policy 78.
[688] Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440, 449; Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).
[689] Under the Companies Act 2006, as will be discussed later in this Chapter.
[690] This means that there is no explicit duty on Members to act in the best interests of the company, as it is assumed that their financial interests will be one and the same: Cabinet Office Strategy Unit, 'Private Action, Public Benefit: Charitable Incorporated Organisation' (Background Paper, Cabinet Office, September 2002), 4 <http://webarchive.nationalarchives.gov.uk/+/http://www.cabinetoffice.gov.uk/media/cabinetoffice/strategy/assets/inc.pdf> accessed on 22nd October 2012

where there is a conflict, which is paramount.[691] This chapter will explore these questions and will examine UK Biobank Ltd's constitutional documents and UK charity and company law, to reveal the implications of such pressures for UK Biobank Ltd. This analysis aims to inform evaluation of the extent to which the legal structuring of UK Biobank Ltd as a charity company assists in the furtherance of its public good mission.

6.2 Constitution of UK Biobank Ltd

It is recalled from the previous chapters that UK Biobank's incorporation as a charity company means it is subject to a dual legal regime that relates both to its charity status (UK charity law) and its structure as a company (UK company law). This legal structure requires UK Biobank to be registered with both Companies House and the Charity Commission, with implications for the administration of UK Biobank as well as its accountability. As will now be demonstrated, such duality also has implications for the Constitution of the Company, which empowers the Members and the Board of Directors to run the Company, as well as the duties owed by the managers, and to whom. These implications will now be examined in turn.

6.2.1 UK Biobank Ltd's Company Objects and Powers: Memorandum and Articles of Association

By virtue of its incorporation as a charity company with Companies House, UK Biobank Ltd's Memorandum and Articles of Association form the Constitution of the Company; detailing the 'objects' of the company and the duties, powers and rights of those involved in the corporate form. This Constitution serves as the benchmark to measure UK Biobank's performance. It provides many of the rules governing the internal operation of the company, and states UK Biobank's charitable objects:

> The objects for which the Company is established are to protect, preserve and advance all or any aspects of the health and welfare of human beings and to advance and promote knowledge and education...[692]

[691] The implications of this for UK Biobank Ltd will be discussed in more detail in the next section of this chapter.

[692] Para 3 Memorandum of Association: UK Biobank Ltd., 'Memorandum and Articles of Association of UK Biobank Limited' (Incorporated 28 November 2003) available at Companies House, company no. 04978912 <https://beta.companieshouse.gov.uk/company/04978912/filing-history> accessed 8 Feb 2016.

When making decisions, granting access and conducting the day-to-day management of UK Biobank, UK Biobank Ltd is granted powers to pursue this overarching object and directors are under a general duty to observe the Constitution.[693] It is commonplace to separately list the powers of the company to attain these objects. This is because in the absence of express powers to carry out its objects, a company will only have those powers that are implied by law. A company incorporated under the Companies Act is considered to have such implied powers as are necessarily incidental to, or consequential upon, the pursuance of the objects stated in its objects clause.[694] Since these implied powers are unlikely to be as extensive or uniquely suited for the running of each particular company, it is important that the powers in the Memorandum are set out expressly and in detail.

The powers of UK Biobank Ltd to pursue its object are listed in paragraph 4 of the Memorandum. These include its power to undertake the project;[695] to collect, gather in, label, store and anonymise information and blood and samples;[696] to develop and operate policies governing and encouraging access and use of the resource and data samples and to grant licenses inside and outside the UK;[697] to receive, investigate and resolve complaints;[698] to hold, grant licenses, sell, lease and deal with or dispose

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'…By engaging in, encouraging and supporting:

(i) Investigations into the separate and combined effects of genetic, environmental (including lifestyle, physiological and environmental exposures) and other factors on human health and welfare and on the risk and causation of diseases in the human population;

(ii) The establishment, holding, operation, management, promotion, support, expansion, improvement and safeguarding of a collection of biomedical, biochemical, epidemiological, genetic and other data and blood and other biological and biochemical samples obtained and developed through, for the purpose of an/or in connection with some or all of the investigations referred to in paragraph (i) and pertaining to a cohort of human Participants ('Data and Samples', for use in a research, knowledge and information resource provisionally known as the UK Biobank ('the Resource');

(iii) Research into the biological and medical sciences and other disciplines which may contribute to the improvement of human health and welfare ('the Biosciences');

(iv) The discovery, invention, improvement, development and application of treatments, cures, diagnostics and other medicinal agents, methods and processed that may in any way relieve illness, disease, disability or disorders of whatever nature in human beings; and

(v) The study and understanding of any of the Biosciences.'

[693] Companies Act 2006 s. 171

[694] *A-G v Great Eastern Railway* [1880] 5 App Cases 473; *A-G v Mersey Railway Co* [1907] AC 415 (HL)

[695] Para. 4(A) Memorandum of Association: UK Biobank Ltd., 'Memorandum and Articles of Association of UK Biobank Limited' (Incorporated 28 November 2003) available at Companies House, company no. 04978912 <https://beta.companieshouse.gov.uk/company/04978912/filing-history> accessed 8 Feb 2016.

[696] Ibid Para. 4(B)

[697] Ibid Para 4(E)

[698] Ibid Para 4(G)

of rights or interest in, the undertaking, property, rights and assets held by the Company, including the Resource;[699] to invest capital held by the Company not immediately required for the objects of the Company in any part of the world in investments;[700] and to acquire any copyright, patent, publication or other intellectual property right in or arising out of the resource, data samples and any other research or research results. [701]

In corporate governance, it is common practice to give the Board of Directors, as centralised management, the broad power to run the company. According to UK Biobank Ltd's Articles of Association this is also the case.[702] To whom, then, do the Board of a charitable company like UK Biobank Ltd owe their duties?[703] Crucially, UK Biobank's incorporation as a charitable organisation means that the Board of Directors owe duties both to UK Biobank Ltd and wider stakeholders including the general public. Additionally, the Board are 'charity trustees' for the purposes of UK charity law[704] and this means that the Board owe fiduciary duties and is accountable to the general public, as well as the Members of UK Biobank Ltd (signatory Members at the time of registration were Colin Blakmore (on behalf of the Medical Research Council) and Mark Walport (on behalf of the Wellcome Trust)).

As will be seen, the dual legal structure creates a series of obligations, which go some way to addressing the series of questions and ethical concerns raised when UK Biobank was created and in the course of its development (Chapter 1, 3 and 4). However, the duality also gives rise to considerable uncertainty as to how exactly the duties imposed on directors by company law overlap with the duties imposed by charity law on trustees. This tension will now be explained in more detail by reference to the Companies Act 2006, and the Charities Act 2011, which both the

[699] Ibid Para 4(J)
[700] Ibid Para 4(K)
[701] Ibid Para 4(Q)
[702] Para 12.1 Articles of Association: UK Biobank Ltd., 'Memorandum and Articles of Association of UK Biobank Limited' (Incorporated 28 November 2003) available at Companies House, company no. 04978912 <https://beta.companieshouse.gov.uk/company/04978912/filing-history> accessed 8 Feb 2016.
'Power of Directors' states: Subject to the provisions of the Statutes, the Memorandum and these Articles and to any directions given by resolution of the Members, the business of the Company shall be manage by the Board, which may exercise all the powers of the Company.
[703] This disconnect is at the heart of the problem with charity companies, and indeed was a persuading factor for the introduction of the new charity form, as will be discussed in this chapter.
[704] Which will be explained in detail later in this chapter.

UK Biobank Ltd Members and Board of Directors (analysed respectively) are subject to.

6.2.2 Members of UK Biobank Ltd: The Wellcome Trust and the Medical Research Council

As Members of a charity run exclusively for charitable purposes and for the benefit of the public, the WT and MRC as signatory Members of UK Biobank Ltd have no financial interest in the outcome of its activities.[705] Since UK Biobank Ltd is a charitable company UK company and charity law regulates the position of Members respectively.[706] Within this dual regime and in contrast to directors, there are limited legal obligations on members. Alternatively, members have a number of rights that stem from both company and charity law, and the extent to which members are under obligations to exercise these rights in a particular way, will now be analysed.

Administrative rights of members fall into two categories: rights which are connected with determining the organisational structure of the charity (e.g. rights relating to the appointment or removal of charity trustees, or to the amendment of the Charity's Constitution); and rights which relate to the operation of the charity, for example a right reserved to a charity founder by the governing document of a charity to direct how the resources of the charity should be applied. Such rights are legally enforceable 'in their capacity as members' in accordance with the provision of s.33 of the Companies Act 2006.

While members of a non-charitable company do not have a general obligation in company law to exercise their rights in the interests of the company,[707] this is not the case for all rights, for example altering the Company's Constitution. A member is more likely to be subject to legal restraint if he has majority voting powers and if the vote involves an alteration of the articles with potential adverse effects on other members.[708] In this instance the majority may be subject to equitable rules,

[705] See *Gaudiya Mission v Brahmachary* [1997] 4 All ER 957

[706] This is also the case for the Board of Directors, which will be the topic of the next section of this Chapter.

[707] A members' motive for voting is normally irrelevant and he can vote for his own interest even if that is against the interest of the company. The position was summarised by Megarry VC in *Estmanco (Kilner House) Ltd v Greater London Council* [1982] 1 WLR 2 [1982] 1 All ER 437 when he said: 'When voting a shareholder may consult his own interest'

[708] Warburton J, 'Charity members: duties and responsibilities' (2006) 70 CPL 330.

enforceable in court, requiring the power to be exercised in good faith for the benefit of the company.[709]

There is also some uncertainty regarding the extent to which members of charitable companies are legally obliged to exercise their voting rights in the best interests of the charity of which they are members. Members' voting rights[710] include the ability to vote, to waive a breach of fiduciary duty,[711] or duty of care by a director,[712] in a general meeting. It has been argued that the members of charitable companies are in the same position legally as the members of non-charitable companies. If this were the case, it may be that there is no such duty to vote in the best interests of the company and members are free from restraint.[713] The courts have only intervened in this scenario in extreme cases regarding fraud on a minority and insolvency.[714]

On this matter, the Charity Commission has urged that in exercising their right to vote and influence the governance of a charity, members of a charity should ensure that their behaviour is not damaging to the running of the charity or to its good name. The Commission takes the view that members have an obligation to use their rights and exercise their vote in the best interest of the charity of which they are members, and asserts that the rights that exist in relation to the administration of a charitable institution are fiduciary regardless of the identity of the person or persons on whom the rights are conferred.[715] In this sense, while it would be hypothetically possible for

[709] Sjafjell B, Johnston A, Anker-Sorensen L, and Millon D 'Shareholder primacy: the main barrier to sustainable companies' in Sjafjell B and Richardson BJ (eds), *Company Law and Sustainability: Legal Barriers and Opportunities* (CUP 2015).
[710] The Charity Commission, (RS7) *Membership of Charities* (Charity Commission 2004), 4 < www.gov.uk/government/uploads/system/uploads/attachment_data/file/284722/rs7text.pdf> accessed 10 November 2012: Lansley J, 'Membership Participation and Ideology in Large Voluntary Organisations: The case of the National Trust' (1996) 7 Voluntas 221
[711] Lansley J, 'Membership Participation and Ideology in Large Voluntary Organisations: The case of the National Trust' (1996) 7 Voluntas 221
[712] By extension, this right applies to directors of a charitable trust who are 'charity trustees' for the purpose of Charities Act 2011 s.177 as those responsible for the management and administration of the charity.
[713] *Phillips v Manufacturers' Securities Ltd* [1917] 116 LT 290 [296] *per* Lord Cozens-Hardy M.R; *Northern Countries Securities Ltd v Jackson & Steeple Ltd* [1974] 1 WLR 1133 [1144] *per* Walton J; *Estmanco (Kilner House) Ltd v Greater London Council* [1982] 1 WLR 2 [1982] 1 All ER 437 [1982] 1 All ER 437 [444] *per* Megarry V.C
[714] The Charity Commission, (RS7) *Membership of Charities* (Charity Commission 2004), 4 < www.gov.uk/government/uploads/system/uploads/attachment_data/file/284722/rs7text.pdf> 10 November 2012; *Muman v Nagasena* [2000] 1 WLR 299, [1999] 4 All ER 178
[715] The Charity Commission advise: 'If, under the terms of the governing document of an institution, administrative rights can be exercised otherwise than in the interests of the institution, without a breach of trust or duty, then the question arises whether the institution is in fact established for exclusively charitable purposes' The Charity Commission, (RS7) *Membership of Charities* (Charity

a company member to use its voting rights without external intervention, it seems that incorporation as a charity opens a company to additional accountability such that voting rights ought to be exercised in the interests of the public as beneficiaries of the company.

In addition to administrative and voting rights, and because the Memorandum and Articles of Association represent a binding contract between the company and its members, members also have the right to enforce these articles in court. However, this right is not without constraint. As has previously been mentioned, the rule in *Foss v Harbottle*[716] historically has meant that the minority of members by votes cannot complain of wrongs done to the company (whether by the directors, the majority of the members, outsiders, or other wrong-doers) or of irregularities in the conduct of the company's internal affairs. Part 11 of the Companies Act 2006 has modified this position;[717] according to which a minority may litigate if they pass strict tests. These hurdles are to avoid pointless or oppressive litigation against companies:[718]

> The courts are essentially seeking a balance between their natural reluctance to become involved in the internal affairs of a company and a desire to see that there is some control over fraud and abuse of power.[719]

For this reason, members also need to obtain consent of the Charity Commissioners to bring an action against the company in the form of charity proceedings under the Charities Act,[720] which will be analysed later in this chapter.

Applied to UK Biobank Ltd, the extent to which the WT and MRC as Members owe a fiduciary duty to exercise their administrative and voting rights in the best interests of the charity is seemingly unclear. For the purpose of this thesis, this is significant in terms of: a) the composition of the Board of Directors of UK Biobank; and b) the

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Commission 2004), 4 <www.gov.uk/government/uploads/system/uploads/attachment_data/file/284722/rs7text.pdf> 10 November 2012

[716] Drury R, 'The Relative Nature of a Shareholder's Right to Enforce the Company Contract' (1986) 45 CLJ 219, 237 cited in Warburton J, 'Charity members: duties and responsibilities' (2006) 70 CPL 330.

[717] 'Derivative claims and proceedings by Members' s 260.

[718] *Gray v Lewis* [1873] 8 Ch App 1035, [1050-1]; *Mozley v Alston* [1847] 1 Ph 790 [799]

[719] Ibid.

[720] Charities Act 2011 s.115

Company Constitution (the Memorandum and Articles of Association). The composition of the Board of Directors has come under scrutiny for the lack of donor or Ethics and Governance Council representation. Currently (2016), the Board is comprised of esteemed experts in public health, epidemiology, bioscience and law, and is chaired by Sir Mike Rawlins, President-Elect of the Royal Society of Medicine and Chairman of the National Institute of Health & Clinical Excellence.[721] Whether or not the absence of donors and EGC representatives in the composition of the Board is appropriate given the range of interests associated with UK Biobank and the running of the company has been reflected upon in the theoretical discussion at the beginning of this chapter, and will be considered in terms of legal accountability in the final section.

Furthermore, the administrative rights of Members to amend the Constitution of UK Biobank Ltd might also be significant in the future, for example, in response to changing societal attitudes to ethical issues associated with biobanking (Chapter 1) or in response to financial difficulty (Chapter 2). On the basis of this analysis, it seems to be the case that when Members of UK Biobank are appointing and/or removing charity trustees, they are not under a legal obligation to exercise their rights in a particular way. On the other hand, this does not appear to be so when it comes to amending the company's Constitution. This finding is interesting if we think back to observations that have been made in Chapter 4 regarding the role of the funding bodies in driving the development of UK Biobank, both historically and in the future. In particular, this conclusion gives rise to the potential risk of conflicts of interest in the hiring of Board members, or preferential treatment (to be raised again in the discussion of the Board of Director's duties below).

However, analysis has also revealed that UK Biobank's incorporation as a charity means that there is a duty to act in accordance with the company's charitable purpose and the Charity Commission urge members of a charity to act in a fiduciary manner. In this regard, Members of UK Biobank will be subject to constraints in exercising their rights for the advancement of health of future generations.

[721]UK Biobank, 'UK Biobank Board' (UK Biobank) <http://www.ukbiobank.ac.uk/uk-biobank-board/> accessed 5 February 2014.

Analysis will now turn to the role of UK Biobank Ltd's Board of Directors and in particular, the implications of UK Biobank's charitable incorporation on the discretionary powers of the Board in running the organisation including the extent to which the Board is publically accountable. As will be demonstrated, while it appears to be the case that Members of UK Biobank Ltd primarily owe duties under company law to the company itself, and charity law limits these duties only to an extent, the UK Biobank Board of Directors act as both charity trustees and company directors, and thus the dual legal basis of UK Biobank gives rise to a number of difficulties regarding the interplay between such obligations.

6.2.3 UK Biobank Board of Directors and 'charity trustees': Duty to the company or the public?

Over time, the definition of 'charity trustee' has necessarily evolved from a narrow understanding that encompasses only trustees of a charitable trust structure, to a broader interpretation that applies to all those responsible for the management and administration of a charity.[722] According to the latter, 'charity' includes any institution, corporate or not, and therefore includes both trustees of a charitable trust and directors of a charitable corporation.[723] This is the definition most recently endorsed by s.177 of the Charities Act 2011, which states:

> In this Act, except in so far as the context otherwise requires, 'charity trustees' means the persons having general control and management of the administration of the charity.

This is explained in UK Biobank's Ethics and Governance Framework:

> *The Board of Directors of UK Biobanks are company directors under UK company law and charity trustees under UK charity law*. They are accountable to the Members of the Company (Medical Research Council and Wellcome Trust), and to the Charity Commission for England and Wales, for the performance of their duties as directors and charity trustees, including the duty to act in the interests of UK Biobank. [724] (Emphasis added)

[722] Luxton P, *The Law of Charities* (OUP 2001), 336
[723] Ibid. 337
[724] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016: III.A 'Management and Accountability Board of Directors'. Furthermore, UK Biobank Ltd's 2011 Report

As 'charity trustees',[725] UK Biobank Directors exercise 'management oversight of UK Biobank.'[726] As 'company directors',[727] the Board is responsible for managing the Business of the Company and 'may exercise all the powers of the Company.'[728] But this power is not unlimited, and when exercising such discretion the Board are accountable under both charity and company law. The Board owe statutory and fiduciary duties, which Directors assume when they take up office according to ss. 170-177 of the Companies Act 2006, and the Charities Act 2011.

Briefly, while the duties of a director of a non-charitable company are owed to the company itself,[729] and are enforceable by its members, trustees of a charitable trust owe their duties to the public. This is because unlike private trusts, there are no individual beneficiaries; charitable trusts must be run for the 'public benefit.'[730] These duties are enforceable by the Charity Commission, amongst others, and subject to Charity Commission oversight. While the company director's duty of care is to act in the best interests of the company and for the benefit of its members,[731] the duty of care imposed on a charity trustee is to act in the best interests of the charity, with an emphasis on both the current and future beneficiaries, who may well not be the same as the members.[732]

In more detail, the Companies Act 2006 relates specifically to the structure of UK Biobank Ltd as a charity corporation.[733] Directors of the company owe statutory

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and Financial Statements recognised that '...the Directors of the Charity are its Trustees for the purpose of charity law and throughout this report are collectively referred to as the Directors...' UK Biobank Ltd, 'Report and consolidated financial statements' (UK Biobank, 30th Sept 2011), 4 <www.ukbiobank.ac.uk/wp-content/uploads/2011/12/UK-Biobank-Limited-Signed-2011-Report-and-Financial-Statements.pdf> accessed 06th Jan 2016.

[725] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016

[726] Ibid. 'Organisation and Funding'

[727] Ibid.

[728] Para 13.1 Articles of Association: UK Biobank Ltd., 'Memorandum and Articles of Association of UK Biobank Limited' (Incorporated 28 November 2003) available at Companies House, company no. 04978912 <https://beta.companieshouse.gov.uk/company/04978912/filing-history> accessed 8 Feb 2016.

[729] *Percival v Wright* [1902] 2 Ch 421; codified in Companies Act 2006 s.170 (1): 'a director of a company owes the general duties specified in sections 171 to 177 to the company.'

[730] Charities Act 2011 s.4

[731] Companies Act 2006 s.170 (1)

[732] Charities Act 2011 s.4

[733] Companies Act 2006 ss. 170-177 codifies the common law position: The Law Commission and Company Law Review recommended a 'high level' statutory restatement of the common law principles of the nature and scope of general fiduciary duties and duties of skill and care which had previously remained largely in the common law: Law Commission and Scottish Law Commission,

duties found in ss.170-177 of the Act, to the company.[734] There has been jurisprudential debate as to how far fiduciary (rather than statutory) duties of directors may be interpreted as being owed directly to shareholders, but in relation to charitable companies, it is difficult to see how this would be an issue given the membership structure and lack of share capital.[735] Therefore, a distinction can be drawn between duties owed directly to shareholders,[736] from the question of how far director's duties owed to the company require directors to take into account the interests of wider stakeholder groups.

The latter is embodied in s.172 of the reformed Companies Act 2006, which requires company directors to have regard for a range of groups, interests and activities in promoting the success of the company. Under common law jurisprudence, this provision has meant a duty to act in the best interests of the company,[737] but the more complicated question has been: whose interests are to be considered the interests of the company?[738]

Before the reform of the Companies Act, the prevailing approach regarding non-charitable companies had been that the collective interests of the members of the company could be equated with the interests of the company.[739] Clearly, this position

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Company Directors: Regulating Conflicts of Interest and Formulating a Statement of Duties (Law Com No 261, 1999), Ch. 3 and Annex C

[734] Companies Act 2006 s.170(1)

[735] Traditionally common law has been reluctant to recognise directors' general duties as being owed to individual shareholders. Recognition of duties owed individually would undermine the collective nature of the shareholders' association in a company. It would also undermine the rule that duties are owed to and are enforceable by the company. If the directors owed to individual shareholders a set of duties parallel to those owed by them to the company, the restrictions on the derivative action could easily be side-stepped by means of the individual shareholder suing to enforce, not the company's rights, but his or her own rights: *Towcester Racecourse Co Ltd v The Racecourse Association Ltd* [2003] 1 BCLC 260.

However, in the decision of the CA in *Peskin v Anderson* [2001] 1 BCLC. 372 Mummery LJ distinguished clearly between the fiduciary duties owed by directors of the company which arise out of the relationship between the director and the company, and fiduciary duties owed to shareholders which are dependent upon establishing 'a special factual relationship between the directors and the shareholders in the particular case.' The crucial question is what sort of dealing needs to take place between director and shareholder in order to trigger a fiduciary or other duty owed to an individual shareholder by the directors. Such a duty will certainly arise where, on the facts, the directors' place themselves, as against shareholders individually, in one of the established legal relationships to which fiduciary duties are attached, such as agency: Cited in Davies PL, *Gower and Davies' Principles of Modern Company Law* (8th edn, Sweet and Maxwell 2008). 480.

[736] Which only arise very rarely, where there is an assumption of responsibility to an individual on the facts: *Peskin v Anderson* [2001] 1 BCLC 372

[737] *Smith and Fawcett Ltd, Re* [1942] Ch 304

[738] Yap JL, 'Considering the enlightened shareholder value principle', (2010) 31 Company Lawyer 35

[739] Ibid.

sits uncomfortably with charitable companies, which must be run for the benefit of the public to attain charitable status. Thus, s.172 (2) was specifically inserted to deal with charities that are companies or similar. This section puts the purposes of the company above those of its members and states:

> Where or to the extent that the purposes of the company consist of or include purposes other than the benefits of its members, subsection (1) has effect as if the reference to promoting the success of the company for the benefit of its members were to achieving these purposes.

Consequently, s.172 is of crucial importance in terms of the public mission of UK Biobank and the range of stakeholders represented by the UK Biobank model. The scope and implications of this duty, and others, for the Board of Directors of UK Biobank will now be discussed in more detail. In particular, the extent to which there is a duty to take into account the public in the running of UK Biobank as well as the potential for participants to be included within this bracket.

In short, as a result of UK Biobank Ltd's dual legal basis, the Board of Directors owe a number of duties under company law, which are enshrined in both the Companies Act 2006 and in equitable principles, as well as a number of fiduciary and statutory duties owed in charity law. The duties that are more likely to be relevant to the UK Biobank Board of Directors and are most interesting in terms of this thesis will now be dealt with respectively.

6.3 Board of Director's duties under company law

As a reminder, the main source of the UK Biobank Board of Directors' powers and constraints on those powers is the Memorandum and Articles of Association; the Company's Constitution. These duties therefore symbolise the principle that the powers held by Directors are not unlimited, and represent one mechanism of control over such power.[740] Under company law, these duties are owed to the Company UK Biobank Ltd rather than the individual members but it is for the majority members of the Company to enforce these duties, and the previous discussion has highlighted the potential limitations on this right. The statutory and fiduciary duties most relevant to UK Biobank Ltd will now be outlined.

[740] Nolan RC, 'Controlling fiduciary power' (2009) 68 CLJ 293.

6.3.1 Duty to act within powers: s.171

According to s.171, directors must 'act in accordance with the company's constitution'[741] and must 'only exercise powers for the purposes for which they are conferred.'[742] A company will break its duty to act within its powers if it acts in breach of this constitution.[743] It is not necessary that those responsible for the breach are shown to be subjectively aware of the unconstitutional nature of their actions,[744] so directors are under a duty to acquaint themselves with the terms of the company's articles and abide by them.[745] An act or decision of the directors that is outside the company's constitution, i.e. where a director professes to have a power that it does not have is void; it is of no effect. Where the directors simply exceed an authority that has been conferred on them the decision is only voidable.[746] If the contravention of the constitution has involved the improper distribution of the company's assets, the directors are regarded as in breach of trust and are liable to replace the assets.[747] The vice, therefore, lies in utilising a power for a purpose, or with an intention, beyond its scope:[748]

> The proper purpose doctrine looks to the particular ends intended to be achieved through certain particular acts and determine whether such ends are contemplated (and therefore authorised) by the power in question.[749]

If directors have exercised their powers for a purpose outside those for which the powers were conferred, this may be a breach of duty according to s.171 (b). Again,

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[741] Companies Act 2006 s.171(a)
[742] Ibid. s.171(b)
[743] This duty was recognised in the early years of modern company law, and is reflected in a number of nineteenth century decisions, usually involving the purported exercise by directors of powers which were ultra vires the company; *Lands Allotment Company, Re* [1894] 1 Ch 616 CA. Or payments of dividends or director's remuneration contrary to the provisions in the company's articles: *Oxford Benefit Building and Investment Society, Re* [1886] 35 Ch D 502. An early example of a company's accounts recognising profits, which had not been earned. Davies PL, *Gower and Davies' Principles of Modern Company Law* (8th edn, Sweet and Maxwell 2008), 498
[744] *Leeds Estate Building and Investment Company v Shepherd* [1887] 36 Ch D 787
[745] Ibid
[746] *Hogg v Cramphorn* [1967] Ch 254, [1966] 3 WLR 995: a decision to attach multiple voting rights to shares issue to the company's pension fund, in breach of the company's articles was ineffective. *Guinness v Saunders* [1990] 2 AC 663, [1990] 2 WLR 324: fixing of directors' remuneration by a board committee, rather than a full board, in breach of the articles meant that the recipient director had to repay the money. Cf. *Hely-Hutchinson v Brayhead Ltd* [1968] 1 QB 549: where the correct body acted by the director was in breach of his obligation under the articles to comply with the disclosure provisions. Cited in Davies PL, *Gower and Davies' Principles of Modern Company Law* (8th edn, Sweet and Maxwell 2008), 499.
[747] Ibid.
[748] Nolan RC, 'Controlling fiduciary power' (2009) 68 CLJ 293.
[749] Ibid.

this is an objective test.[750] When deciding whether a particular purpose is proper the courts have taken a broad reading of the constitution, rather than a narrow analysis of a particular clause.[751] Thus, in *Mills v Mills*[752] it was held that the courts must try to ascertain 'the substantial object the accomplishment of which formed the real ground of the board's action' and then judge that to be proper or improper according to the purposes of the power in question. Where the directors act for an improper purpose, their act is voidable by the company, not void, as it is in the case where the directors purport to exercise a power they do not have.[753]

Applying this proper purpose doctrine, it has been demonstrated that UK Biobank's charitable purpose is the advancement of health and the saving of lives, for the benefit of the public. Difficulties arise however, since the Companies Act is primarily concerned with shareholding rather than membership, and this doctrine has mainly been applied to instances where the proper purpose concerns the Directors' powers to allot shares etc. Nevertheless, the Memorandum of Association of UK Biobank states the powers of its Board, including the power:

[750] *Howard Smith Ltd v Ampol Ltd* [1974] AC 821, [1974] 2 WLR 689: which concerned the power of directors to issue new shares.

[751] *Smith and Fawcett Ltd, Re* [1942] Ch 304 [306]: where the clause in question (regarding the admission of new Members to a small company) was widely construed so as to produce the effect equivalent to the partnership rule of strict control by the board over the admission of new Members. The case of *Gaudiya Mission v Brahmachary* [1998] Ch 341, [1997] 4 All ER 957 concerned a company limited by guarantee and formed for the purpose of campaigning for the adoption of a particular policy in a certain area of social life. It was held that the director's powers to expel Members with contrary views should not be cut down on the grounds that the directors were seeking to control the composition of the general meeting. Davies PL, *Gower and Davies' Principles of Modern Company Law* (8th edn, Sweet and Maxwell 2008), 503.

[752] *Mills v Mills* [1938] 60 CLR 150 [185-186] *per* Dixon J

[753] 'The distinction between 'void' and 'voidable' turns on the reasons why a transaction or purported transaction can be questioned. If the flaw in what happened was that the fiduciary had no authority to act as he did, the prima facie his decision to act will be void in equity, and his action pursuant to that decision will also be treated as void in equity. If that result is not possible, then the fiduciary's decision to act will still be void in equity, but the result of his actions (for example, the creation of new legal property) will necessarily fall to be treated as only voidable in equity. Context matters vitally to remedies… One good example of this situation is the improper allotment and issue of shares in a company. By contrast, if the fiduciary did have the authority to do what he did, but acted on the basis of a flawed decision, then his action should in principle be voidable: in private law at least, flawed exercise of authority is still an exercised of authority until set aside.' Nolan RC, 'Controlling fiduciary power' (2009) 68 CLJ 293.

> To receive and apply money and other property from persons desiring to promote the objects of the company on such terms as shall be thought desirable by the Board; and to hold funds in trust for the same.[754]

Thus, if the Board were to apply money in a manner other than in pursuit of its Company object and wider charitable purpose this could constitute a breach of s.171, and it is for the Members of UK Biobank Ltd to enforce this duty.

Interestingly, the Board has the power:

> To invest all or part of the capital or income held by the Company not immediately required for the objects of the Company in Investments and to administer, manage, sell, realise and deal in such Investments, in each case as may be permitted by law and to the extent permitted by law hereunder and under the Articles, having regard to the need for diversification of investments in so far as it is appropriate to the circumstances of the Company, and to the suitability of any proposed investments for the Company, and to such other matters as the Company thinks fit and where appropriate after obtaining advice from a financial expert.

While this power seems to give the Board a wide discretionary power to make investments, this will be constrained by UK Biobank's overriding charitable purpose for the benefit of the public. One example of such an investment is the UK Biocentre; a wholly-owned UK Biobank subsidiary created to help other health studies enhance the quality and cost-effectiveness of their projects.[755] Any profits from UK Biocentre will be put back into UK Biobank to strengthen the resource.

6.3.2 Duty to promote the success of the company: s.172

Perhaps the most controversial duty[756] codified by the Companies Act 2006 is the s.172 duty to promote the success of the company.[757] This duty is also most

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[754] UK Biobank Ltd., 'Memorandum and Articles of Association of UK Biobank Limited' (Incorporated 28 November 2003) available at Companies House, company no. 04978912 <https://beta.companieshouse.gov.uk/company/04978912/filing-history> accessed 8 Feb 2016. Memorandum of Association Para 4(O)

[755] UK Biobank, 'UK Biocentre' (UK Biobank) <http://www.ukbiobank.ac.uk/uk-biocentre-2/> accessed 21 January 2016

[756] See, for example, the debates in the House of Commons in Standing Committee D, 11 July 2006 (Col 543) <http://www.publications.parliament.uk/pa/cm200506/cmstand/d/st060711/am/60711s01.htm> accessed on 10 November 2012

[757] This duty was particularly controversial because it was proposed by the Company Law Review that it should not simply repeat the common law, which had previously formulated the principle that

significant for this analysis since it makes express reference to companies which are not-for-profit, like UK Biobank Ltd. Section 172(1) requires directors to act 'in the way he considers, in good faith, would be most likely to promote the success of the company for the benefit of its members as a whole' and then sets out a non-exhaustive list of matters which are means to the end of the benefit of members as a whole. In so doing, this 'enlightenment' principle requires members to have regard for interests other than those of shareholders, over the long term (Chapter 5).

In relation to a non-profit company, however, it needs to be remembered that s.172(2) puts the purposes of the company above those of its members and the Explanatory Notes to the Companies Act state:

> Where the purpose of the company is something other than the benefit of its members, the directors must act in the way they consider, in good faith, would be most likely to achieve that purpose. It is a matter for the good faith judgment of the director as to what those purposes are, and, where the company is partially for the benefit of its members and partly for other purposes, the extent to which those other purposes apply in place of the benefit of the members.[758]

Applied to UK Biobank, this therefore places a duty on the Board to act in ways that they consider most likely to promote the success of UK Biobank Ltd for the benefit of the public in light of its charitable status. So, for example, when granting access decisions, the Board is obliged under company law to take into account the likely contribution of the research to UK Biobank's object of research in the public interest. Under company law it will be for the Members to enforce this duty, but the decision as to what constitutes 'success' is one for the good faith judgment of the Board of Directors;[759] thereby granting them broad discretion. On this matter, according to UK Biobank Ltd's own financial report the charity's mission is to maximise the

directors were required to act in good faith in the way they believed to be 'in the best interests of the company.' Davies PL, *Gower and Davies' Principles of Modern Company Law* (8th edn, Sweet and Maxwell 2008), 506

[758] Explanatory Notes to the Companies Act 2006, para 330.

[759] The common law position has been modified slightly by s.174 Companies Act 2006, which will be described in turn.

value of the biomedical research resource, and the success of this strategy is measured according to the amount of research usage and the results generated.[760]

6.3.3 Duty to exercise independent judgment: s.173

This duty is fairly uncontroversial. The duty does not prevent directors seeking and acting on advice, but directors must regard themselves as taking responsibility for the decision reached.[761] Neither does this duty prevent delegation of the directors' functions, so long as this power is conferred upon the directors in the company's constitution. Section 173 does not, in itself, give directors the power of such delegation.[762] In the case of UK Biobank, paragraph 15.1 of the Articles of Association 'Delegation of the powers of the Board' states:

> The Board may from time to time provide for the management and transaction of the affairs of the Company in such manner as it thinks fit. In particular, the Board may delegate any of its powers and discretions to:
>
> a) Committees; or
> b) To any person, whether or not a Director, chief officer, Secretary, employee or officer of the Company or any other person.

Accordingly, the Board has appointed an 'Access sub-committee', which is responsible for making key access decisions, particularly regarding the use of depleting samples or potentially contentious research, in accordance with the access requirements laid down in UK Biobank's own 'Access Procedures' policy document.[763] Furthermore, according to UK Biobank Ltd's Memorandum and Articles of Association, in the event that UK Biobank is shut down or goes into liquidation the EGC will be responsible for what happens to the samples contained in the biobank. Given the EGC's commitment to the public interest, this goes some way to ensuring that the samples will not be exploited in the future, thereby honouring participant's consent to research that is in the public interest.

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[760] UK Biobank Ltd., 'UK Biobank—Summary Information Return 2013' (Charity Commission Online, submitted 10 April 2014) <http://apps.charitycommission.gov.uk/SIR/ENDS32/0001101332_SIR_20130930_E.PDF> accessed 08 February 2016.

[761] Davies PL, *Gower and Davies' Principles of Modern Company Law* (8th edn, Sweet and Maxwell 2008), 525

[762] Explanatory Notes to the Companies Act 2006, para 333-335

[763] UK Biobank 'Access sub committee' (UK Biobank) <http://www.ukbiobank.ac.uk/access-to-the-resource/> accessed 10 November 2012

6.3.4 Duty of skill, care and diligence: s.174

This section codifies the director's duty to exercise reasonable skill, care and diligence in the performance of their position. Traditionally, the courts employed a subjective test which did not require the directors to exhibit a greater degree of skill than may reasonably be expected from a person with their knowledge and experience.[764] Under the 2006 Act, however, the director's subjective level of skill only sets the standard if it improves upon the objective standard of the reasonable director.[765] Section (a) sets a standard, which all directors must meet, and it is not dependent upon the particular director's capabilities; (b) adds a subjective standard, which operates only to increase the level of care required of the director:

a) The general knowledge, skill and experience that may reasonably be expected of a person carrying out the functions carried out by the director in relation to the company; and
b) The general knowledge, skill and experience that the director actually has[766]

Accordingly, UK Biobank's Board of Directors ought to consider the scientific advantages, weighed against any disadvantages for the public when exercising their functions. If the Board is found to be acting below this minimum objective standard, and the individual ought to have subjectively known better due to a special skill or experience, then they will be found to be in breach of their duties under company law. In very rare circumstances, if breach is so proven, directors may be held personally liable to compensate for the loss.[767] Lack of due care and skill does not in itself vitiate a transaction, but instead will require compensation to reimburse the Company for the harm caused to it by the Directors' breach.[768] Directors' breach may take the form of acting in bad faith or for improper purposes. It is evident that the spirit of s.174 runs through all the directors' duties.

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[764] *City Equitable Fire Insurance Co, Re* [1925] Ch 407 [1924], 3 All ER 485: a director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience.' *per* Romer J [427]
[765] Davies PL, *Gower and Davies' Principles of Modern Company Law* (8th edn, Sweet and Maxwell 2008), 490
[766] S.174 Companies Act 2006 is said to mirror the tests laid down in the Insolvency Act 1986 s.214, which includes an objective assessment of a director's conduct.
[767] But not if it can be proven that the director acted in good faith: *IBM United Kingdom Holdings Ltd v Dalgleish* [2014] EWHC 980 (Ch)
[768] *Bristol and West Building Society v Mothew* [1998] Ch 1, [1997] 2 WLR 436 Millet LJ stated: 'it is inappropriate to apply the expression [breach of fiduciary duty] to the obligation of a trustee or other fiduciary to use proper skill and care in the discharge of his duties.'

6.3.5 Duty to avoid conflicts of interest: s.175

The duty to avoid conflicts of interest requires a director of a company to 'avoid a situation in which he has, or can have, a direct or indirect interest that conflict, or possibly may conflict, with the interests of the company.'[769] Good faith must not only be done, but must manifestly be seen to be done; the duty focuses not on the scope of power but instead on the process of decision making by the director, which lies behind an exercise of power.[770] This core 'no conflict' principle underlies the subsequent duties to be discussed; the duty not to receive benefits from third parties; and the duty to declare an interest.

S.175(2) states that this applies particularly to the 'exploitation of any property, information or opportunity.' This may be controversial given that paragraph 5(v) of UK Biobank's Memorandum states:

> Members and Directors (and any firm, body, company or academic institution (including a Member) of which a Director is a member, officer or employee) may have access to and use the Resource as a beneficiary of the Company in accordance with the terms of access and use adopted by the Company from time to time.

In light of stringent access requirements, this has the potential to put Directors and Members in a favourable position. Those involved in the set-up and running of UK Biobank are invariably more knowledgeable regarding the terms of access and can manipulate their access applications for the greatest chance of success. There is however, a binding duty on Directors to disclose any interest they may have in the meeting of the Board, and if this interest is deemed to be material they will not vote.[771] If this procedure is followed, the Director shall not be accountable to the Company for any benefit or gain that they derive from any such interest.[772]

Importantly, s.180(4) of the Companies Act 2006 authorises members of a company to approve conflicts that would otherwise constitute a breach of this duty. On this issue, Chapter 4 and the theoretical discussion in Chapter 5 have in combination

[769] Companies Act 2006, s.175(a)
[770] Nolan RC, 'Controlling fiduciary power' (2009) 68 CLJ 293.
[771] UK Biobank Ltd., 'Memorandum and Articles of Association of UK Biobank Limited' (Incorporated 28 November 2003) available at Companies House, company no. 04978912 <https://beta.companieshouse.gov.uk/company/04978912/filing-history> accessed 8 Feb 2016. Articles of Association Para 18.1
[772] Ibid. Para 18.3

highlighted the risk of conflicts of interest in the running of UK Biobank Ltd. This risk is magnified because a number of the Board members are involved with the main funding bodies.[773] Therefore, it is possible that Members' powers to vitiate breaches and elect Board members could result in the prioritisation of researchers who are involved with the WT and the MRC. As such, the power of Members to vitiate conflicts could potentially threaten the public accountability of the resource, and this threat is a direct consequence of the incorporation of UK Biobank as a private corporation.

6.3.6 Duty not to accept benefits from third parties: s.176

S.176 provides that a director 'must not accept a benefit from a third party conferred by reason of a) his being a director or b) his doing (or not doing) anything as a director.' This duty is linked to the previous duty, and the two are not mutually exclusive but instead cumulative.[774] This duty is self-explanatory.

6.3.7 Duty to declare an interest in proposed transaction or arrangement: s.177

This duty requires that if a director of a company is in any way, directly or indirectly, interested in a proposed transaction or arrangement with the company, he must declare the nature and extent of that interest, either at a meeting of the directors or by notice. Again, this is linked to the s.175 duty to avoid conflicts of interest.

6.4 Fiduciary and Statutory duties of the Board of Directors as 'charity trustees' under charity law

If directors' duties under the Companies Act are owed to the company, at the other end of the spectrum are the directors' duties as charity trustees owed to the public under the Charities Act.[775] This section will outline the most relevant fiduciary and statutory duties that UK Biobank charity trustees owe under Charity law, before reflecting on the interplay between the dual legal structure of a charity company, and

[773] UK Biobank, 'UK Biobank Board' (UK Biobank) <http://www.ukbiobank.ac.uk/uk-biobank-board/> accessed 5 February 2016

[774] Davies PL, *Gower and Davies' Principles of Modern Company Law* (8th edn, Sweet and Maxwell 2008), 575

[775] *Bray v Ford* [1896] AC 44 (HL), [1895-99] All ER Rep 1009: these common law principles are precedent for charitable companies, since the Trustee Act 2000 strictly applies to charitable institutions with a trust structure.

the implications of this duality for the enforcement of such duties and the accountability of the legal structure.

In the landmark case of *Re French Protestant Hospital*[776] it was held that the directors concerned, although not technically trustees of a trust, were in the same fiduciary position as trustees in respect of the affairs of the corporation. Therefore, there was a duty owed to the public not to make profit for or benefit from a position of conflict of interest. This was a clear statement that the courts were more concerned with the role of directors as trustees,[777] rather than the structure of a corporation:

> It seems to me that in a case of this kind the court is bound to look at the real situation which exists in fact. It is obvious that the corporation is completely controlled under the provisions of the charter by the governor, deputy governor and directors, and that those are the persons who in fact control the corporation and decide what shall be done. It is plain that those persons are in a fiduciary position as trustees in regard to any acts which are done respecting the corporation and its property.[778]

Thus, the courts have shown a tendency to give priority to charity rather than company law when dealing with a charity company limited by guarantee. However, the multi-faceted approach is both complex and burdensome for charitable organisations of a company structure. The dual character of the duties creates a defect of legal uncertainty as to the scope of the duties and standing. This may be problematic in terms of management and enforcement, since duties owed to the company under company law may be reviewed by the company itself, and certain breaches can be ratified by special resolution without intervention. But if these duties relate to the application of company property to its charitable purpose, ratification of a breach will require consent from the Charity Commission.[779] Even if consent is

[776] [1951] Ch 567
[777] In *Liverpool and District Hospital for Diseases of the Heart v Att. General* [1998] Ch 1 [209] Slade J. held that a charitable company is in a position analogous to that of a trustee in relation to its corporate assets. Warburton J, 'Charity members: duties and responsibilities' (2006) 70 CPL 330.
[778] *per* Danckwerts J at [940].
[779] Charities Act s.115

granted, such breaches may ultimately be used as evidence justifying investigation from the Charity Commission.[780]

The general standard of care and skill required of any trustee (including company directors for the purpose of the Charities Act) is that of the prudent man of business acting in the management of his own affairs.[781] A trustee who is honest and reasonably competent is not to be held responsible for a mere error of judgment, and a trustee is not therefore liable merely because his decision is wrong and results in a loss to the trust.[782] A trustee is to be judged 'not so much by success as by absence of proven default.'[783] It is therefore clear from the analysis above that the position under charity law is in line with s.174 of the Companies Act. Fiduciary duties include: the duty to participate in the management of the charity; the duty not to deviate from the terms of the trust or exceed their powers; and duties relating to the exercise of their powers. A charity trustee owes a duty of undivided loyalty to the trust and must therefore avoid conflicts of interest.[784]

The Charities Act also imposes statutory duties upon directors as 'charity trustees.'[785] These are mainly matters of internal management and administration, such as the duty to apply for registration of the charity[786] and obligations on directors to file accounts, reports and returns.[787] If these charitable fiduciary or statutory duties are breached it may give rise to civil and criminal obligations[788] and if such breach constitutes 'misconduct or mismanagement in the administration of the charity,' this will enable the Charity Commission,[789] following inquiry[790] to exercise their remedial powers to protect charities, including the removal or suspension of trustees.[791]

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[780] Ibid.
[781] *Speight v Gaunt* [1883] 9 App Cas 1 [19]
[782] *Barnett v Barclays Bank Trust Co Ltd (No.1)* [1980] Ch 515 [531]
[783] *Nestle v National Westminster Bank Plc* [1993] 1 WLR 1260 [1270]
[784] Luxton P, *The Law of Charities* (OUP 2001), 385
[785] Charities Act 2011 s.177
[786] Ibid. s. 30
[787] Ibid. Part 8 ss. 135 - 136
[788] Ibid. ss. 195 - 196
[789] Ibid. ss. 15 (1-2)
[790] Ibid. ss. 114-115
[791] Ibid. ss. 79-80

Such oversight will now be the topic of the remainder of this chapter. As we have seen, the Act makes clear that an organisation will not attain charitable status if it is not of public character, that is, for the benefit of the public.[792] The result is that the duties of directors under charity law are subject to 'state intervention'[793] and oversight, and are therefore enforceable via the Charity Commission, the Attorney-General (A-G), or a 'person interested' in charity proceedings.[794] This intervention is justified to ensure that a company's 'property' is applied to its exclusively charitable object. As will be demonstrated later in this chapter, anyone taking charity proceedings involving a charitable company must satisfy the requirements of s.115 of the Charities Act 2011, and obtain the authorisation of either the Charity Commission or the court. However, the courts have not shown themselves eager to intervene in the decision making of those responsible for the running of charities, since 'to impose too stringent a test may impose intolerable burdens on trustees who often undertake heavy responsibilities for no financial reward.'[795]

6.4.1 Conclusions on the accountability of UK Biobank via the Board of Directors

The important conclusion to be drawn from the analysis so far is that the Board of Directors of UK Biobank Ltd owes both statutory and fiduciary duties, to the company and the public under charity and company law. This raises questions as to the effectiveness of the legal duties of the Directors in terms of accountability to the public interest. Arguably, the dual nature of Director's duties leaves the model vulnerable to criticism that the private model has lessened the public accountability of the company and has complicated the extent to which the private interests of the donors are protected or furthered in the running of the company. Clearly, the difficulties that arise from the dual legal structure go beyond those articulated by shareholder and stakeholder models of corporate governance (Chapter 5) and are reflective of the challenges that led to company law reform. These shortcomings are especially pertinent given the availability of alternative legal forms with simplified legal regimes such as the Charitable Incorporated Organisation (CIO).

[792] Ibid. s.2(1)(b); s.4
[793] Luxton P, *The Law of Charities* (OUP 2001), 312
[794] Charities Act 2011 s.115
[795] *Scott v National Trust for Places of Historic Interest or Natural Beauty* [2000] 1 WLR 594 [718]

In light of such tensions, the remains of this chapter will further investigate the potential oversight mechanisms that are available to hold UK Biobank Ltd to its public good mission and to promote the range of interests that the model seeks to protect.

6.5 UK Biobank Ltd: Accountability and oversight in charity and company law

Now that the various obligations (and rights) of UK Biobank's Board of Directors and Members have been analysed, which arise by virtue of its structure and status as a charity company, analysis next focuses on the corresponding avenues of oversight applicable to this institution and the implications of UK Biobank's private legal structure in terms of its accountability and discharging its public good mission. This analysis will show that the Members of UK Biobank Ltd (the WT and MRC), the Charity Commission, the A-G, High Court, EGC and any 'person interested in the charity' are all in a position to be able to supervise, report, or call to account the considerable discretionary power of the Board of Directors. However, as will be discussed, this avenue of redress is limited in terms of the scope of the challenges that may be made, as well as the constituencies who are likely to be able to bring such challenge.

Ultimately, this section is one of the key and novel contributions of this thesis to existing scholarly debate (including Winickoff and Hunter & Laurie discussed in the previous chapter) because it highlights one of the legal lines of accountability that exists within the dual legal structure of UK Biobank, which may be utilised to hold UK Biobank to account and to its stated aims.

6.5.1 Members as a means of accountability and control

It is remembered from previous discussion that it is the members of the company who can enforce director's duties. In this sense, Members of UK Biobank Ltd are an important means of accountability and control over the UK Biobank Ltd Board of Directors. In particular, analysis has revealed the crucial function of Members for the appointment (or removal) of Directors at the annual general meeting, although this is

a constrained right.[796] In addition, matters referred to Members at the general meeting, for example breach of the duties previously outlined in this chapter, may be submitted to higher review via the Charity Commission as evidence of 'misconduct or mismanagement in the administration of the charity.'[797] However, the extent to which this is a reliable means of accountability has been called into question by the identification of a risk of conflicts of interests between Members, the Board of Directors and the running of UK Biobank Ltd. This risk is a significant consequence of UK Biobank Ltd's incorporation as a private company, which would not necessarily exist had UK Biobank been established on a statutory footing for direct public accountability.

Nevertheless, incorporation as a charity does reduce this risk, because it opens accountability avenues in charity law, which will now be investigated. In fact, there are two mechanisms by which the running of UK Biobank Ltd could be overseen. First, the Charity Commission has the power to investigate issues brought to their attention by anyone who alerts them to a problem and second, but only once this avenue has been exhausted, charity proceedings may be brought against UK Biobank by someone with legal standing to do so. These avenues for redress will now be investigated in turn.

6.5.2 Charity Commission oversight

By virtue of its charitable status, the duties and responsibilities of the UK Biobank Ltd Board of Directors and Members are subject to a higher level of oversight via charity law. The Charity Commission is a statutory regulator with legal powers to achieve this role. Accordingly, s.46 of the Charities Act 2011 gives the Charity Commission the general power to institute inquiries into charities like UK Biobank Ltd. For the purpose of such an inquiry the Commission may direct any person to provide accounts, statements[798] and copies of other documents[799] of evidence relevant to the matter in question. A search warrant may be granted,[800] and results of an inquiry may be published as the Commission sees fit.[801] If the Commission is

[796] *Foss v Harbottle* restricts the ability of Members to control the affairs of the company.
[797] Charities Act 2011 ss. 114-115
[798] Charities Act 2011 s.47(2)(i)(ii)
[799] Charities Act 2011 s.47(2)(b)
[800] Ibid. s.48
[801] Ibid. s.50

satisfied that there has been misconduct or mismanagement in the administration of the charity,[802] or that it is necessary or desirable to act to protect the property of the charity or for securing proper application for the purposes of the charity or of property coming to that charity,[803] then they may exercise their remedial powers and appoint, suspend or remove a charity trustee of their own motion.[804]

It is arguable that the company law and charity law duties of the Directors and the Members could all be subject to investigation via the Charity Commission. Matters of internal management, or breach of director's duties under Company Law, could constitute evidence of 'misconduct or mismanagement' for the purpose of s.115 Charities Act 2011. Breach of Directors and Members' duties under charity law will trigger direct investigation via the Charity Commission. In fact, there are no limits to who has standing to report issues to the Charity Commission, which in turn may initiate an inquiry. One issue with the commencement of charity proceedings is the likelihood of anyone triggering them. In the context of UK Biobank, however, we might assume that given the public profile of the endeavour there are a number of potential sources that could generate a trigger. So, for example, the Chair of the EGC may initiate an enquiry. The Chair sits in on Board meetings and has access to all materials it deems necessarily for the performance of its mandate (as identified in Chapter 4 and evidenced in the EGC modus operandi). Or an inquiry might be initiated by a journalist who is given a lead by someone within UK Biobank or associated with UK Biobank in some way, and reports such information to the Charity Commission for their investigation.

Procedurally,[805] all concerns raised with the Charity Commission are referred to the Commission's 'First Contact' area, which evaluates the risks[806] to decide whether it is a matter for the Commission. While some problems can be resolved by the charity

[802] Ibid. s.76(1)(a)
[803] Ibid. s.76(1)(b)
[804] Ibid. s.76(3)
[805] Charity Commission *Where the Charity Commission Investigates Charities* (Policy paper, Charity Commission, 23rd May 2013) <www.gov.uk/government/publications/where-the-charity-commission-investigates-charities> accessed 22 January 2016
[806] By applying a 'risk framework': which involves examining all allegations and causes for concern to: determine the level of risk; decide whether a statutory inquiry should be opened; and indicate the type of intervention required if a statutory inquiry is not appropriate.
Charity Commission, 'Our regulatory approach to protecting the public's interest in charity—how we assess and manage risks' (Risk Framework, Charity Commission, June 2012) <www.gov.uk/government/uploads/system/uploads/attachment_data/file/313453/risk-framework-our-regulatory-approach-to-protecting-the-public_s-interest-in-charity.pdf> accessed 22 January 2016.

trustees themselves, others will be examined and resolved by the Commission. However, in the most serious cases the Commission may deem it necessary to formally investigate matters further. In this instance, the Charity Commission may conduct an inquiry the outcome of which may lead to charity proceedings by the Charity Commission themselves.

Alternatively, once the Charity Commission is convinced that it cannot resolve the matter appropriately itself,[807] according to s.114 of the Charities Act 2011 charity proceedings[808] may be brought directly against the Charity by the Attorney General,[809] the charity trustees[810] and a 'person interested'.[811] However, legal standing will first need to be proven within the Charities Act. The final section of this chapter will now discuss charity proceedings as an avenue of accountability of UK Biobank Ltd.

6.6 Charity Proceedings: The Attorney General, the Charity Commission and a 'Person interested in the Charity'[812]

Crucially, legal standing must be proven under the Charities Act before charity proceedings may be brought directly against a charity.[813] The Attorney General, representing the Crown *parens patrea* (i.e. on behalf of the 'beneficiaries' of a trust) has the power under charity law to intervene and protect a charity's property if it has been, or there is threat of it being, applied in breach of trust for non-charitable purposes.[814] Since the 'beneficiaries' of a charitable trust are the general public, the Attorney General may be considered to protect the public interest.[815] The Charities Act 1993 also granted the Charity Commission a new power to institute legal

[807] The Charity Commission have warned that the majority of causes for concern brought to the attention of the Charity Commission are unfounded.
[808] Charities Act 2011 s.115
[809] Ibid. s. 113(2)
[810] Ibid.115(1) (b)
[811] Ibid.115(1) (c)
[812] Charities Act 2011 s.115(1)(c)
[813] Proceedings concerning a charity's administration
[814] Luxton P, *The Law of Charities* (OUP 2001), 511
[815] Ibid.

proceedings themselves.[816] In terms of who constitutes a person 'interested in the charity' for the purpose of 'charity proceedings'[817] it has been stated that:[818]

> If a person has an interest in securing the due administration of a trust materially greater than, or different from, that possessed by an ordinary member of the public… that interest may, depending on the circumstances, qualify him as 'a person interested.'[819]

Jurisprudence has declined the opportunity to provide a clear definition. Generally, a distinction has been made between a person interested in the charity and a person interested in charity property.[820] Those falling under the latter category, for example those with a contract with the charity, are deemed to be outside the scope of the Act:

> Those who have some good reason for seeking to enforce the trust of a charity or secure its due administration may readily be accepted as having an interest in the charity, whereas those who merely have some claim adverse to the charity, and seek to improve their position at the expense of the charity, will not. The phrase, I think, is contemplating those who are on the charity side of the fence, as it were, however much they may disagree with what is being done or not being done by or on behalf of the charity. The phrase does not refer to those who are one the other side of the fence, even if they were in some way affected by the internal affairs of the charity.[821]

Charity proceedings may be taken with reference to a charity either by the charity,[822] any of the charity trustees,[823] or by any person interested in the charity.[824] Except where legal proceedings are taken by the Attorney General, charity proceedings cannot be pursued unless the taking of proceedings is first authorised by the Charity Commission.[825] Furthermore, the Commission must not, without special reasons, authorise the taking of charity proceedings where in its opinion the case can be dealt with by the Commission under its s.114 powers, discussed above.[826] These filter

[816] Charities Act 1993 s. 32
[817] Charities Act 2011 s.115(1)(c)
[818] *Re Hampton Fuel Allotment Charity* [1989] Ch 484, [493] *per* Nicholls LJ
[819] Luxton, P. *The Law of Charities* OUP 2001, 521
[820] *Halesmere Estates v Baker* [1982] 1 WLR 1109, [1982] 3 All ER 525
[821] Ibid. *per* Sir Megarry V-C [1122]
[822] Charities Act 2011 s.115(1)(a)
[823] Ibid. s.115(1)(b)
[824] Ibid. s.115(1) (c)
[825] Ibid. s.115(2)
[826] Ibid. s.115(3)

mechanisms aim to minimise the number of claims against charities, avoiding frivolous and ill-founded claims.[827]

Following on from the previous discussion in this chapter, state intervention via the A-G, the Charity Commission or a 'person interested' (dealt with next) is more likely where there has been an application of property to non-charitable purposes, i.e. for substantive breaches rather than performance of director's duties under the Companies Act.[828]

> The court's desire not to become involved in a charity's internal administration mirrors a similar desire of the courts not to become involved in internal management of a company, where it has given rise to an analogous principle, the rule in *Foss v Harbottle*. One of the principles enshrined in this rule…is that matters of internal regulation are under the control of the majority, thereby precluding applications to the court to regulate many matters of internal management.[829]

Charity proceedings are proceedings in any court in England or Wales brought under the court's jurisdiction with respect to charities, or proceedings brought under the court's jurisdiction with respect to trusts in relation to the administration of a trust for charitable purposes.[830] Subsequently, jurisprudence has concluded that litigants may not rely on charity proceedings to enforce a personal right,[831] such as an action in tort[832] or for breach of contract or another right at common law or equity.[833] On the other hand, an action brought against a trustee for breach of a fiduciary duty is likely to fall within the definition of charity proceedings.[834] Expensive litigation is discouraged in the charitable sphere; sitting uncomfortably with the nature of

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[827] *Re Hampton Fuel Allotment Charity* [1989] Ch 484
[828] Which are likely to be resolved by the company itself-general meeting etc.
[829] Luxton P, *The Law of Charities* (OUP 2001).
[830] Charities Act 2011 s.115(8)
[831] In *Rooke v Dawson* [1895] 1 CH 480: Here the trust deed provided for the award of a scholarship to the pupil achieving the best performance in an examination. The trustees declined to award the scholarship to the plaintiff, who had obtained the highest mark and who sought a declaration that he was entitled and an order directing the trustees to make him the award. Chitty J decided that, there being no contract between the plaintiff and the trustees, the formers action was not to enforce a personal right, but rather to enforce the administration of the trusts of the charitable deed. As the Charity Commissioners certificate had not been obtained under the Charitable Trusts Act 1853, s.17, his Lordship held that the action could not proceed.
[832] *British Diabetic Association v Diabetic Society of Great Britain* [1995] 4 All ER 812 [1996] FSR 1
[833] In *Rendall v Blair* [1890] 45 ChD 139. At [160] Fry LJ expressed the view that an action to enforce 'an individual equitable right, not relating to the administration of the trusts of the charity' would be outside the Charitable Trusts Act 1853, s.17
[834] *Construction Industry Training Board v A-G* [1973] Ch 173, [1972] 3 WLR 187

donation. With these limitations in mind, and in response to concerns that donors and the EGC are underrepresented in the running of UK Biobank (Chapter 4 and 5), the potential for UK Biobank donors or the EGC to bring direct charity proceedings against UK Biobank Ltd will now be investigated.

6.6.1 UK Biobank donors: 'Person interested'

In the aforementioned case of *Rooke*, the distinction was drawn between a person interested in the charity and a person interested in charity property,[835] with the latter unqualified to bring charity proceedings. This precedent significantly limits the scope of proceedings that may be brought against charities and seems to indicate that only issues relating to mismanagement or maladministration of the charity for its charitable purposes (e.g. fraud) may be the subject of a claim. Applying the *Rooke* rationale, it is arguable that UK Biobank could be challenged, for example, for fraudulent spending of profit that ought to be reinvesting in the resource according to its charitable purposes (a risk identified in Chapters 1, 4 and 5).

Thus, based on an interpretation of the principles of charity law and the spirit of the Charities Act, even if a donor could prove legal standing as a 'person interested' in the charity, this line of accountability would only enable them to challenge the running of the company for its charitable purpose rather than, for example, breaches such as misuse of their samples or personal harm. Nevertheless, with legal standing as a 'person interested' in charity proceedings, a participant could theoretically challenge decisions made by the Board of Directors that present a conflict of interest, or a decision not made in the public interest, for example. However, bearing in mind that there are no donor representatives on the Board, it is difficult to imagine how they would gain the knowledge of such activity.

On the other hand, it has been identified in this chapter (and Chapters 4 and 5) that the Chair of the EGC may sit in on Board meetings, and has the right to request whatever documentation or information it deems necessary for the performance of its remit to ensure UK Biobank is run in accordance with its public mission and to advise on the interests of its donors and the wider public. As such, the potential for

[835] *Halesmere Estates v Baker* [1982] 1 WLR 1109, [1982] 3 All ER 525

the EGC to bring direct charity proceedings against UK Biobank will now be explored.

6.6.2 UK Biobank Ethics and Governance Council: 'Person Interested'

Charity law precedent does not clarify whether the EGC would have legal standing to bring proceedings against UK Biobank Ltd as a Council, if individual members such as the EGC Chair could bring proceedings, and in what capacity. This gives rise to an interesting (and uncertain) legal question as to whether members of the EGC would be restricted to bringing charity proceedings in their capacity as members of the EGC (a capacity in which the EGC are accountable to the WT and the MRC) or as individuals. By extension, there are uncertainties as to who would fund such litigation given the not-for-profit nature of UK Biobank and inclusion of public funds. Moreover, according to the EGC modus operandi, members of the EGC are actually appointed by the UK Biobank Ltd Members themselves (WT and MRC),[836] which compounds the question of its independence. Therefore, the EGC is on unprecedented legal territory which warrants further future investigation.

For now, analysis will proceed on the assumption that the Chair of the EGC attempted to bring proceedings within their capacity as a member of the EGC and given their representative role in Board meetings in which issues of concern may arise.[837] It is recalled that the remit of the EGC includes acting as an independent guardian of the UK Biobank EGF; monitoring and reporting publicly on the conformity of the UK Biobank project with the EGF.[838] In pursuing this remit:

> The Council will engage with, and render accounts to, a number of internal and external audiences. Internal dialogues will be with the Board of Directors, the CEO/PI and the funders. External dialogues could be with participants, regulatory or government bodies, other interested parties, and the general public. The Council will

[836] UK Biobank Ethics and Governance Council 'Terms of Reference and Modus Operandi' <http://egcukbiobank.org.uk/sites/default/files/terms%20of%20reference%20and%20modus%20operandi.pdf> accessed 22 January 2016
[837] Ibid.
[838] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> Section III.A.2 Ethics and Governance Council; Annex: 'UK Biobank Ethics and Governance Council Terms of Reference'

> not speak 'on behalf of' UK Biobank, as this will be the responsibility of the Board; instead it will speak 'about' UK Biobank.[839]

To fulfil this remit, the EGC will be able to require from parties involved in UK Biobank 'whatever information and discussion are necessary.'[840] Importantly:

> Normally the Council will communicate its reflections and criticisms informally. If the Council is not satisfied with UK Biobank's response, it could make a formal statement of concern (e.g. to the Board or the funders) or, if necessary, make a public statement that certain actions should or should not be taken. In the extreme, members of the Council could resign in protest and announce this publicly.[841]

Herein lies a potentially crucial implication of UK Biobank's legal structure as a charity company. As a 'person interested' in the running of the charity, the EGC Chair may have the remit to report UK Biobank performance to the Charity Commission in the event that the Council is dissatisfied or concerned. As the EGF and modus operandi demonstrates, the Council has access to all documentation and accounts that are important to the running of UK Biobank, which could theoretically be passed onto the Charity Commission as the basis of their inquiry.

The fact that the EGC's primary function is to monitor UK Biobank's conformance with the Ethics and Governance Framework, coupled with its role representing the public, could be used as evidence to support the conclusion that the EGC has a legal interest in the running of UK Biobank Ltd in accordance with the Biobank's charitable purpose. This is an important potential strength of the EGC, which as we have seen in Chapter 3 and 5, is often criticised for lack of legal standing to hold UK Biobank to its obligations and goes beyond the avenues of accountability described in the EGF.[842] However, it is noted that this avenue of accountability within the charity law framework is by no means straightforward and is limited in its scope in much the same way as was the case for donor accountability previously discussed.

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[839] Ibid.
[840] Ibid.
[841] Ibid.
[842] As highlighted in Chapters 3, 4 and 5: UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 5 February 2016

6.7 Conclusions

There are a number of important conclusions to be drawn from this chapter's detailed analysis of UK Biobank's legal structure as a charitable company, which has identified some of the implications and limitations of the private model according to its dual legal basis. These conclusions go some way to answering the research questions of this thesis regarding the extent to which this chosen model assists in the furtherance of UK Biobank's public good mission.

Building on the background debate about the best design for UK Biobank discussed in Chapter 4, the theoretical debate between Winickoff and Hunter & Laurie in Chapter 5 has shown some of the interests that are (or are not) represented in UK Biobank's governance model and has raised some of the risks that consequently emerge for these interests. However, the authors ground their observations in the theoretical underpinnings of corporate governance, specifically stakeholder and shareholder perspectives, and do not investigate the ways in which UK Biobank's legal structure as a charity company may be utilised to address such risks. As such, this chapter has attempted to deconstruct the complicated duality of UK Biobank's legal basis in both company and charity law, to analyse the implications of this structure in terms of the lines of accountability to hold UK Biobank to its stated aims, and to protect the range of interests identified by Winickoff and Hunter & Laurie in the running of the resource. Investigation has revealed a number of findings, which will now be briefly recapped.

On the basis of in depth analysis of the duties of the Board of Directors and the Members of UK Biobank Ltd, it seems that the duties owed by the Board of Directors are enforceable by the Members under company law. Yet there are only limited ways to intervene to ensure that these duties are exercised in pursuit of the interests of the public. In fact, analysis of the constitutional documents of UK Biobank Ltd and UK company and charity law suggests that there are few legal qualifications on the exercise of Member's administrative and voting rights to ensure these rights are exercised in the interests of the public. As a result, there appears to be no legal requirement for the Members to appoint directors for the Board in pursuit of the public good mission of UK Biobank. This finding may go some way to explaining why the composition of the Board does not include any direct

representation of donors or the EGC,[843] which one might expect if the Board was elected to be representative of the stakeholders of UK Biobank and run in the interests of the public.

However, to be registered as a charity in the first place, UK Biobank is legally obliged under charity law to act in accordance with its charitable purpose and for the benefit of the public. One of the main consequences of UK Biobank's incorporation as a charity is that it is subject to oversight by the Charity Commission, the Attorney General, and 'person[s] interested' in UK Biobank. Duties of the Board of Directors owed under charity law are more likely to be subject to state intervention. Breach of company law duties will be regarded as a breach of trust, since the relationship between Directors (exercising all the rights of the Company) and the resource is one of fiduciaries over a jointly held resource managed for the public beneficiaries. Furthermore, a breach of Directors' duties under company law may constitute evidence of 'misconduct or mismanagement' of UK Biobank for the purposes of charity law. If there is sufficient evidence of this, then so long as it can be proven that the reason for the action is to hold UK Biobank to application of its resources to its charitable objects, which are stated in its Memorandum and Articles of Association and are binding under charity law by virtue of its status as a charity company, the actions of UK Biobank could be challenged via charity proceedings by the Charity Commission, the A-G, the EGC and perhaps even participants.

On this basis, this chapter has investigated the possibility of using charity law mechanisms of oversight of UK Biobank Ltd's activities, for the furtherance of the biobank's public good mission. However, this line of accountability is by no means straightforward and is limited in scope. A donor or a member of the EGC (or any individual) would not need to prove legal standing to report an issue to the Charity Commission, but a prerequisite of charity proceedings would require the Commission to be satisfied that they are not able to resolve the claim, before the claimant got to the question of if they had standing to bring proceedings. Even then, claims would need to relate to the proper running of the charity in accordance with its charitable purpose and would not enable donors to challenge UK Biobank Ltd for personal harm, for example. This deduction raises further legal questions as to what

[843] Although, it has been noted earlier in this chapter that it is common procedure for the Chair of the EGC to attend Board Meetings.

remedies may be available to redress such personal harm, which will be the topic of the next Chapter.

Another key observation is that UK Biobank Ltd is subject to the same dysfunctions and uncertainties that were the very reason for the introduction of new legal forms for charities in the UK.[844] In particular, this chapter has illustrated the overlapping and complicated nexus of duties owed by the Board of Directors, to both the Company UK Biobank Ltd under UK company law, and to the public as beneficiaries of the charity under UK charity law, by virtue of UK Biobank Ltd's structure as a charity and a company. In fact, legal challenges such as dual regulation, administrative burdens and uncertain accountability pathways cut across the socio-legal debate to date, and have justified the statutory creation of new legal forms such as the CIO.[845] Today, the Charity Commission alone regulates CIO's; resolving issues associated with the applicability of dual regimes to charitable companies, including uncertainty of trustee and director duties.[846] Only charity law regulates duties of Directors, and there will be an explicit duty on Members and trustees to exercise their powers and discharge their duties in relation to the CIO, solely in the interests of the CIO.[847] Under the new legal form for charities, Members of a CIO are under a duty to exercise their powers 'in the way he decides, in good faith, would be most likely to further the purposes of the CIO.'[848]

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[844] Cross SR, 'New legal forms for charities in the United Kingdom' [2008] Journal of Business Law 662, 667: 'The assumption that there is a need for a new and dedicated incorporated form for charities has been widely accepted and there has been no substantive disagreement or indeed even comment on the validity or otherwise of the policy arguments supporting the introduction of a new form.' In their Report (Department of Trade and Industry, *Modern Company Law for a Competitive Economy: Developing the Framework* (URN 00/656, 2000) the Company Law Review Group followed the approach taken by the Charity Commission's Advisory Group and did not recommend that transfer to CIO status should be made compulsory, 'or that other routes for the incorporation of charities should be closed off. This approach takes into consideration the difficulty and costliness of compelling charities to change legal form and the burden this would place on the Charity Commission. It may, however, represent a lost opportunity to streamline incorporated charities: Cross SR, 'New legal forms for charities in the United Kingdom' [2008] Journal of Business Law 662.

[845] And lay at the heart of the earliest calls for the introduction of a new legal form: See Warburton J, 'Charity corporations: the framework for the future' [1990] Conveyancer and Property Lawyer (March-April) 95; Warburton J, 'Charity members: duties and responsibilities' (2006) 70 CPL 330.

[846] However, the new legal form also creates a complicated web of options for existing and new charities, raising issues of comparability and choice. The Home Office will review this position five years after the introduction of the CIO, but-for now the new forms will be available alongside existing corporate forms: Cross SR, 'New legal forms for charities in the United Kingdom' [2008] Journal of Business Law 662.

[847] Ibid.

[848] Charities Act 2011 s. 220.

As the CIO is an additional and not compulsory structure for charities, this raises the question of whether members of charities under existing structures are subject to a similar duty.[849] So far, the Charity Commission have produced two model constitutions for CIOs: the 'foundation' model is for charities whose only voting members will be the charity trustees; and the 'association model', for charities that will have a wider membership, including voting members other than the charity trustees.[850] On the whole, it is submitted that but-for the timing of UK Biobank Ltd's incorporation in 2003, the CIO would have been a more suitable model. Indeed, if it adopted the association model, this could facilitate direct representation of the EGC and the donors, thereby enabling socio-legal suggestions to improve the current model (Chapter 5). It is therefore arguable that UK Biobank's model is out-dated and could be converted to a CIO to ensure future sustainability of the resource. Further research is needed to understand the practical implications of such conversion and how burdensome this would be.[851] However, while such conversion may arguably enhance the public accountability of UK Biobank via the Charity Commission for reasons that have been outlined in this chapter, there are limits as to what charity law will remedy, and most notably this is unlikely to include personal harm.

Overall, this chapter has illustrated that UK Biobank Ltd's existing complicated legal framework opens UK Biobank to criticism because there are limited accountability mechanisms arising from the structure to carry forward public and private interests in the running of the charitable company. This criticism would not stand if UK Biobank Ltd had been created as a statutory body, or if UK Biobank Ltd funders were wholly public, because this would have enhanced UK Biobank's regulatory and political accountability to the public. It is therefore recommended that evidence of the decision to structure UK Biobank Ltd as a charity company is made freely available, as is not currently the case.

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[849] Ibid.
[850] Ibid.
[851] It is submitted that such research is particularly worthwhile in light of the pertinence of new corporate forms to other large-scale organisations in the future, e.g. Genomics England, which, is currently established as a company wholly owned by the Department of Health: <http://www.genomicsengland.co.uk/about-genomics-england/> accessed 26 January 2016

Moving forward, analysis of the lines of accountability available within the legal structure of UK Biobank Ltd in this chapter has prompted investigation as to the additional avenues of accountability outside this structure. Therefore, the extent to which UK Biobank owes 'private' duties to individuals in negligence will be the topic of Chapter 7 and the potential for UK Biobank to owe 'public' duties is the subject of Chapter 8. However, building on discussion in the Introduction and Chapter 1, these chapters will demonstrate that such a public/private dichotomy may not be appropriate or desirable in the context of UK Biobank Ltd.

Part 3: Common law avenues for UK Biobank Ltd accountability

Chapter 7: Liability of UK Biobank Ltd in Negligence

7.1 Introduction

Summary of issues

As part of this thesis' investigation into the extent to which participants may use 'private' and 'public' law mechanisms to hold UK Biobank Ltd to account, this chapter considers whether UK Biobank Ltd might owe a duty of care to protect the 'private' interests of UK Biobank participants from personal harm from the perspective of the law of negligence. It is recalled from the Introduction to this thesis that 'private' law traditionally sets out the nature of the legal obligations owed by individuals to each other (either as natural or legal persons), in contrast to 'public' law which is concerned with the relationship between individuals and the State (Chapter 8). It is also remembered from Chapter 1 that biobanking may give rise to a number of risks of personal harm including, for example, misuse of information, harm arising from negligent collection of samples, or non-feedback of research results, which may therefore be remedied by 'private' law.

Chapter 1 has identified that some of the private interests that are at stake in the process of participating in biobanking include physical privacy, informational privacy, decisional privacy and proprietary privacy.[852] Tort law, within which

[852] Results from the 'Privileged' project: <http://www.privileged.group.shef.ac.uk/> cited in Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315, 2; Taylor MJ and Townend D, 'Issues

negligence is only one avenue of redress, operates to protect an individual's physical privacy. Hence, the tort of battery forbids the intentional and direct application of force to another person[853] without their consent.[854] The tort of negligence has traditionally operated to protect individuals from physical personal 'harm', as well as economic loss and damage to property.[855] In the context of medical treatment, negligence is increasingly relied upon to protect and redress physical harm, including that which stems from interference with informational and decisional privacy interests.[856] On this basis, informed consent has developed as a doctrine of both medical and tort law to protect these interests in research and medical treatment (Chapter 1).[857]

Although informed consent has been broadly defined in research circumstances (Chapters 1 and 4), it is arguable that the way in which tort law is evolving to protect informational and decisional privacy may have implications for biobanking research and the future of UK Biobank. In particular, the issue of how best to protect an individual's interests in biobanking has been the topic of a growing debate regarding the feedback of individual research results during the course of biobank participation and subsequent biobank research. Rights-based arguments are being made (in the literature, but not yet in the courts) that individuals ought to receive feedback in certain circumstances on the grounds that individuals have a right to know, or not know, results derived from their participation in research. In the realm of negligence, this debate questions the extent to which there is (or there ought to be) a duty to feedback such results and in what circumstances.

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in protecting privacy in medical research using genetic information and biobanking: the PRIVILEGED project' (2010) 10 Med Law Int 253.

[853] *Collins v Wilcock* [1984] 1 WLR 1172; [1984] 3 All ER 374

[854] While an individual cannot consent to harm (*R v Brown* [1993] 2 All ER 75) English medical law recognizes an absolute right to consent or refuse to medical treatment, even where this might result in harm or ultimately, death: *Re C (Adult, refusal of treatment)* [1994] 1 All ER 819; *Re B (Adult, refusal of medical treatment)* [2002] 2 All ER 449; *St George's Healthcare NHS Trust v S, R v Collins and others, ex parte S* [1998] 3 All ER 673 [1998] 2 Fam CR 685

[855] Horsley K and Rackley E, *Tort Law* (2nd edn, OUP 2011).

[856] In the context of information provided prior to medical treatment, a high standard of information disclosure is now required: in line with *Chester v Afshar* [2004] UKHL 4, [2005] 1 AC 134, *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [2015] 2 WLR 768 recently upheld the patient's expectations of information, and set a duty of care to meet a 'reasonable patient standard' that requires disclosure of small yet significant risks prior to intervention, whereas previous precedent had held the standard of care to be the reasonable professional.

[857] Kaye J, Bell J, Briceno LM and Mitchell C, 'Biobank Report: United Kingdom' (forthcoming) JLME

As a key issue for biobanking, this chapter will focus on the potential for a legal duty to return results to participants to prevent personal harm. By volunteering to donate to UK Biobank, there is potential for individual results pertaining to the participant's health to be discovered during each of the following three stages: upon assessment; during DNA analysis; and during the course of subsequent research using the resource.[858] The challenge for UK Biobank has been to develop a policy to manage these results, in line with participant's expectations and interests. In fact, UK Biobank adopts a broad no-feedback policy towards individual results urging that enrolment in UK Biobank does not provide a 'health check', and explaining the difficulties that are associated with the value of feedback communicated outside a clinical setting and outside the context of an individual's full medical record.[859]

Summary of arguments

Crucially, to date, the law has not yet recognised a duty to feedback research results obtained in the research context. Therefore, the priority for the purpose of this thesis will be to test a legal argument for a novel duty of care on the part of UK Biobank Ltd to prevent the materialisation of a risk of physical harm. First, this chapter will make an argument for the imposition of a direct duty relationship between UK Biobank Ltd and UK Biobank participants. By virtue of UK Biobank Ltd's separate legal personality, this chapter will proceed on the basis that a claim in negligence would most likely be brought against the Company UK Biobank Ltd, rather than the individual Members or Directors responsible for the management of UK Biobank (Chapters 4 and 6).[860] From the outset, this is a difficult premise because of the nature of the relationship between UK Biobank Ltd and the researchers using the resource.

[858] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 1 August 2013
[859] Ibid. 7. The UK Biobank EGF states:
'As a consequence, the significance of the observations might not be clear and UK Biobank staff would not be in position to interpret their implications fully. Further, it is not likely to be constructive, and might even be harmful (including causing undue alarm and having potentially adverse effects on insurance and employment status), to provide information without prior counselling or support (which UK Biobank will not be able to provide: as explained below). For these reasons, UK Biobank will generally not provide health information to participants, and a clear explanation of this policy (and the few exceptions) will be provided in the participant information material.'
[860] From the outset, this is a difficult premise because of the relationship between UK Biobank Ltd and the researchers using the resource, as will be explained in due course.

Second, 'harm' in the context of this chapter will broadly refer to the manifestation of individual research results that are so serious they are 'likely to threaten life span, quality of life or major body functions.'[861] Focusing analysis in this way is necessary to test whether a duty to feedback results might be owed in this novel context, since physical harm is widely recognised to be actionable damage in negligence law.[862] It is noted that a range of harms could be argued to stem from non-disclosure of results, including interference with participant autonomy and human dignity,[863] or loss of a chance to act on results.[864] However, these harms are yet to be clearly recognised in English tort law and will not be considered in this chapter.

Third, the argument made in this chapter is that UK Biobank Ltd may cause harm by virtue of a failure to act to return individual research results to participants, and this failure or 'omission' could constitute a breach of their duty of care. Therefore, jurisprudence founded on omissions to act will be used as primary precedent. Fourth, analysis in this chapter will apply a line of negligence jurisprudence related to establishing a duty of care owed by a public body, and the difficulties this gives rise to. This avenue is pursued on the basis of UK Biobank's potentially 'public' character for the purposes of public law, which will be the topic of Chapter 8 of this thesis.

Ultimately, to be successful in this claim, a UK Biobank participant (claimant) would have to establish all four of the following requirements; that:

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[861] Since this is the approach taken by UK Biobank in relation to the imaging study: UK Biobank 'Biobank Imaging Assessment Participant Information Leaflet' October 2014 (UK Biobank) <http://imaging.ukbiobank.ac.uk/> accessed 2 January 2015.

[862] Stapleton J, 'The Gist of Negligence: Part I: Minimum Actionable Damage' (1988) 104 LQR 213.

[863] As opposed to other approaches in the literature which have sought to establish new categories of recognised harm. In particular, Chico makes an argument for the non-disclosure of genetic information to be characterised as an interference with an individual's autonomy, which, on the basis of recent court ruling such as *Chester v Afshar*, ought to be protected by tort law. On the other hand, Brownsword argues for the recognition of a 'new blockbuster tort based on human dignity as a way of responding to novel genomic claims'. Brownsword, R. 'An Interest in Human Dignity as the Basis for Genomic Torts' Washington Law Journal 2003, 42, 3, 413-487, cited in Chico, V. *Genomic Negligence: An Interest in Autonomy as the Basis for Novel Negligence Claims Generated by Genetic Technology*. Routledge: London and New York, 2011

[864] The courts have not reacted favourably to reformulating damage in the lost chance of avoiding personal injury, and complex calculations of causation have prevented the success of a number of cases: *Hotson v East Berkshire HA* [1987] AC 750, [1987] 3 WLR 232; *Gregg v Scott* [2002] EWCA Civ 1471, [2002] All ER 418

1) UK Biobank Ltd (the defendant) owed the claimant a duty of care to avoid causing the particular type of injury (actionable damage) of which the claimant complains;
2) UK Biobank Ltd has breached the duty of care by falling below the standard of reasonable care which the law demands of a Body that professes to exercise that particular skill or profession;
3) The breach by UK Biobank Ltd (either a positive act, or an omission) caused the particular damage complained of by the participant; and
4) The damage suffered by the claimant is not too remote (unforeseeable) at law to be recoverable.[865]

Even if it was established that UK Biobank Ltd owes its participants a duty of care to return serious results, claimants would still need to prove breach of the standard of care and causation of the actionable harm. However, to answer research questions posed by this thesis; namely how public and private law pertains to the UK Biobank model, the purpose of this chapter need not be so ambitious as to try and satisfy all the requirements for a successful claim in negligence. It is hoped that investigation into minimum actionable damage and duty of care will highlight the potential vulnerability of UK Biobank Ltd to liability in negligence for non-feedback of individual research results, and therefore the enforceability of obligations to participants beyond the scope of UK Biobank's self-regulatory EGF.

7.2 Incidental findings in UK Biobank

Individuals donating to UK Biobank have all consented to the collection, storage and use of their biological samples, lifestyle and environmental information, which will be available to researchers conducting a wide variety of investigations. As part of their participation, donors answer questionnaires on health, lifestyle and diet, memory, work and family history, and 'non-invasive' measurements are taken including blood pressure, pulse rate, height, weight, body fat, vision, fitness, grip strength, bone density and lung function. Donors give samples of blood, saliva and urine for long-term storage and analysis, including genetic data analysis. Donors consent to receive information about the key results of their baseline assessment measurements in the form of a printed report, which they may act upon as necessary.

[865] Mulheron R, Medical Negligence: Non-Patient and Third Party Claims (Ashgate 2010), 28.

Their measurements are compared to population standard ranges so participants have some indication of whether their results fall outside the 'normal' range, although the visit 'is not intended to be a 'health check'' and individual results are not released 'to your doctor or anyone else'.[866]

At the time of consent, donors have been made aware that UK Biobank has the facilities in place for re-contact, and so consent on the grounds that they may be re-contacted for repeat assessments or further questionnaires in the future.[867] It is recalled from Chapter 1 that 20,000 participants have returned for a second assessment at UK Biobank's Co-ordinating Centre[868] and 7,184 participants have taken part in UK Biobank's enhanced imaging study.[869] Genotyping has also been performed on 50,000 participants in conjunction with Affymetrix, and the remaining 450,000 are currently being genotyped. While participants have provided separate consent to the imaging study, genotyping has been considered within the scope of the original consent provided by participants in their initial assessment.

During the course of these various studies there is a risk that 'findings' (in various guises) with clinical, reproductive or personal significance for the person from whom the sample or data is derived will be 'discovered', whether intentionally or incidentally, and either related to the aims of the research being conducted or not. These findings are broadly understood to be 'incidental findings', but consensus in

[866] UK Biobank 'Participant Information Leaflet' April 2010 (UK Biobank) <http://www.ukbiobank.ac.uk/wp-content/uploads/2011/06/Participant_information_leaflet.pdf?phpMyAdmin=trmKQlYdjjnQIgJ%2CfAzikMhEnx6> accessed 2 June 2014

[867] The consent form states: 'I understand that I may be re-contacted by UK Biobank (e.g. to answer some more questions and/or attend another assessment visit), but this is optional.' UK Biobank 'Consent form: UK Biobank' Version: 20061124: <http://www.ukbiobank.ac.uk/wp-content/uploads/2011/06/Consent_form.pdf?phpMyAdmin=trmKQlYdjjnQIgJ%2CfAzikMhEnx6> accessed 2 June 2014

[868] Re-contact will become available to more UK Biobank participants in other parts of the country in due course: UK Biobank 'Have you been invited to a repeat assessment?' (UK Biobank) <http://www.ukbiobank.ac.uk/2012/06/repeat-assessments-adding-value-to-this-exciting-resource/> accessed 1 August 2014

[869] UK Biobank 'Imaging Study' <http://imaging.ukbiobank.ac.uk/> accessed 1 August 2014
In September 2013 UK Biobank announced funding granted totalling £37.M (including £9.6.M from the Medical Research Council) to conduct imaging assessments including magnetic resonance imaging of the brain, heart and abdomen. A pilot study of 6,000 participants was undertaken between 2013-2015, to be followed by a second phase assessment of 100, 000 participants over a 5-6 year period. So far, UK Biobank has released imaging data on 5,000 scanned participants: UK Biobank 'Imaging data' (UK Biobank) <http://www.ukbiobank.ac.uk/imaging-data/> accessed 5 February 2016

this definition has by no means been reached[870] and is often misunderstood.[871] Generally, health information valuable for biobank participants can be generated at different stages in the biobank process: during the physical measurements of the assessment process, during the laboratory tests on fresh blood samples prior to storage, during the DNA genotyping by Affymetrix, during the imaging scanning, and during the subsequent research itself using stored samples and data. Categories of the kinds of findings which may be discovered during these stages have emerged from policy makers attempting to guide researchers, technicians, and clinicians in the field. In December 2013, the US Bioethics Commission published a definitional taxonomy of incidental findings in the clinical, research and DTC contexts. The Commission described five categories of findings:

> Primary findings: findings that are the principal purpose for the practitioner conducting the test.
>
> Incidental findings: findings beyond the scope of the primary purpose of the test. Divided into anticipatable (possible results of a particular test or procedure, including well documented findings) and un-anticipatable incidental findings (findings which cannot be expected or anticipated at the time the test is conducted but arises nonetheless).
>
> Secondary findings: findings which are not the primary purpose of the test but that the practitioner seeks nonetheless. (The Bioethics Commission has recommended that more practitioners develop a list of such findings so that instead of stumbling upon incidental findings, practitioners can plan for anticipatable incidental findings and perhaps actively seek them as secondary findings).
>
> Discovery findings: findings that result from a broad test conducted to discover anything of interest (E.g. DTC companies).[872]

These guidelines helpfully categorise the kinds of findings that are likely to arise in different contexts, and the difference between findings discovered 'accidentally'

[870] Knoppers BM and Dam A, 'Return of Results: Towards a Lexicon?' (2011) 39 JLME 577; Zawati MH and Rioux A, 'Biobanks and the Return of Research Results: Out with the Old and In with the New?' (2011) 39 JLME 615.
[871] Cho MK, 'Understanding Incidental Findings in the Context of Genetics and Genomics.' (2008) 36 JLME 280.
[872] Presidential Commission for the Study of Bioethical Issues, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts* (Presidential Commission for the Study of Bioethical Issues 2013) <http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf> accessed 27 February 2014

compared to those searched for. For the purpose of this chapter, discussion will now turn to the specific approach of UK Biobank to results discovered during the course of baseline assessment, imaging scans and genetic research (including genotyping).

7.2.1 Baseline assessment and imaging scans

According to the terms of the participant consent form, individuals volunteer to take part in UK Biobank on the understanding that 'none of my results will be given to me (except for some measurements during this visit) and that I will not benefit financially from taking part (e.g. if research leads to commercial development of a new treatment)…'[873] These measures include blood pressure, lung function, bone density, weight, and estimated amount of fat at the assessment stage of participation.[874]

Feedback during UK Biobank's enhanced-imaging pilot study, which has been underway since 2013,[875] is considered to be comparable to baseline assessment measures. It is recalled from Chapter 4 that incidental findings in the course of imaging research are reported to be common. Following a pilot study of 6,000 participants,[876] the approach of UK Biobank is to provide limited feedback for findings considered to be potentially 'serious' (defined in this context as 'likely to threaten life span, quality of life or major body functions') that are observed during the data acquisition or quality control stage of the imaging process. Separate consent has been obtained from participants choosing to take part in the imaging study on the following grounds:

> I give permission for UK Biobank to inform me and my General Practitioner (GP) if a potentially serious abnormality is found on a scan (i.e. one that indicates the possibility of a condition which, if confirmed, carries a real prospect of significantly threatening life span, or of having a substantial impact on major body functions or quality of life).

[873] UK Biobank 'Consent form: UK Biobank' (UK Biobank) Version: 20061124: <http://www.ukbiobank.ac.uk/wp-content/uploads/2011/06/Consent_form.pdf> accessed 2 June 2014
[874] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 18 December 2013
[875] UK Biobank Imaging Study: <http://imaging.ukbiobank.ac.uk/> accessed 2 June 2014
[876] Peterson SE and others, 'Imaging in population science: cardiovascular magnetic resonance in 100, 000 participants of UK Biobank- rationale, challenges and approaches' (2013) 15 Journal of Cardiovascular Magnetic Resonance doi:10.1186/1532-429X-15-46.

> I understand that, if UK Biobank does not contact me and my GP about a potentially serious abnormality, this does not imply that no abnormality exists, but simply that no such abnormality was noticed by the staff taking the scans.
> I understand that none of my imaging scans will be given to me at the end of the visit.

Combined, baseline assessments measures are the only feedback that individual UK Biobank participants receive.

Crucially, the participant information leaflet and consent form that is given to participants upon arrival for the imagining scan stress that individuals partaking in the imaging study, and the professionals conducting the imaging scans, do so in a research capacity. Participants provide their additional consent to the imaging study on the understanding that imaging assessment 'Is not a health check and is not a replacement for any clinical appointment. The scans being performed are not intended for diagnostic use and are not designed to identify any particular abnormalities. Instead, the images will be stored for future research use.'[877] Hence, 'Staff conducting the scans will look at the images to ensure their technical quality is good, rather than to identify particular clinical problems. The scans will not be routinely reviewed by specialists or other doctors.'[878]

However, participants are made aware of the possibility that the technicians conducting the scan may 'happen to notice something unusual in the scan, that they think may be potentially serious'.[879] In this event, participants are advised that the technician will 'refer the image to a specialist doctor… In the unlikely event that a potentially serious abnormality is confirmed to be present on one of your scans, we [UK Biobank] will write to you and your GP within about two weeks of your visit, so that your GP can make arrangements for further investigation, if required.'[880]

On the matter of what constitutes 'something serious', the participant information expands:

[877] UK Biobank 'Imaging Assessment Participant Information Leaflet' October 2014: V5 081014 (UK Biobank) <http://imaging.ukbiobank.ac.uk/> accessed 5 February 2016
[878] Ibid.
[879] Ibid.
[880] Ibid.

> Something would be considered potentially serious if it indicated the possibility of a condition, which, if confirmed, would carry a real prospect of seriously threatening life span, or of having a substantial impact on major body functions or quality of life. For example, you and your GP would be informed if we saw an abnormality on one of your scans that looked like a tumour. However, we would not inform you if we saw an abnormality that looked like gallstones or a simple cyst, as such findings are common in healthy people and not considered serious.[881]

As a final waiver, the participant information states:

> However, because the scans are being done for later research, they are not checked in the same way as a scan that might be done for medical care. So if UK Biobank does not contact you about a potentially serious abnormality, this does not imply that no abnormality exists. It simply means that no such abnormality was noticed.

As an indication of the likelihood of findings during the course of the scans, during the pilot stage of the imaging project statistics were released for the period up to 2014. Of the 200 participants which had been scanned, 30 potentially serious incidental findings were discovered (0 Head, 16 Heart, 17 Abdomen), 26 of these were referred by the radiographers and 5 were considered potentially serious incidental findings by the radiologists.[882] The information leaflet declares that UK Biobank estimates that 'about 10 to 15% of participants may have an abnormality considered to be potentially serious'. By extension, this could mean that as many as 15,000 of the 100,000 participants to be scanned may have 'serious' incidental findings. This percentage is particularly significant when considering the 'foreseeability' of personal harm in relation to a negligence claim (discussed later in this chapter).

Seemingly, UK Biobank Ltd have assumed responsibility for the feedback of 'serious' incidental findings, although at the same time they excuse liability for failure to notice such findings. Whether this position gives rise to a novel duty of care in negligence will be explored in due course. For now, it is important to note that the experience of UK Biobank so far indicates that serious findings will be

[881] Ibid.
[882] Sellors J, 'Feedback of Incidental Findings during the Imaging Pilot Study' (UK Biobank) <http://www.ukbiobank.ac.uk/wp-content/uploads/2014/06/1630-Jonathan-Sellors-4.30pm-incidental-findings.pdf> accessed 5 February 2016

discovered during the imaging scans, and that statistically this will happen relatively frequently.

7.2.2 Findings in the course of subsequent genetic research

In conjunction with genomics technology company Affymetrix, samples from all 500,000 participants of UK Biobank are currently being genotyped and linked to data held by UK Biobank. Genotyping is taking place in the interim between assessment upon enrolment and downstream research conducted by researchers. The genotyping project is distinct from the baseline assessment scenario in that the blood samples have been stored since their collection from the individual, and personal identifiers may have since been removed from these samples, before they are accessed by Affymetrix. This interim stage is also distinct from the scenario of a subsequent researcher who is granted access to samples in UK Biobank for their own research project.[883]

Significant progress in genetic technology has enabled researchers to sequence whole genomes instead of targeted genetic analysis.[884] This shift to whole genome sequencing (WGS) in medical research has infiltrated UK Biobank and in 2013 Biobank received its first application for access for WGS of a few hundred participants.[885] While such technological advances offer considerable advantages, WGS generates unprecedented amounts of raw genomic data and with the entire genome in play, the research community has started to grapple with questions about how best to manage and interrogate this rich resource.[886]

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[883] The EGF deals with findings 'prior to storage of samples' but this cannot include the DNA analysis process since DNA will be extracted from blood already stored in Biobank:
'Prior to storage of samples, UK Biobank is planning to conduct routinely only those few investigations that cannot be done subsequently on stored samples (i.e. haematology). As is the case with other measurements that may be conducted on stored samples (see below), these baseline measurements are being conducted outside of a clinical setting without prior counselling and support. Moreover, all such analyses will be conducted on anonymised samples without other relevant medical information about the individual. Consequently, these individual results with personal identifying details will not be provided to a participant or to anyone else. A clear explanation of this policy will be included in the participant information material.'
UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007), 7, <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 5 February 2015

[884] Discussed in Chapter 1 of this thesis.

[885] Although it is observed that the success of this application is not yet publically available on the UK Biobank website at the time of writing (26 January 2016).

[886] Cho MK, 'Understanding Incidental Findings in the Context of Genetics and Genomics.' (2008) 36 JLME 280.

By extension, this has raised deeper questions and concerns about whether, when researchers generate and interrogate this vast amount of data, they have any obligation to look within the data for potential variants associated with severe or life-threatening diseases.[887] This issue has arisen in light of the reality of genomics research and the process of incidental findings discovery, and is only very recently attracting the attention of academics and policy makers, but is widely appreciated by the geneticists and researchers conducting the studies:

> Most of the existing literature about genomic incidental findings assumes that incidental findings will be relatively uncommon and that they will rarely be 'stumbled upon' during the course of research. This assumption, however, is at odds with the realities of genomic research: If one looks carefully enough, any individual genome is likely to reveal important medical information.[888]

The reality of progress in genetics research means that today researchers using UK Biobank have unprecedented access to information that might be relevant for a participant.[889] Researchers have it within their means to purposely isolate and identify such information, rather than 'happening' upon it, and whether this reality matches the expectations of UK Biobank participants at the time of their original consent is a moot point.

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[887] The standard view is that 'researchers generally have no obligation to act as clinicians and affirmatively look for IF's.' Wolf SM, Paradise J and Caga-anan C 'The Law of Incidental Findings in Human Subjects Research: Establishing Researchers' Duties' (2008) 36 JLME 361.
This is challenged in Gliwa C and Berkman M, 'Do Researchers Have an Obligation to Actively Look for Genetic Incidental Findings?' (2013) 13 American Journal of Bioethics 41, 44: 'Our goal in this article is to challenge the notion that a 'stumble strategy' is universally acceptable, arguing that researchers who generate and analyse genomic sequences could also generate certain positive obligations for themselves vis-à-vis the data. It is conceivable that in specific circumstances researchers might have an obligation to actively examine their data for clinically significant findings beyond those required for their research.'

[888] Cho MK, 'Understanding Incidental Findings in the Context of Genetics and Genomics.' (2008) 36 JLME 280.

[889] Defining 'relevance' is not straightforward. For example in the context of genetic testing, clinical utility is partly used to determine the 'usefulness' of the test but, even this has a number of meanings: Clinical utility in its narrowest sense refers to the 'ability of a screening or diagnostic test to prevent or ameliorate adverse health outcomes such as morality, morbidity, or disability through the adoption of efficacious treatments conditioned on test results.' A screening or diagnostic test alone does not have inherent utility; because it is the adoption of therapeutic or preventative interventions that influence health outcomes. Therefore the clinical utility of a test depends on effective access to appropriate interventions. Clinical utility can more broadly refer to any use of test results to inform clinical decision-making. In its broadest sense, clinical utility can refer to any outcomes considered important to individuals and families (e.g. reproductive decisions and psychosocial support): Grosse SD and Khoury MJ, 'What is the clinical utility of genetic testing?' (2006) 8 Genetic Med 448.

UK Biobank has not detailed the approach taken to findings that may arise during the course of the genotyping project, nor the relationship with Affymetrix.[890] The UK Biobank website simply states that the genetic data will be returned to UK Biobank so that researchers can study the relevance of the genetic differences together with other factors, but participant anonymity will be maintained.[891] Unlike the imaging scans, genotyping has been deemed to be within the terms of a participant's original consent (previously described) and participants have consented on the grounds that they will not receive any results of such genetic analysis.[892]

So far, data on 150,000 UK Biobank participants has been released, and it is anticipated that the genotype data for the next 350,000 will be released in 2016.[893] The breadth of information that will be available after the genotyping phase is complete will have significant implications for the kinds of findings that may be encountered by researchers using the resource. When applying for access to the resource, researchers must sign a Material Transfer Agreement (MTA) that binds UK Biobank and the researcher in a contractual relationship. Currently, this MTA does not obligate researchers to feedback findings encountered during the course of research. The Agreement only stipulates that a researcher is obliged to contact UK Biobank should the researcher 'inadvertently identify the participant'[894] with no provision for individual findings. If it is found that UK Biobank owes a duty of care to participants to prevent avoidable harm, it could be argued that UK Biobank should

[890] It is acknowledged that since the time of writing some of this information has been made available: UK Biobank 'Genotyping and quality control of UK Biobank, a large-scale, extensively phenotyped prospective resource: Information for researchers.' (Interim Data Release, 2015): <http://www.ukbiobank.ac.uk/wp-content/uploads/2014/04/UKBiobank_genotyping_QC_documentation-web.pdf>; accessed 5 January 2016; UK Biobank 'DNA Extraction at UK Biobank' (UK Biobank October 2014): <http://www.ukbiobank.ac.uk/wp-content/uploads/2014/04/DNA-Extraction-at-UK-Biobank-October-2014.pdf> accessed 5 January 2016

[891] UK Biobank 'Key genetics study underway: video' (UK Biobank) <http://www.ukbiobank.ac.uk/2013/09/genetics-study-targets-serious-disease-video/> accessed 27 February 2014

[892] UK Biobank 'Consent form: UK Biobank' Version: 20061124: <http://www.ukbiobank.ac.uk/wp-content/uploads/2011/06/Consent_form.pdf?phpMyAdmin=trmKQlYdjjnQIgJ%2CfAzikMhEnx6> accessed 2 June 2014

[893] UK Biobank 'Genetic data' (UK Biobank) <http://www.ukbiobank.ac.uk/scientists-3/genetic-data/> accessed 2 June 2014

[894] UK Biobank, 'Material Transfer Agreement' <www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Material-Transfer-Agreement.pdf> accessed 27 July 2014.

require researchers to notify them of serious and actionable results that could be fed back to participants. [895]

A brief overview of the technicalities of genetics research will now be provided to inform understanding of the kinds of genetic findings that, arguably, a UK Biobank participant would benefit from knowledge of. By extension, these will be argued to be the kinds of findings which, for the purpose of a novel negligence claim, would most likely to cause actionable physical damage if they are not disclosed, and which it would be reasonably foreseeable to expect that if they are not disclosed, the risk will materialise causing personal injury to the claimant.

A brief overview of genetics research to inform legal analysis

It is recalled from Chapter 1 of this thesis that developments in genetics research have led to an improved understanding of single gene diseases like Huntington's disease, and genetically complex diseases like diabetes. The likelihood of developing a single gene disorder or a genetically complex disease can be expressed in terms of 'absolute risk' or 'relative risk'. An absolute risk is the chance an individual has of developing a disease over a time period. In single-gene disorders, absolute risk for family members can be accurately predicted. For example, in the dominantly inherited Huntington's disease, the siblings and offspring of an affected individual have a 50 per cent absolute risk of developing the disease themselves.[896]

Previous scientific and medical attention to genetic disorders mainly focused on understanding rare, single gene disorders like Huntington's disease. However in

[895] Issues associated with this are noted in: Wolf SM and others, 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets' (2012) 14 Genet Med 361. The authors recommend that biobank should consider writing into their contractual agreements with collection sites on the one end of the process and secondary researchers on the other end (i.e. into collection agreements, MTAs, and DAA's or DUAs) provisions for how IFS will be addressed.

[896] Chico V, *Genomic Negligence: An Interest in Autonomy as the Basis for Novel Negligence Claims Generated by Genetic Technology* (Routledge, 2011), 11:
'…the relative predictive power of genetic testing depends on the condition being considered. Directly obtained genetic information for high penetrance monogenetic disorders such as Huntington's disease will be highly predictive of the onset of that particular disease. Furthermore, once a person has tested positive for a particular genetic disorder the likelihood that her siblings or offspring will carry that disorder can be predicted with some accuracy. Dominant single-gene disorders, in particular, have a tendency not to manifest themselves until later in life. Where a person tests positive for a monogenic, dominant genetic disorder there is a 50 per cent chance that her siblings will possess the gene if one of her parents possesses the gene, and a 75 per cent chance that they will possess the gene if both parents do. Furthermore, there is a 50 per cent chance that each of her children also possesses the gene, rising to a 75 per cent chance if her reproductive partner is also affected.'

recent years, attention has shifted toward understanding the basis of common complex disorders. It is much more difficult to determine a person's risk of manifesting a multifactorial disorder. In such genetically complex diseases the effect of inheriting a particular susceptibility gene is often expressed as a relative risk, which is used to compare the risk in two different groups of people.[897] Although multifactorial disorders often run in the family, they do not have clear-cut patterns of inheritance and a person's genetic make-up merely makes them more susceptible to the particular disorder in question. The interactive nature of multifactorial genetic conditions means it might be possible to reduce or eliminate a person's risk of manifesting a particular genetic disorder by informing them of the environmental/lifestyle factors which, combined with their particular genetic make-up, increases their susceptibility to the particular condition.

'Penetrance' is also an important predictive factor. This is the proportion of individuals who carry a particular disease variant who will go on to develop the disease. The breast cancer genes BRCA1/2 are examples of genes with 'high penetrance' because over 80 per cent of individuals who carry the mutation in one of these genes will develop breast or ovarian cancer in their lifetime. Genetic variants associated with common diseases are mostly of 'low penetrance', because the increased risk of developing the disease that is conferred by carrying the gene is relatively low.[898] Unfortunately, while progress in the identification of genetic disease has been impressive, progress in the treatment of such disorders has been much slower. The challenge for scientists still lies in discovering ways to alter those genes that are defective.[899]

This scientific overview is important for consideration of the types of 'risks' that participants might hypothetically want to know about. Once concrete links are made between genes and the environment it may be easy in the future, from a theoretical

[897] For example, the absolute lifetime risk of developing a disease may be five in 100 in the general population, and the relative risk of the disease may be increased by 20 per cent in people who carry a particular genetic variant. The 'relative' risk ascribed to this genetic variant is defined as 1.2, because the risk has arisen from 1.0 ('normal' population risk) to 1.20 (increased risk for people carrying the genetic variant). In this population, this 20 per cent increase in relative risk represents an increase in absolute risk from five in 100 to six in 100. While a (relative) risk increase of 20 per cent sounds high, the absolute risk increase of one in 100 extra cases provides a more practical indication of risk to a member of that population: House of Lords Science and Technology Committee, *Genomic Medicine* (HL 2008-09, 107-I), 14

[898] Ibid.

[899] Ibid. For example via gene therapy, preventative surgery etc.

perspective, to avoid certain risks.[900] So, would participants want to be informed of absolute risks for untreatable genetic predispositions? What about high penetrance genes such as BRCA1/2? Or single gene disorders for which there is no cure? Or susceptibility genes that currently carry a low risk that will significantly increase with time, diet and lifestyle?

These concerns have led to the formulation of 'lists' of gene mutations that are considered so important and clinically relevant to individuals that they ought to not only be disclosed but also actively searched for. In 2013[901] the American College of Medical Genetics and Genomics released recommendations for a list of 'incidental findings' that should be searched for and disclosed to individuals, during the course of clinical exome and genome sequencing in the laboratory.[902] Although not intended for application to the biobank setting, this list acts as an interesting benchmark of genetic variants that have been deemed to be so significant to an individual's health that they justify added obligations on the laboratories performing the sequencing. While all of the disorders on the list are rare, most of the gene and variant categories were selected because they are associated with the more common of the single gene disorders. The Recommendations specify a set of disorders and the relevant associated genes, and certain categories of variants that should be reported, based on consensus driven assessment of clinical validity and utility. Disorders for which preventative measures and/or treatments are available are prioritised, along with disorders in which individuals with pathogenic mutations[903] might be asymptomatic for long periods of time. The list includes the hereditary breast and ovarian cancer genes BRCA1 and BRCA2. Significantly, the ACMG adopt an opt-out approach, such that if individuals do not want to know such the results of such research, they should not consent to take part in the studies.

It will be argued later in this chapter that lists such as these may be used as examples of the kinds of findings which, if not disclosed, will foreseeably manifest and cause

[900] Common non-genetic factors that influence the manifestation/progression of genetic diseases include diet, stress, alcohol, drugs and exposure to toxic chemicals or radiation: Ibid.
[901] Green RC and others, 'ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing' (2013) 15 Genetics in Medicine 565.
[902] The Working Group's definition of these as 'incidental' is misleading and paradoxical in light of their acknowledgment of the distinction between stumbling upon, as opposed to actually searching for, particular findings.
[903] An error in the gene that causes impairment of the production of a protein and hence certain clinical symptoms: House of Lords Science and Technology Committee, *Genomic Medicine* (HL 2008-09, 107-I)

physical harm. While some findings will not necessarily be meaningful for the participant, for example a genetic predisposition to brown hair, at least for some of the subsequent studies researchers may find (and could indeed search for) clinically relevant findings. The categories and lists of incidental findings are helpful in as much as they delineate the foreseeable range of findings which if not disclosed will result in serious individual (and potentially familial) harm. On this basis, for the purpose of building a novel duty of care to disclose such findings, 'findings' will be broadly conceived as any findings during the course of research that relate to the individual participant which that person ought to be informed of in order to prevent the manifestation of a 'serious' risk of harm. Using UK Biobank's own definition, 'serious' means 'likely to threaten life span, quality of life or major body functions.'

From the perspective of negligence, these are the findings most likely to be deemed 'actionable' in a novel claim in negligence. Although this is a narrow interpretation of actionable harm, it is necessary to facilitate further legal analysis of the potential duties that are owed and it is enough that there is scope for argument that manifestation of a risk discovered in the course of research could cause physical injury, which is reasonably foreseeable.[904] Therefore, the question that remains is whether UK Biobank should be directly, or vicariously, responsible for failure to communicate such findings. The conclusion to be drawn from analysis so far is that technicians conducting imaging scans or researchers using UK Biobank will discover information pertaining to participants during the course of their research, whether intentionally or accidentally. It is debatable whether at the time of consent individual donors were in a position to appreciate the kinds of findings that researchers might subsequently uncover, given the broad terms of their consent and subsequent decisions for genotyping of all participant samples. However, UK Biobank have seemingly waived responsibility to feedback and how tenable this position is in negligence will now be explored. Arguably, there may be a gap between how UK Biobank has been set up and the delivery of its existing legal standards for participants, which could leave Biobank vulnerable to being sued.[905]

[904] *Page v Smith* [1996] 1 AC 155, [1995] 2 WLR 644 [190]: In order to establish foreseeability it must be determined whether the defendant can reasonably foresee that his conduct will expose the claimant to the risk of personal injury. If so, then the person comes under a duty of care to that plaintiff.

[905] It is noted that UK Biobank's no feedback policy is currently under discussion.

7.3 Building a novel duty of care to return 'serious' findings in UK Biobank

On the assumption that non-disclosure of serious risks may result in actionable physical harm, the next step in a negligence claim is to argue that UK Biobank Ltd owes a duty of care to participants to prevent such harm by feeding back such risks. There have been no cases in English tort law that have addressed the specific issues raised by feedback of findings in the course of research. Since this is a novel duty scenario, three tests have been used by the courts in determining a duty of care:[906]

a. Whether any duty owed would be 'incremental' to previously decided cases;[907]

b. Whether there has been an assumption of responsibility by the defendant towards the claimant (and consequential reliance by the claimant upon the defendant conducting himself with due care and skill);

c. Whether the three-fold *Caparo*[908] test of foreseeability, proximity and that a duty would be 'fair, just and reasonable', has been met.

The *Caparo* test has been preferred as the primary test for a novel duty of care.[909] In practice, the courts will often consider all or some of these requirements as part of the same duty analysis.[910] The next section of this chapter will begin by considering whether it is possible to establish an analogous duty scenario, followed by analysis of whether it is foreseeable, proximate, and just, fair and reasonable to impose such a duty on UK Biobank Ltd in the circumstances. In the courts, whether there has been an 'assumption of responsibility' is often indicative of 'proximity' within the *Caparo* test, and this is the approach followed in this chapter.

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[906] For discussion of these three tests see, e.g. *Her Majesty's Commissioners of Customs and Excise v Barclays Bank Plc* [2006] UKHL 28, [2007] 1 AC 181 [4] *per* Lord Bingham, [82] *per* Lord Mance.
[907] *Donoghue v Stevenson* [1932] SC (HL) 31, [1932] AC 562
[908] *Caparo Industries plc v Dickman,* [1990] 2 AC 605, [1990] 2 WLR 358
[909] *Van Colle v Chief Constable of the Hertfordshire Police* [2008] UKHL 50 [2009] 1 AC 225 [42] *per* Lord Bingham and endorsed in *Mitchell v Glasgow City Council* [2009] UKHL 11; [2009] 1 AC 874, [21] *per* Lord Hope.
[910] The interdependence of novel duty criteria such as foreseeability, proximity, assumption of responsibility and just, fair and reasonableness has recently been illustrated in *ABC v St Georges Healthcare NHS Trust and Others* [2015] EWCA 1394 (QB).

7.3.1 Reason by analogy

There are no directly analogous cases in UK negligence law. It is well established that doctors owe their patients a duty of care in English tort law.[911] The extent to which doctors owe a duty outside the clinical setting is uncertain and case law suggests that the further removed the circumstances are from the clinical setting, the more difficult it will be to establish a duty. For example, while the ruling in *Baker v Kaye*[912] had suggested that a duty of care towards the claimant existed in English law (beyond not injuring the person), the Court of Appeal in *Kapfunde v Abbey National and Daniel*[913] found against a duty in circumstances where a doctor had been employed by a company to carry out medical assessments on potential employees; since the doctor had not met the patient, and had based assessment on a questionnaire, there was found to be no proximity or 'special relationship' between the doctor and the patient.

Beyond the doctor-patient relationship, the *Creutzfeldt-Jakob Disease Litigation*[914] held that researchers owed a duty of care to research participants 'akin to that of doctor patient, one of close proximity'. To date, this is the only English negligence case that has considered the position of researchers. It remains to be seen whether and how this ruling could be applied in the future, given that the facts of the case were such that the 'research' in question was a clinical trial that became a large therapeutic program adopted by the Department of Health and the National Health Service. On this basis, it has been argued that the close relationship between research and therapy could be persuasive in finding a duty of care,[915] which may be significant in the context of imaging scans (as will be discussed). International authority has also imposed a duty of care on researchers in the context of clinical

[911] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, [121]; *Bolitho v City and Hackney Health Authority* [1998] AC 232, [1997] 3 WLR 1151

[912] *Baker v Kaye* [1996] 39 BMLR 12 (QB) held that a doctor owed a duty of care for pre-employment health assessment (outside the clinical context) but the claim was dismissed on the ground that there was no breach of that duty.

[913] *Kapfunde v Abbey National plc and Dr D Daniel* [1998] 46 BMLR 176 (CA), [1999] Lloyd's Rep Med 48 *Kapfunde* and *Baker* are discussed in: Kennedy I and Grubb A, *Medical Law* (3rd edn, Butterworths 2000).

[914] *Creutzfeldt-Jakob Disease Litigation* QB 41 BMLR 157, [164]

[915] Kaye J, Boddington P, de Vries J, Gowans H, Hawkins N, Heeney C and Melham K, *Ethical, Legal and Social Issues Arising from the Use of GWAS in Medical Research* (Wellcome Trust 2009).

trials,[916] but again it is likely that this scenario is too factually different to be deemed analogous by a UK court.[917]

Established precedent states that professionals owe a duty of care to exercise their professional skills to a standard that is expected of a reasonable professional possessing that particular skill. Thus, the radiographers ('technicians') conducting imaging scans owe a duty of care to do so to the standard of a reasonably skilled radiographer.[918] In the clinical context, a radiographer would likely owe a duty of care to the patient to conduct the imaging to a clinical professional standard, look for findings in relation to the diagnostic reason for the scan, and act on such findings accordingly. However, in the research context the scope of this duty is likely to be considerably narrower and therefore distinguishable.

In the case of UK Biobank, there are multiple 'actors' involved in the participation and research process who are acting in a research, rather than clinical, capacity. According to the terms of their contracts, these professionals are more likely to owe contractual duties to UK Biobank as their employer to do their job properly. In light of distinctions made regarding doctor/patient relationships outside the clinical setting, it is unlikely that professionals in a research setting would be held to this higher standard.

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[916] *Grimes v Kennedy Krieger Institute, Inc.* 366 Md 29, 782 A2d 807 (2001)
This case discussed the issue of researcher duties extensively and held that 'the very nature of nontherapeutic research on human subjects can create special relationships out of which duties arise': 'A special relationship giving rise to duties, the breach of which might constitute negligence, might… arise because, generally, the investigators are in a better position to anticipate, discover and understand the potential risks to the health of their subjects. Practical inequalities exist between researchers, who have superior knowledge, and participants, 'who are often poorly placed to protect themselves from risk.' [3]
'Given the gap in knowledge between investigators and participants and the inherent conflict of interest face by investigators, participants cannot and should not be solely responsible for their own protection.' [78]
The duty required the protection of the research subjects from unreasonable harm and required the researcher to completely and promptly inform the subjects of the potential hazards which existed, because of the profound trust that participants place in investigators, institutions and the research enterprise as a whole to protect them from harm. The case concluded:
'… Informed consent agreements in nontherapeutic research projects, under certain circumstances can constitute contracts… under certain circumstances, such research agreements can, as a matter of law, constitute 'special relationships' giving rise to duties, out of the breach of which negligence actions may arise.' [90]
[917] This case is distinguishable on its facts, because on the facts the research project arguably put its participants in a more dangerous position by virtue of taking part. The same cannot be said in the legal argument at hand; UK Biobank donors are not endangered by taking part, they are just more likely to suffer harm if significant findings are encountered and not fed back, preventing action to minimise such harm.
[918] *Phillips v William Whiteley Ltd* [1938] 1 All ER 566**;** *Wells v Cooper* [1958] 2 QB 265; *Wilsher v Essex Area Health Authority* [1988] AC 1074

7.3.2 The 'Caparo' test

To establish a novel duty of care in negligence, *Caparo*[919] requires the following: the risk of harm is foreseeable; there is sufficient proximity between the parties; and it is just, fair and reasonable to impose a duty of care. Although *Caparo* articulates these individual criteria, negligence jurisprudence has demonstrated that there is considerable overlap between the elements, which have been described as 'merely facets of the same thing.'[920] For this reason, while some issues will be discussed in proximity, these may also be considered to be issues of just, fair and reasonableness. Such overlap is arguably unavoidable:

> [p]roximity is convenient shorthand for a relationship between two parties which makes it fair and reasonable one should owe the other a duty of care.[921]

Foreseeability

According to the well-known 'neighbour principle' introduced in the landmark ruling of *Donoghue v Stevenson*,[922] 'reasonable foreseeability' means a duty will be owed where the defendant ought reasonably to foresee that his failure to take care/omission to act may cause injury to another:

> The rule that you are to love your neighbour becomes, in law, you must not injure your neighbour; and the lawyer's question 'who is my neighbour' receives a restricted reply. You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour. Who then, in law, is my neighbour? The answer seems to be- persons who are so closely and directly affected by my act that I ought reasonably to have them in contemplation as being directly affected when I am directing my mind to the acts or omissions which are called into question.[923]

The burden of proof is on the claimant to prove that a reasonable person in the position of the defendant would have foreseen that injury of some type would, or would be likely to be suffered by the claimant if the defendant did not exercise due care and skill.[924] There is no strict definition of what constitutes reasonable

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[919] *Caparo Industries plc v Dickman* [1990] 2 AC 605, [1990] 2 WLR 358
[920] Ibid. [634]
[921] *Stovin v Wise* [1996] AC 923; [1996] 3 WLR 388 [932]
[922] *Donoghue v Stevenson* [1932] SC (HL) 31, [1932] AC 562
[923] Ibid. [31]
[924] Mulheron R, Medical Negligence: Non-Patient and Third Party Claims (Ashgate 2010). 29

foreseeability of harm, and in *Islington LBC v University College London Hospital NHS Trust*, Buxton LJ remarked that it was a matter of 'fluidity or flexibility' and 'to a large extent a matter of impression.'[925] The test of reasonable foreseeability must be applied to the particular defendant; in this case UK Biobank Ltd.

It follows then that the question is whether UK Biobank should have reasonably foreseen that the act or omission would, or would be likely to give rise to injury to the claimant.[926] Analysis in Chapters 4 and 6 of this thesis has revealed the composition of experts who make up UK Biobank Ltd, including scientific, legal, technical and ethical experts. Moreover, analysis of scientific developments in research earlier in this chapter has shown how improved knowledge and understanding of genetic diseases has led to the identification of certain gene mutations with high penetrance,[927] and scientific research is moving towards an understanding of the clinical utility of information relating to genetic disorders (single or multifactorial) and health in general. Arguably, it would be reasonable to assume that UK Biobank Ltd would be aware of such developments, as well as the potential for researchers to be in a privileged position to identify (look for) and understand clinically significant findings.

What is important for the purpose of this chapter is that certain genetic variations have been deemed to be so significant and actionable that the individual must be informed of them in order to prevent harm. It is submitted that these lists of disclosable variants are influential to the identification of the kinds of risks that could constitute actionable harm for the purpose of a claim in negligence. In other words, these are the findings that will cause personal injury, which is reasonably foreseeable to UK Biobank Ltd if they are not disclosed, and therefore could warrant the imposition of a duty of care.

But to establish a novel duty, precedent has long recognised that foreseeability alone will not be sufficient[928] and in addition 'some further ingredient' is needed to establish the requisite proximate relationship. On this matter, precedent suggests that a failure to warn falls into the category of omissions, for which proximity will be

[925] *Islington LBC v University College London Hospital NHS Trust* [2005] EWCA Civ 596, [14]
[926] Ibid.
[927] Green RC and others, 'ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing' (2013) 15 Genetics in Medicine 565.
[928] *Hill v Chief Constable of West Yorkshire Police* [1989] AC 53; [1988] 2 WLR 1049

difficult to prove. In relation to feedback of results, the challenge will be to establish a close or direct enough relationship between the participant and UK Biobank Ltd, which is by no means straightforward, and will depend on the context in which the results are discovered as well as the type of result itself. Establishing proximity will be difficult because of the chain of relationships between UK Biobank Ltd, radiographers, researchers and participants. Currently this only requires limited communication in certain circumstances and so in the main enhanced communication between the parties, set out in contractual (or consent) documents, would be required. Even more problematic is that our argument for a duty to feedback is based on a failure to warn, which potentially constitutes an omission.[929]

Liability for omissions

Generally, the common law of negligence does not impose liability for 'mere omissions', as they are referred to in *Smith v Littlewoods Organisation Ltd*.[930] This rule has been expanded in omission cases such as *Mitchell v Glasgow CC,*[931] in which the House of Lords essentially categorised a failure to warn as a 'mere omission' and explained that, exceptionally, an omission could give rise to a duty of care. In this instance, some 'additional feature' will be necessary, examples of which include:

> The requisite additional feature that transforms what would otherwise be a mere omission, a breach at most of a moral obligation, into a breach of a legal duty to take reasonable steps to safeguard, or to try to safeguard, the person in question from harm or injury may take a wide variety of forms. Sometimes the additional feature

[929] *Stovin v Wise* [1996] AC 923, [1996] 3 WLR 388
[930] *Smith v Littlewoods Organisation Ltd* [1987] 1 AC 241, [1987] 2 WLR 480
The various reasons for this were explained in political, moral and economic terms in *Stovin v Wise* [1996] AC 923, [1996] 3 WLR 388:
'It is one thing for the law to say that a person who undertakes some activity shall take reasonable care not to cause damage to others. It is another thing for the law to require that a person who is doing nothing in particular shall take steps to prevent another from suffering harm….One can put the matter in political, moral or economic terms. In political terms it is less of an invasion of an individual's freedom for the law to require him to consider the safety of others in his actions than to impose upon him a duty to rescue or protect. A moral version of this point may be called the 'why pick on me?' argument. A duty to prevent harm to others or to render assistance to a person in danger or distress may apply to a large and indeterminate class of people who happen to be able to do something. Why should one be held liable rather than another? In economic terms, the efficient allocation of resources usually requires an activity should bear its own costs….So liability to pay compensation for loss caused by negligent conduct acts as a deterrent….But there is no similar justification for requiring a person who is not doing anything to spend money on behalf of someone else….So there must be some special reason why he should have to put his hand in his pocket.' [943-44]
[931] *Mitchell v Glasgow City Council* [2009] UKHL 11, [2009] 1 AC 874

> may be found in the manner in which the victim came to be at risk of harm or injury. If a defendant has played some causative part in the train of events that have led to the risk of injury, a duty to take reasonable steps to avert or lessen the risk may arise. Sometimes the additional feature may be found in the relationship between the victim and the defendant (e.g. employee/employer or child/parent) or in the relationship between the defendant and the place where the risk arises… sometimes the additional feature may be found in the assumption by the defendant of responsibility for the person at risk of injury… in each case where particular circumstances are relied on as constituting the requisite additional feature alleged to be sufficient to cast upon the defendant the duty to take steps that, if take, would or might otherwise have avoided or lessened the injury to the victim, the question for the court will be whether the circumstances were indeed sufficient for that purpose or whether the case remains one of a mere omission.[932]

Applied to the case at hand, if the failure to warn participants is going to be deemed to be more than a mere omission, an additional factor will need to be proven to warrant a duty of care. Such factors will be discussed within proximity and just, fair and reasonableness (below), but is it also worth briefly noting that proving breach and causation (also necessary for a successful negligence claim) would also be considered by the courts.

Claimants may find it difficult to prove that non-feedback of research results is a failure to meet the standard of care expected in the circumstances.[933] Proving causation is also likely to be problematic due to the multifactorial nature of many diseases (briefly explained in this chapter) and the burdensome all or nothing approach to the balance of probabilities in tort law, which would require the claimant to prove that there was a greater than 50 per cent chance that she could have avoided the harm had she known of the risk.[934] In relation to genetic disease, for example, while scientific research has paved the way for medicine to predict genetic conditions, it remains difficult to prevent the fate that those genes predispose,[935] and

[932] Ibid. [40]
[933] Which since *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [2015] 2 WLR 768 would arguably be the 'reasonable patient standard', although this case related to the well established doctor/patient relationship.
[934] *Barnett v Chelsea and Kensington Hospital Management Committee* [1969] 1 QB 428, [1968] 2 WLR 422
[935] Chico V, *Genomic Negligence: An Interest in Autonomy as the Basis for Novel Negligence Claims Generated by Genetic Technology* (Routledge, 2011), 142

it is well noted in the literature that this would be problematic for a claimant seeking to establish both factual and legal causation.[936]

Proximity

The concepts of proximity and fairness have been described by the House of Lords in *Caparo* as 'little more than convenient labels to attach the features of different specific situations which, on a detailed examination of all the circumstances, the law recognises pragmatically as giving rise to a duty of care of given scope.'[937] Thus, there is no single formula that will determine whether or not a proximate relationship exists between the claimant and the defendant, and the task for the claimant is to identify an additional feature beyond mere foreseeability that proves there was sufficient proximity between the parties. The closer or more direct the relationship; the more likely it will be that a duty will be owed.[938] The well-established doctor/patient relationship has already been highlighted in this chapter, which arguably does not extend beyond the clinical context. In the research context, no such duty exists beyond that to take reasonable care as a skilled professional in the circumstances.

In some cases, the existence of a 'special relationship' has been sufficient to warrant a novel duty of care in omission cases. In *Home Office v Dorset Yacht Co. Ltd*[939] the House of Lords imposed a duty of care on prison officers who failed to prevent young boys escaping from a borstal camp, resulting in damage to the claimant's yacht. This was by virtue of the fact that the prison officers had a special relationship with the boys and the yacht owners were clearly exposed to a particular risk of damage if the boys escaped. Because of this proximate relationship, a duty was found.[940] Later, *Barrett v Ministry of Defence*[941] held that 'the characteristic which distinguishes those [special] relationships is reliance expressed or implied in the

[936] Ibid. See also Johnston C and Kaye J, 'Does the UK Biobank have a Legal Obligation to Feedback Individual Findings to Participants?' (2004) 12 Medical Law Review 239
[937] *Caparo Industries plc v Dickman* [1990] 2 AC 605, [1990] 2 WLR 358 [618] *per* Lord Bridge [633] *per* Lord Oliver.
[938] *Donoghue v Stevenson* 1932 SC (HL) 31, [1932] AC 562
[939] *Home Office v Dorset Yacht* [1970] AC 1004, [1970] 2 WLR 1140
[940] Ibid. [1032].
[941] [1995] 3 All ER 87, [95]

relationship which the party to whom the duty is owed is entitled to place on the other party to make provision for his safety.'[942]

Applied to our case, it is perhaps arguable that the existence of an established procedure for reporting serious findings for verification builds the requisite relationship (whether 'special' or 'assumed') between the participant, radiographer, and UK Biobank, such that proximity will be satisfied. On this basis, proximity may be easier to establish in relation to results of imaging scans than genetics results. Potentially, a direct and proximate relationship between the radiographer and the participant under examination is more likely because it is foreseeable that if a 'serious' finding is present but not disclosed, the participant physically in front of the radiographer will suffer personal harm should the finding manifest. Subsequently, it will be down to the court to decide whether UK Biobank's waiver of responsibility for serious findings not noticed at this stage is reasonable in the circumstances, or whether it would be just, fair and reasonable to impose a duty on UK Biobank who would be vicariously liable for the radiographer's failure to warn of such findings.[943]

On the other hand, proximity may be more problematic in relation to feedback of genetic results, not least because all samples and data are de-identified (Chapter 1) before they are released for research use. UK Biobank is open for international access, which means theoretically, a researcher on the other side of the world could discover a research result pertaining to a de-identified participant. It is difficult to imagine how this would qualify as a close and direct relationship, but, it is noted that this de-identification is reversible in order to allow further re-contact in future and to enable linkage of different sources of information to an individual participant's research file.[944]

In the absence of a pre-existing or analogous tortious relationship to bind UK Biobank to the hypothetical claimant, the UK courts have, in novel circumstances where proximity has been an issue, looked beyond contractual relationships or denial

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[942] *Smith v Littlewoods Organisation Ltd* [1987] 1 AC 241 [1987] 2 WLR 480, [271] previously held that people may owe a duty not to harm others by omission if there is a *prior* relationship between the parties.

[943] UK Biobank would be vicariously liable for data collector who is 'employed' to collect the samples: *Cassidy v Ministry of Health* [1951] 2 KB 343, [1951] 1 All ER 574 (CA); *Roe v Ministry of Health* [1954] 2 QB 66 [1954] 2 WLR 915; *Lister v Hesley Hall Ltd.* [2001] UKHL 22, [2002] 1 AC 215

[944] UK Biobank, *Ethics and Governance Framework* (Version 3.0, UK Biobank 2007) 'Anonymisation' <http://www.ukbiobank.ac.uk/resources/> accessed 26 January 2016.

of responsibility and by virtue of the harm and the circumstances imparted a new duty of care on the grounds of a 'special relationship' or an 'assumption of responsibility.'[945] The principle of assumption of responsibility applies to situations in which:

> Someone possessed of a special skill, undertakes, irrespective of contract, to apply that skill for the assistance of another person, who relies on that skill; a duty of care will arise.[946]

However, assumption of responsibility as the basis of extra-contractual liability emerged in the context of claims for the compensation of types of non-intentional harm other than physical personal injury, including psychological and psychiatric harm, nervous shock and pure economic loss,[947] and this will have implications for the weight such precedent could be given to the scenario at hand.

Hedley Byrne v Heller[948] was a landmark case of pure economic loss resulting from a negligent misstatement. The question was whether a banker owed a duty of care to the party seeking information in respect of a reference gratuitously supplied. Previously, the notion that a party may owe another a duty of care for negligent misstatements had been rejected, with the only remedy being in contract law. In contrast, the claim was allowed and the principle on which the new duty of care not to make careless statements was founded was an assumption of responsibility by the maker of the statement, coupled with a detrimental reliance by the party seeking the information or advice:

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[945] Lord Reid in *Home Office v Dorset Yacht* [1970] AC 1004, [1970] 2 WLR 1140 [1027]:
'In years later, there has been a steady trend towards regarding the law of negligence as depending on principle so that, when a new point emerges, one should ask not whether it is covered by authority but whether recognised principles apply to it. Donoghue v Stevenson may be regarded as a milestone, and the well-known passage in Lord Atkin's speech should, I think, be regarded as a statement of principle. It is not to be treated as if it were a statutory definition. It will require qualification in new circumstances. But I think that the time has come when we can and should say that it ought to apply unless there is some justification or valid explanation for its exclusion.'

[946] *Hedley Byrne & Co Ltd v Heller & Partners Ltd* [1964] AC 465, [1963] 3 WLR 101[503]

[947] *Leach v Chief Constable of Gloucestershire* [1999] All ER 215 (CA). In this case the Court of Appeal accepted that voluntary assumption of responsibility could create a duty of care to protect from psychiatric harm. The case concerned a claimant who had been asked by the police to assist in the interrogation of a serial killer by being present as 'appropriate adult' during police interviews and also in the police cell where he was kept, as required by the practice code of the police. The claimant suffered severe psychological trauma following no help or counselling. The Court refused to strike out her claim, pointing out that there should be no difference between physical and psychiatric harm when assumption of responsibility is concerned. The assumption of responsibility leading to the creation of a duty of care was to advise the claimant to seek proper counselling while assisting the police, which was to be objectively recognized.

[948] *Hedley Byrne & Co Ltd v Heller & Partners Ltd* [1964] AC 465, [1963] 3 WLR 101

> Relationships which may give rise to a duty of care in word as well in deed… include: relationships '*equivalent to contract*', that is, where there is an assumption of responsibility in the circumstances in which, but-for the absence of consideration, there would be a contract… I do not understand any of your Lordships to hold that it is a responsibility imposed by law upon certain types of persons… It is a *responsibility that is voluntarily accepted or undertaken* either generally where there is a general relationship, such as that of a solicitor and client or banker and customer, is created, or specifically in relation to a particular transaction.[949] [Emphasis added].

Henderson v. Merett Syndicates[950] extended the scope of *Hedley* to include negligence performance of services and held that when the relationship is equivalent to contract, the test of assumption of responsibility is objective and based on reasonableness. *Williams v. Natural Life Ltd*[951] articulated this as such:

> The touchstone of liability is not the state of mind of the defendant, an objective test means that the primary focus must be on the things said or done by the defendant or on his behalf in dealings with the plaintiff.[952]

So, it matters not whether UK Biobank intended to assume responsibility for their participants in this way. The question for the courts would be whether or not such responsibility would be reasonable in the circumstances. Although cases such as *Hedley Byrne* and *Henderson* were cases of economic loss, it is arguable that they facilitate an interesting analysis of the relationship between participants, professionals (conducting the imaging scanning), researchers and participants. For example, this chapter has already discussed the apparent assumption of responsibility for feedback of serious findings during in imaging scanning which are referred to professionals, on the one hand, and their express waiver of responsibility for results that are not noticed by professionals conducting the scans, on the other. From a legal perspective, because imaging is being conducted in a research setting, strictly speaking there is no legal precedent which dictates that UK Biobank were obliged to take this approach, and debatably, by doing so UK Biobank have gone over and above the research duty to take reasonable care. However, by assuming responsibility for some findings and waiving responsibility for others, it is arguable

[949] Ibid [530]
[950] *Henderson v Merritt Syndicates Ltd* [1995] 2 AC 145, [1994] 3 WLR 761
[951] *Williams & Anor v Natural Life Health Foods Ltd & Anor* [1998] UKHL 17, [1998] WLR [830]
[952] Ibid. [836]

that a relationship is established between participants and UK Biobank, such that the waiver is not justifiable.

Applying principles in *Hedley* and *Henderson*, perhaps the necessary 'quasi-contractual' relationship between UK Biobank Ltd and participants could be argued to stem from their signing a consent form.[953] On this basis, an argument could be made to the effect that such a waiver of responsibility is not effective[954] and a double standard, and that UK Biobank have assumed responsibility for reporting all 'serious' findings during the imaging scans. This argument would be contingent on reliance by participants,[955] which must be reasonable[956] in the circumstances.

It would be more difficult to argue that UK Biobank Ltd has assumed responsibility for feedback of genetic research results, given the blanket restriction on such results outlined in the participant consent form. Although, perhaps an argument could be made in the future that the EGF document has been created as a 'living document' so that it can be reflexive and revised in light of public attitudes and societal change.[957] Could this contribute to an 'undue expectation' that UK Biobank's no feedback policy could be revised; given the momentum of progress in scientific and genetics research, and the apparent move towards identification and feedback of certain genetic findings (outlined above)? Taking this one step further, was the informed consent document clear enough so as to prevent a 'diagnostic misconception;'[958] in other words 'the expectation of personal health-related information as a reward for

[953] Although, it is recalled that feedback would be contingent on communication between the radiographer and UK Biobank, which at present will not always strictly be the case.

[954] *Smith v Eric S Bush* [1990] UKHL 1, [1989] 2 WLR 790
This was an economic loss case, in which it was held that a mortgage valuer owes a duty of care to the purchaser of the valued property to exercise reasonable skill and care, which cannot be avoided by the use of a disclaimer. A duty of care was held to be owed, and the question was whether or not the disclaimer was effective, in light of the Unfair Contract Terms Act (UCTA) 1977. It was held that the disclaimers were not effective to avoid liability, because it was not fair and reasonable for them to apply the circumstances of the case.

[955] *Her Majesty's Commissioners of Customs and Excise v Barclays Bank Plc* [2006] UKHL 28, [2007] 1 AC 181

[956] Also stated in *Williams & Anor v Natural Life Health Foods Ltd & Anor* [1998] UKHL 17, [1998] WLR 830, [838]:
'The test [of reliance] is not simply reliance in fact. The test is whether the plaintiff could *reasonably* rely on an assumption of personal responsibility by the individual who performed the services on behalf of the company.'

[957] Laurie G, 'Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law' (2011) 130 Human Genetics 347.

[958] Nobile H and Borry P, 'Why do participants enroll in population biobank studies? A systematic literature review' (2013) 13 Expert Rev Mol Diagn 35, 44

the donation of biological material for research?'[959] In this instance, reliance could be based on participants' expectations at the time of consent; who may not have comprehended the range of research uses that the UK Biobank resource is being used for and the potential for findings pertinent to their health.

Overall, while potentially arguable in relation to the imaging study, establishing a duty of care to feedback genetic results based on assumption of responsibility is tenuous at best. Even so, a duty of care may still feasibly be imposed by reason of the '*Caparo'* test. Indeed, even if an express assumption of responsibility and reliance cannot be proved, evidence of an assumption may well be considered evidence of 'proximity' for the purpose of this test.

Just, fair and reasonable

Even if foreseeability and proximity are proven, establishing a novel duty of care may fail if the courts decide that such a duty would not be just, fair and reasonable in the circumstances. The just, fair and reasonableness of importing a novel duty of care is usually determined by the 'public policy considerations'[960] of the claim. Of particular relevance here is the potential argument that UK Biobank is a 'public body', which is a thorny issue in negligence, and relatedly, the purpose for which UK Biobank was founded and the fair and just allocation of its resources. These will be dealt with in turn below.

It is noted that the next chapter of this thesis will discuss the potential for argument that UK Biobank Ltd is a quasi-public body for the purpose of judicial review; engaging public law mechanisms to protect participants from the risk under discussion. Often, allegations made against a public body are on the grounds that they have been negligent in failing to exercise a discretionary function. If reference can be made to a statute as evidence that the authority had either a public law power or duty to act, this will strengthen the claimant's argument that the authority also had a duty of care to act at common law for the purposes of a negligence action.[961] That being said, UK Biobank is not a statutorily created 'public body' (if the existence of

[959] On this question, Chapter 8 will explore whether an argument could be made for a 'legitimate expectation' of feedback of results in public law.
[960] Mulheron R, *Medical Negligence: Non-Patient and Third Party Claims: Non-Patient and Third Party Claims* (Ashgate Publishing 2010) , 30
[961] McIvor CM, *Liability in Tort for the acts of third parties; in search for coherence* (PhD Thesis, Durham University 2003), 94

a Parliamentary statute envisaging its operation is the understanding of a public body[962]) so there is not the same Parliamentary concern as has been problematic in other cases.[963]

However, analysis in this thesis so far has investigated the extent of UK Biobank Ltd's discretion as a private charity company limited, and this does not include a broad obligation to feedback. Thus, a central tension emerges which is instrumental to this thesis as a whole; the problematic boundary between public and private law to protect public and private interests. The issue of public body liability in negligence embodies the issue of how to deal with public law in a private law context. The reverse of this situation, namely how public law obligations could be related to private institutions should UK Biobank fail to meet the traditional public body test, will be dealt with in the next chapter. The current chapter proceeds on the basis that UK Biobank Ltd could be categorised as a public body, with important implications for the likelihood of a successful claim in negligence.

Public body liability

Public authorities are regarded as having special status in negligence, warranting the application of exceptional rules designed to restrict their duty of care and thus, liability. These are usually justified on the basis that imposing liability would operate to the detriment of society and the common good. Unlike private persons, the sole purpose of these bodies is to serve the community; they have been specifically created to carry out functions designed to benefit the community and to this end are paid for by the taxpayer. The main objection, then, is that holding public bodies liable means compensation comes out of their allocated funds so the amount of money that is available to perform their relevant functions is reduced. By extension, the whole community suffers for the benefit of one aggrieved individual. There is also the floodgates concern that the 'deep-pocketed' public authorities will be targeted for scheming claims. The other main argument against public body liability is the defensive practice concern; the threat of liability may cause public servants to adopt excessively cautious approaches to their work. This then leads to inefficient use of time and resources, as well as the sacrifice of the purpose for which the

[962] Which will be debated in the next chapter.
[963] *X (minors) v Bedfordshire County Council* [1995] 2 AC 663, [1995] 3 WLR 152; *Hill v Chief Constable of West Yorkshire Police* [1989] AC 53; [1988] 2 WLR 1049

authority was created. The creation of UK Biobank using public funds to build a resource to facilitate research for the public good seems to fit this requirement.

The hesitance of tort law to impose a duty on public bodies such as the police was demonstrated in *Hill v. Chief Constable of West Yorkshire*. In this case, the mother of the Yorkshire Ripper's last victim brought a claim against the police, arguing that they omitted to realise that Peter Sutcliffe was the killer. It was argued that had they conducted their investigations with due care and attention, Sutcliffe would have been apprehended before killing her daughter. The House of Lords effectively granted the police blanket immunity from such an action. Such immunity was deemed to be necessary since the imposition of a duty might encourage the police to perform their duties in a defensive manner,[964] which could divert resources away from the police force's 'most important function; the suppression of crime.'[965]

This reasoning was followed in *Palmer v. Tees HA*[966] where the trial judge relied on *Hill* and held that as a matter of public policy it would not be just, fair and reasonable to impose such a duty of care in the circumstances; health professionals might be encouraged to engage in 'defensive practice' in an effort to avoid liability, thereby neglecting their primary responsibilities of diagnosing and treating illness.[967] However, the effects of these decisions have since been mitigated, in light of their incongruence with the Human Rights Act and the duty on public bodies to act in accordance with the ECHR (Chapter 8). Thus *Osman v UK*[968] held that blanket immunity for the police was not compatible with the ECHR. Subsequently, *D v East Berkshire Community NHS Trust*[969] formally overruled *X (Minors) v Bedfordshire County Council*[970] and found a duty of care was owed.[971]

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[964] Ibid. *Hill v Chief Constable of West Yorkshire Police* [64].
[965] Ibid.
[966] *Palmer v Tees Health Authority* [1999] EWCA Civ 1533, [2000] PIQR P1
[967] Ibid. [14].
[968] *Osman v United Kingdom* (23452/94) [1999] 1 FLR 193, [2000] 29 EHRR 245
[969] *D v East Berkshire Community NHS Trust and others* [2005] UKHL 23, [2005] 2 AC 373
[970] *X (Minors) v Bedfordshire County Council* [1995] 2 AC 663, [1995] 3 WLR 152
[971] It is not within the scope of this chapter to analyse whether a rights-based argument based on the implications of the Convention may be made for a duty to feedback information. This line of argument has already been well made in relation to the potential engagement of an Article 2 Right to life (Johnston C and Kaye J, 'Does the UK Biobank have a Legal Obligation to Feedback Individual Findings to Participants?' (2004) 12 Medical Law Review 239) and Article 8 Right to Private and Family Life (Laurie G, 'Obligations Arising from Genetic Information: Negligence and the Protection of Familial Interests' (1999) 11 Child and Family Law Quarterly 109; Laurie G, 'In Defence of

Thus, it is no longer the case that public bodies such as the police force are automatically immune from liability by virtue of their standing. However, the courts may well be hesitant to impose such a duty on UK Biobank given its public good mission to facilitate research that is in the public interest for the benefit of future generations, not the participants themselves (Chapters 1, 3 and 4). Indeed, this is relied upon by UK Biobank as one of the justifications behind its no feedback policy; to impose a duty otherwise may well be to misconstrue the reasons behind UK Biobank's creation in the first place, and the interests it was created to benefit (Chapter 4): 'Biobank may well argue that it is in the business of research and that the reasonableness of any obligation to feedback clinical information should be judged relative to this fundamental mission.'[972]

This approach was evident in *Caparo*, which involved the duties owed by a public body to private individuals. It was held that the company in question owed a duty only to its shareholders and not private individuals, since the purpose of the company's accounts was not to benefit unknown private individuals relying on audit to make a profit, it was to help shareholders at general meeting:

> In seeking to ascertain whether there should be imposed on the adviser a duty to avoid the occurrence of the kind of damage which the advisee claims to have suffered it is not, I think, sufficient to ask simply whether there existed a 'closeness' between them in the sense that the advisee had a legal entitlement to receive the information upon the basis of which he has acted or in the sense that the information was intended to serve his interest or to protect him. One must, I think, go further and ask, *in what capacity was his interest to be served and from what was he intended to be protected?* …Before it can be concluded that the duty is imposed to protect the recipient against harm which he suffers by reason of the particular use that he chooses to make of the information he receives, one must, I think, *first ascertain the purpose for which the information is required to be given.* [Emphasis added][973]

Such authority may well go against the imposition of a duty of care on UK Biobank Ltd. On the other hand, there are a number of policy arguments that could be asserted in favour of a duty of care, although to date, these have been made out of

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Ignorance: Genetic Information and the Right Not to Know' (1999) 6 European Journal of Health Law 119)

[972] Brownsword R, 'The Ancillary Care Responsibilities of Researchers: Reasonable but not Great Expectations' (2007) 35 JLME 679.

[973] *Caparo Industries plc v Dickman* [1990] 2 AC 605, [1990] 2 WLR 358 [652] *per* Lord Roskill

court and are evident in academic debate and professional guidelines. Significantly, policy considerations are also likely to be shaped by societal and cultural change. Science and technology has rapidly developed and there has been a wealth of professional and academic literature and guidance dedicated to the implications of such progress for participants in terms of feedback of research results.

Policy concerns in context

There is mounting evidence that professionals (biobanks, researchers, technicians) are routinely returning certain 'disclosable variants' (as discussed earlier in this Chapter). Academics have argued that if these practices become commonplace, alongside the lists of findings routinely returned (outlined above), this may create an obligation to look at least for such variants in other contexts such as research.[974] In the future, researchers conducting sequencing may assume responsibility for such findings given the momentum of policies moving towards such an approach and ultimately this could contribute towards a participant's expectation to receive feedback.[975] Notably, empirical literature has highlighted that many individuals wish to receive their incidental findings and individual research results, especially if researchers find something serious.[976] A recent report commissioned by the WT and the MRC found that 'participants showed overwhelming support for the return of health related findings to research participants, particularly where a condition is

[974] Gliwa C and Berkman M, 'Do Researchers Have an Obligation to Actively Look for Genetic Incidental Findings?' (2013) 13 American Journal of Bioethics 41

[975] And whether or not this expectation is 'legitimate' will be the focus of the next chapter in this thesis. This issue was raised by Borry et al in 2013 in their literature review, which aimed at reviewing studies addressing the reasons to participate in biobank studies in order to provide data on the therapeutic misconception/diagnostic misconception in population biobank studies. The review noted that 8 studies found expectation of personal benefit through health-related research, indicating a misunderstanding amongst participants of magnitude. Their review was inspired by the literature on 'therapeutic misconception' which was coined in the 1980's by Appelbaum and Lidz; describing the results of a study on research participants' understanding of the information provided during the recruitment of a psychiatric trial. After receiving information about randomisation and use of placebo as planned in the trial, some participants still were convinced they would receive a treatment appropriate to their condition. Through their misunderstanding of the trial's main features, these participants actually failed to identify the specific aims of the research practice and confused them with the clinical practice: Appelbaum PS, Roth LH, Lidz CW, Benson P and Winslade W, 'False hopes and best data: consent to research and the therapeutic misconception' (1987) 17 Hastings Cent Rep 20. Cited in Nobile H and Borry P, 'Why do participants enroll in population biobank studies? A systematic literature review' (2013) 13 Expert Rev Mol Diagn 35.

[976] Murphy J, Scott J, Kaufman D, Geller, G LeRoy L and Hudson K , 'Public expectations for return of results from large-cohort genetic research' (2008) 8 American Journal of Bioethics 36.
See also: Cited in Wolf et al. 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets.' Genetics in Medicine Special Article (2012) 7.

serious and treatable.'[977] Generally, participants in the report felt that the benefits of feedback outweighed the harms, but the participants wanted to receive the results from someone with medical knowledge and expertise, who could ensure that the finding was followed up effectively (usually a GP or a specialist healthcare professional).[978]

There are also examples of international biobanks (albeit a minority) that provide individual research results to participants. For example, Chapter 2 has highlighted that the Estonian Genome Project[979] allows participants to access their 'genetic data, hereditary characteristics and genetic risks obtained as a results (sic) of genetic research.'[980] The Human Genes Research Act 2000 (which created the Project) also explicitly recognises a participant's right not to know about their genetic data.[981]

In the literature, discussion has now progressed to consideration of how such results should be fed back and by whom.[982] Some authors have argued for the responsibility of researchers,[983] while others argue for the responsibility of the biobank itself.[984] It has been suggested that there may be an 'intermediate'[985] researcher duty of care, distinct from that of physicians:

> [G]rounded on the 'subject's vulnerability and entrustment of her well-being to the researcher… The challenge is to reformulate the duties of researchers themselves toward research participants in light of important clinical information that researchers may discover…[986]

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[977] Opinion Leader, 'Accessing Public Attitudes to Health Related Findings in Research' (Wellcome Trust, April 2012) <www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtvm055196.pdf> accessed 19 November 2013.
[978] Ibid. 'Executive Summary' 5
[979] Estonian Genome Project 'Gene Donor Consent Form' <http://www.geenivaramu.ee/en/> accessed 4 September 2013
[980] Zawati MH and Rioux A, 'Biobanks and the Return of Research Results: Out with the Old and In with the New?' (2011) 39 JLME 615.
[981] Human Genes Research Act 2000, s 11(1).
[982] Wolf SM and others, 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets' (2012) 14 Genet Med 361.
[983] Wolf SM, Paradise J and Caga-anan C 'The Law of Incidental Findings in Human Subjects Research: Establishing Researchers' Duties' (2008) 36 JLME 361, 364
[984] Wallace S and Kent A, 'Population Biobanks and Returning Individual Research Results - Mission Impossible or New Directions?' (2011) 140 Human Genetics Journal 395.
[985] Richardson HS and Belsky L, 'The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking about the Clinical Care that Researchers Owe to their Subjects' (2004) 34 Hastings Centre Report 25.
[986] Ibid

Richardson and Belsky argue that participant vulnerability and researcher 'fiduciary duties' mean researchers owe a limited duty of 'ancillary care' (care beyond that required to carry out the research safely). The authors argue that when research participants entrust otherwise private information to a researcher, or provide researchers access to some aspect of the participants body, this 'partial entrustment' carries with it certain researcher duties including the duty to offer back information discovered of clinical importance.[987] In the same way, Miller et al[988] argue that the researcher's ethical obligation to return incidental findings is based on the researcher's professional relationship with the participant, privileged access to private information about the participant, and discovery of an incidental finding bearing on the participant's health.[989]

On the other hand, Illes et al[990] maintain that researcher duties to manage and offer the return of incidental findings flow from ethical duties to respect participant autonomy and interests. They suggest that researchers, whose work depends on the generosity of research participants and their willingness to be part of research, bear a duty of reciprocity. Accordingly, Kohane et al[991] argue that offering discoveries back to individual research participants allows them to be 'partners in research rather than passive, disenfranchised purveyors of biomaterials and data.'[992] Commentators have also argued that the depth of the relationship between the researcher and the participant should determine whether or not results are fed back:[993]

> Researchers have a stronger moral responsibility to engage with a fuller range of participants' needs when the relationship is deeper.[994]

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[987] Ibid.
[988] Miller FG, Mello MM and Joffe S, 'Incidental findings in genomic research: what do investigators owe research participants?' (2008) 36 JLME 271. Cited in Wolf SM and others, 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets' (2012) 14 Genet Med 361, 7
[989] Ibid.
[990] Illes J, Kirschen MP, Edwards E and others, 'Ethics: Incidental findings in brain imaging research' (2006) 311 Science 783. Cited in Wolf SM and others, 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets' (2012) 14 Genet Med 361.
[991] Kohane IS, Mandl KD, Taylor PL, Holm IA, Nigrin DJ and Kunkel LM, 'Medicine; Re-establishing the researcher-patient compact' (2007) 316 Science 836.
[992] Ibid. Cited in Wolf SM and others, 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets' (2012) 14 Genet Med 361.
[993] Ravitsky V and Wilfond BS, 'Disclosing individual genetic results to research participants' (2006) 6 Am J Bioethics 8. Cited in Wallace S and Kent A, 'Population Biobanks and Returning Individual Research Results - Mission Impossible or New Directions?' (2011) 140 Human Genetics Journal 395.
[994] Beskow LM and Burke W, 'Offering individual genetic research results: Context matters' (2010) 2 Sci Trans Med 38cm20.

Conversely, when the relationship is more distant this can mitigate the obligation to return results, and Wallace and Kent[995] refer to 'the case of a healthy volunteer's data in a population biobank being used by a 'secondary researcher.'' The latter are defined as those researchers who are not involved in the original project but are '…accessing the data through managed data access mechanisms'[996] (much like researchers granted access to UK Biobank). The authors argue that the relationship between a secondary researcher and a participant is often too physically distant from the research that is taking place in another constitution or country, and furthermore, the secondary research project may take place long in the future, 'creating a gap between the time of joining the biobank and the time of discovery.' [997]

On the other hand, Knoppers et al have argued for the imposition of a duty on researchers accessing large-scale population biobanks like UK Biobank, rather than the biobank institution itself:

> It is for this very purpose that large population biobanks were funded: to provide reliable, baseline data for more specific research in the future. Imposing the return of results that is applicable in disease research or clinical trials into the broader resource mission of population biobanks will undermine their longitudinal goals (to say nothing of the creation of untoward legal liability.) Most importantly, it would create unrealistic expectations and harm the credibility and transparency of population biobanks.

There is also a growing body of literature arguing for direct responsibility for the management of incidental findings on the part of biobank institutions. Most notably, a project funded by the National Institute of Health recently recommended that where re-identification of individual contributors is possible, biobanks should work to enable the biobank to discharge four core responsibilities:

1) Clarify the criteria for evaluating findings and the roster of returnable findings;

2) Analyse a particular finding in relation to this;

3) Re-identify the individual contributor; and

[995] Wallace S and Kent A, 'Population Biobanks and Returning Individual Research Results - Mission Impossible or New Directions?' (2011) 140 Human Genetics Journal 395.
[996] UK10K Project (2010) cited in ibid.
[997] Wallace S and Kent A, 'Population Biobanks and Returning Individual Research Results - Mission Impossible or New Directions?' (2011) 140 Human Genetics Journal 395.

4) Re-contact the contributor to offer the finding.[998]

The special article recommended:

> Findings that are analytically valid, reveal an established and substantial risk of a serious health condition, and are clinically actionable should generally be offered to consenting contributors.[999]

In addition, moral arguments have been made for imposing a duty on UK Biobank to feedback incidental findings to those participants with a 'reasonable expectation' of such information.[1000] Brownsword starts from the hypothetical that a participant in a research trial claims to have a reasonable expectation of ancillary-care advice or assistance[1001] from the research team; 'a novel claim' for 'ethicists and lawyers alike:'

> In the absence of express undertaking or bespoke legal support, (of the kind that simply does not currently exist), how might such a claim be made out… If there is no… immediate anchoring point in practice, what then? The claimant might, in good faith, have the relevant expectation, but this is little more than a *de facto* expectation. On what basis is the claimant's expectation to be presented as reasonable?[1002]

Brownsword articulates the following four-stage test, which is helpful to the analysis of the balance of benefits and burdens that the courts would be engaged in:

i) Is A in a position to assist B?

ii) Does A have the capacity to assist B in any material respect?

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[998] Wolf SM and others, 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets' (2012) 14 Genet Med 361.
[999] Ibid.
[1000] Brownsword R, 'The Ancillary Care Responsibilities of Researchers: Reasonable but not Great Expectations' (2007) 35 JLME 679.
[1001] Which include the 'responsibility to advise or assist participants who have medical condition X in circumstances where the research concerns medical condition Y, and the research did not contribute to the presence of condition X in participants, nor did the having of condition X contribute to the research.' Ibid. 679
[1002] Ibid. 680: Brownsword notes that the case is 'easily made out' (1) if the relevant undertaking (assuring advice, assistance, or treatment) has been given prior to enrolment; (2) if it is an explicit term of the contract to participate; or (3) if the responsibility to offer such ancillary care is generally acted upon as a matter of common custom and practice.
Regarding the latter, Brownsword was writing in 2007 and it is submitted that potentially the claim is more easily made out today, in light of recent trend towards disclosure of incidental findings.

iii) Even though A is in a position to assist B and has the relevant capacity, would the burden of responsibility on A be unreasonable relative to A's own essential interests?

iv) Even though A is in a position to assist B, has the relevant capability, and the imposition of responsibility on A would not be unreasonable (relative to A's essential interests), would B be taking unfair advantage of A if A were required to assist B?[1003]

Brownsword maintains that UK Biobank is 'plainly' in a position to assist volunteer participants and has information that is material to the health and well-being of a participant. Indeed, the submission in earlier sections of this chapter has been that UK Biobank is in a privileged position with regard to the types of research projects granted access to the resource and by extension the kinds of findings that may arise. Furthermore, UK Biobank has the capability to disclose the information, as acknowledged in its EGF and proven by the recent re-contact of individuals for the second phase of assessment.[1004] Finally, there is no implication of 'free-riding or the like' because 'Biobank participants receive no significant material or financial inducement) and their participation is essentially public spirited.' This leads Brownsword to the conclusion that 'seemingly, then, the Biobank has a prima facie background obligation to feedback to participants important personal medical information where it happens to have it.'[1005]

To summarise, an apparent shift in attitudes towards feedback of findings in the research context could pervade the courts in the future. It is arguable that given the intentional reflexivity of the EGF, UK Biobank's policy towards feedback of incidental findings could be reviewed to reflect this developing landscape. Despite international policies supporting an ethical and legal duty to return,[1006] the latest

[1003] Brownsword questions: 'What are the responsibilities of researchers in relation to such findings should they inform participants? If they didn't, could they be liable in breach of contract or tort? Would any guidance to researchers be susceptible to judicial review?' Ibid.
[1004] For Brownsword, while the burden is 'more than trivial,' it 'falls a long way short of being unreasonable' because 'this is just the kind of special pleading that the community [of rights] has neutralised by tying the notion of essential interests to those basic interests shared by all agents.' Ibid.
[1005] Ibid.
[1006] Knoppers BM and Kharaboyan L, '"Deconstructing" Biobank Communication of Results' (2009) 6 SCRIPTed 677, 684.
For example: UNESCO International Declaration on Human Genetic Data 2000, Article 10 indicates that there is a right to be informed of results during research:
'When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the

guidelines published in 2014 by the WT and the MRC (two of UK Biobank's main funders and drivers of the project – Chapters 3 and 4) suggest that the fact that UK Biobank has a policy on feedback of findings is enough.[1007]

The issue of feedback has not escaped the attention of the UK Government and in a seminar given in Oxford in 2014 the Minister for Life Sciences indicated that this was an impending matter for Parliament and legislation is envisaged for the future.[1008] It was suggested that Government intends to move towards a 'participant empowerment' model; whereby participants are contractually empowered to consent to participation in research and therefore entitled to feedback. Indeed, this would be in line with progress in the medical context, which has moved towards a patient centric rather than professional standard of care for informed consent.[1009]

7.4 Conclusion

Since its establishment, UK Biobank has developed policies designed to facilitate the return of 'serious' findings discovered during the course of imaging scanning. However, UK Biobank's broad no-feedback policy is yet to be amended in the context of genetic research, despite the likelihood of such findings during the course of research and an increasing trend to return certain genetic information in light of 'lists' that are being developed on the ground. The extent to which this approach is sustainable in the future is therefore questionable.

The purpose of this chapter has been to investigate whether the private law of negligence could pertain to UK Biobank Ltd as an avenue of accountability for the

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person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in such a research. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results.'

In addition, the Oviedo Convention states:

'Everyone is entitled to know any information collected about his or her health.

This is a right to know all information that is collected about an individual's personal health: Whether it be a diagnosis, prognosis or any other relevant fact.'

The Convention also acknowledges that 'the wishes of individuals not to be so informed will also be observed,' but interestingly this may be overridden as it 'may be of vital importance for patients to know certain facts about their health, even though they have expressed the wish not to know them.' However, the UK is yet to sign and ratify this Convention, so the legal effect of the Convention on the UK (and UK Biobank) questionable.

[1007] Medical Research Council and Wellcome Trust, *Framework on the feedback of health-related findings in research* (MRC, March 2014) <www.mrc.ac.uk/documents/pdf/mrc-wellcome-trust-framework-on-the-feedback-of-health-related-findings-in-researchpdf/> accessed 09 July 2015.

[1008] George Freeman MP speaking at Oxford Seminar Series on Genetic Privacy (2014)

[1009] *Montgomery v Lanarkshire Health Board* (2015) UKSC 11 [2015] 2 WLR 768.

protection of participant interests in knowing about serious findings relevant to their health. In sum, a participant would have to overcome significant hurdles to prove that UK Biobank Ltd ought to be liable for its failure to feedback. First, the harm in question would have to be characterised as the physical injury suffered as a result of the manifestation of a risk, which was not disclosed by UK Biobank, but was foreseeable so as to be actionable.

Second, omissions are generally more difficult to recover damages for in negligence. To augment a failure to warn of such risks from a 'mere omission' an additional feature is required. In the context of imaging scans this may be provided by the proximity of the radiographer, and the pathways in place for validation of serious findings, as well as the procedures put in place by UK Biobank for return of such results, which may or may not constitute an assumption of responsibility. On the other hand, such proximity is difficult to establish in the context of genetic research, where, theoretically, researchers who discover 'serious' findings could be based on the other side of the world and have no obligation to return such information according to the terms of their MTA with UK Biobank Ltd. Finally, there are significant policy issues associated with the imposition of liability on an institution like UK Biobank; set up with a public good mission and (partly) funded by public money such that UK Biobank Ltd may arguably be characterised as a 'public body'. However, international and professional guidelines suggest that the landscape for the return of results is changing, and a position of no return of research results is arguably becoming increasingly untenable.

Indeed, there is currently limited protection for UK Biobank participants who may be at risk of serious, treatable diseases. UK Biobank's negative feedback policy, combined with the absence of a legislative backdrop (Chapter 4) and significant hurdles to legal mechanisms for liability at common law, leave participants poorly protected from this kind of risk. In the absence of statutory guidelines or a contractual agreement, a participant of UK Biobank may use the tort of negligence to try and further their interests in feedback of serious research results. However, on the basis of analysis of precedent for novel duty of care scenarios, this claim would be fraught with hurdles and difficulties.

Alternatively, the next chapter will discuss the potential of a remedy in public law for the protection of a participant's interests in the running of UK Biobank, including the prevention of harm as a result of failure to feedback research results.

Chapter 8: UK Biobank Ltd: Quasi-Public Body for the Purpose of Administrative Law

8.1 Introduction

Summary of issues

A number of conclusions have been drawn in the preceding chapters of this thesis that are instrumental to the present chapter's analysis of public law. Analysis so far has concluded that UK Biobank Ltd has the power to make decisions that could adversely affect participants, individuals and the general public interest and that the

private legal structure of UK Biobank as a charity company calls into question the public accountability of UK Biobank Ltd. Chapters 6 and 7 have also shown that it is unlikely that UK Biobank donors' interests in protection from personal harm would be upheld in private company, charity and negligence law. With these conclusions in mind, this chapter analyses the applicability of public law to UK Biobank Ltd's discretionary power, to explore whether public law could provide a remedy for individual donors to hold UK Biobank accountable to its public mission and protect their interests. In other words, the chapter investigates whether the power that UK Biobank exercises is 'public' so as to give rise to remedies in public law.[1010]

The public law remedy is worth exploring because it offers a range of alternative potential methods for 'controlling' the exercise of power by a body, such as UK Biobank, that purports to operate in the public interest. Although it should be noted that, as alluded to in Chapter 1, public law proceedings may also be used to defend private interests, as in human rights proceedings for instance.

Of the most notable powers of the Administrative Court, it can quash decisions, issue injunctions, and impose duties and standards of good administration on decision makers.[1011] If UK Biobank is deemed to be a public body, this would place all of its formal policy decisions and day-to-day activity in the public realm.[1012] As a result, an interested party could bring judicial review proceedings against one of its decisions or managerial acts. Indeed, at the heart of administrative law is the concept of accountability; which includes the notion that individuals affected by decisions should have the ability to call to account those responsible for those decisions to the rule of law.[1013] However, to be susceptible to public law proceedings and the enhanced legal obligations required under administrative law, various procedural

[1010] Theoretical questions around public power will be raised in the last section of this chapter; i.e. even if not found to be a public body exercising public functions, UK Biobank's power is public and therefore ought to be subject to heightened duties of administration, as was the approach pre- O'Reilly case law: *O'Reilly v Mackman* [1983] 2 AC 237 (1982)

[1011] Borrie G , 'The Regulation of Public and Private Power' [1989] Public Law 552.

[1012] Capps B, Campbell V and Meulen R, 'Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good' (Commissioned Report, UK Biobank 2008) < http://egcukbiobank.org.uk/meetingsandreports> accessed 26 January 2016.
Importantly, by bringing questions of human rights to the fore, arbitration by independent Judges in regard to both UKB's policies and the Government's demands will be initiated. This would mean that criticisms of UKB will be aired in public courts; exposing unjustified policies (on the part of UKB) and challenges (on the part of government authorities) at the highest level.

[1013] Gamble A and Thomas R, 'The Changing Context of Governance: Implications for Administration and Justice' In Alder M, *Administrative Justice in Context* (Hart 2010), 19

hurdles have to be overcome. Above all, UK Biobank must first be deemed a 'public' body or a body that 'functions' as a public body. As a charitable company limited, it is not certain whether or not this is the case given the 'private' nature of this legal structure. Of necessity, therefore, this chapter analyses the detail of public law.

Summary of arguments explored

The first section of this chapter will analyse the arguments for and against UK Biobank's characterisation as a public body. In both judicial review and human rights jurisprudence examples have arisen of 'non-public' bodies that challenge our understanding of the legal question; 'what constitutes a public body'? Three analytical approaches to this question have underpinned judicial review and human rights jurisprudence. First, the landmark case *R v. Panel on Takeovers and Mergers, ex p. Datafin Plc* (*Datafin* hereafter)[1014] prioritised the importance of the nature of a public function, over the source of a body's power. The regulatory function of the body in question was determinative of its 'publicness'. Later, this was modified by the 'but-for' test: 'power will be public if exercised pursuant to the carrying out of a function in circumstances where, in the absence of a non-governmental body to perform the function, the government itself would almost invariably carry out the function.'[1015]

In the context of human rights, two further approaches have emerged. The majority in the leading case of *YL v Birmingham City Council* adopted the 'severability thesis'.[1016] This distinguishes and separately considers public bodies' 'functions' (s.6(3)(b) HRA) and 'acts' (s.6(5) HRA). In *YL*, the private company charged with providing the public service of housing provision was deemed not to function as a public body because the nature of the act in question (termination of a tenancy) was a private one. Alternatively, the 'continuum thesis' recognises the interrelatedness of functions and acts and this was the prevailing approach in the more recent case of

[1014] *R v Panel on Take-overs and Mergers, ex parte Datafin plc.* [1987] QB 815, [1987] WLR 699, [1987] 1 All ER 564
[1015] Campbell C, 'The Nature of Power as Public in English Judicial Review' (2009) 68 Cambridge Law Journal, 92
[1016] *YL v Birmingham City Council (Secretary of State for Constitutional Affairs intervening)* [2007] UKHL 27 [2008] 1 AC 95 [23] Lord Scott; [129] Lord Neuberger

Weaver v London and Quadrant Housing Trust [2008].[1017] Significantly, all three approaches can be found in the *YL* case; the continuum thesis underpins Lord Bingham's leading dissenting judgment, and the prioritisation of a body's public function was a moot point for Elias LJ.

Thus, the question 'what constitutes a public body' is unresolved.[1018] While there exists three differing jurisprudential models for how to understand this legal question, in this chapter the analysis and application of each will demonstrate that UK Biobank Ltd also does not fit neatly within this framework. Nevertheless, it is arguable that UK Biobank Ltd is a timely example of a quasi-public body that challenges the definitional boundaries of 'public' and 'private'. If the reasoning of leading decisions in *Datafin, YL* and *Weaver* are applied, it is submitted that there are strong legal arguments to conclude that UK Biobank Ltd has a sufficiently public nature to be deemed a public body for the purpose of judicial review and the HRA. This conclusion is based on evidence from UK Biobank's Ltd's constitution, together with the significant public investment and Government involvement in UK Biobank, and crucially, UK Biobank's public good mission.

Therefore, once it has been established that UK Biobank could be a public body, Part 2 of this chapter will proceed to analyse the potential grounds for challenge of UK Biobank Ltd's discretion; first under judicial review and next, human rights.

First, in English law, the role of the courts in judicial review is to test the legality, not the merits, of a public body's decision. Under Part 54 of the Civil Procedure Rules, judicial review is a claim regarding a decision, action or failure to act in relation to the exercise of a public function.[1019] Classically, judicial review is a remedy of last resort to be used when all other mechanisms for challenging an administrative decision have been exhausted.[1020] As a residual remedy, judicial

[1017] Weaver v London and Quadrant Housing Trust [2008] EWHC 1377 (Admin), [2009] 1 All ER 17
[1018] Allison contends that 'due to the lateness and limited extent of administrative centralisation in England, there does not exist in English law a 'prevailing and well-developed theory of the state' appreciative of the distinctness of the administration and its role.' Allison JWFA, *Continental Distinction in the Common Law* (revised edn, Oxford 2000), 72
[1019] *Associated Provincial Picture Houses v Wednesbury Corporation* [1948] 1 K.B 223, [1947] 2 All ER 680.
[1020] However, time limits for a judicial review claim are shorter (2-3 months) than for private law actions. This practical pressure may require a claimant to bring a judicial review claim first, and it may be unreasonable for the courts to deny this: Law Commission, *Administrative Redress: Public Bodies and the Citizen* (Law Com No 322, 2010), 2.19

review applicants have to overcome a number of arduous obstacles. In particular: claimants must seek the court's permission for a hearing;[1021] show the case is of a public law nature;[1022] and demonstrate that they have an arguable case and standing.[1023] Currently, the standing rules for judicial review are wide,[1024] and the 'sufficient interest' test[1025] has been interpreted by the courts as including cases where it is in the public interest for an issue to be examined.[1026]

The decisions and day-to-day running of UK Biobank may impact a number of different stakeholders, for example: donors, researchers, wider interest groups such as NGO's, and the Ethics and Governance Committee. So, could an aggrieved researcher bring judicial review proceedings against a decision to refuse them access to the resource? Or, could an interested party challenge a decision to grant access to a private company with dubious commercial intentions? What if the biobank was forced to close, or was sold, perhaps for reasons of bankruptcy? Could a sale to a private company be reviewable?

More recently, the Human Rights Act 1998 has imposed an additional ground of action in public law; making it unlawful for public bodies to act incompatibly with Convention rights.[1027] While judicial review cases are concerned with the question of whether bodies are under duties of legality, fairness and rationality in their decision making, the HRA adds direct 'vertical'[1028] duties to act compatibly with Convention rights. Following analysis of the traditional administrative law grounds for review, this chapter will subsequently consider how far UK Biobank's no feedback policy

[1021] Civil Procedure Rules Part 54.4
[1022] Senior Courts Act 1981 s. 31; *O'Reilly v Mackman* [1983] 2 AC 237 (1982)
[1023] *R v Inland Revenue Commissioners ex parte National Federation of Self-Employed & Small Businesses Ltd* [1982] AC 617, [1981] 2 WLR 722; *R v Inspectorate of Pollution, Ex parte Greenpeace Ltd (No. 2)* [1994] 4 All ER 329, [1994] Env LR 76
[1024] However, it is notable that the current Government is seeking ways to reduce the breadth of these rules: Ministry of Justice, *Judicial Review: Proposals for further reform* (White Paper, Cm 8703, 2013).
[1025] The Senior Courts Act 1981 s. 31(1) requires that the court should not grant leave for an application for judicial review to be made unless the court 'considers that the claimant has a sufficient interest in the matter to which the application relates'. This was interpreted widely in *Greenpeace v Commission* (Case T-585/93) [1995] ECR II-02205, which reinforced that an individual bringing an action does not need to be directly affected by the decision.
[1026] *R v Secretary of State for Foreign and Commonwealth Affairs, ex p Lord Rees-Mogg* [1994] QB 552
[1027] The Human Rights Act 1998 s. 6(1) states 'It is unlawful for a public authority to act in a way which is incompatible with a Convention right.'
[1028] Oliver D, 'The frontiers of the State: public authorities and public functions under the Human Rights Act' [2000] PL 476, 8

could be challenged as incompatible with Convention rights such as Article 2 and the right to life, or Article 8 and the right to private and family life. For example, a challenge might be made by a donor who, after being diagnosed with a life threatening illness which could have been disclosed during the participation process, claims such non-disclosure is a breach of their human rights. Taken one step further, could Biobank's no-feedback policy be reviewable in its entirety? This discussion will be informed by the growing body of literature which argues for disclosure of 'incidental' findings on the grounds of human rights.[1029]

Finally, this chapter will raise wider theoretical questions regarding the appropriateness of the 'public'/'private' divide for the purpose of judicial review. Dawn Oliver's scholarship on the potential 'horizontal effect' of administrative justice is applied to consider the reasons why, even if UK Biobank is not recognised as a public body, administrative law principles ought to be applicable to the management of the resource. As a closing remark, this section invites critical reflection on the relevance of the public/private distinction in the case of UK Biobank at all, given the reality of its incorporation as company and rhetoric of its public good mission.

8.2 Is UK Biobank Ltd a Public Body?

Bearing in mind the traditional definitional boundaries between public and private law that have been outlined in this thesis (Introduction), in order to fall subject to public law, UK Biobank must be proven to be sufficiently 'public' and acting in a public rather than private law capacity. However, as will be shown in this chapter, these boundaries are increasingly blurred and there are a number of arguments in the literature that consider how public values may be upheld in private law. Potentially, such arguments may suggest that this dichotomy may not be appropriate in the context of UK Biobank as a corporation with a public mission.

In the abstract, there are a number of factors that may suggest that this is the case. Despite its lack of statutory footing, it can be argued that UK Biobank sets itself up as delivering a public good, only conducting research that is in the 'public

[1029] As discussed in Chapter 7 of this thesis.

interest'.[1030] It is recalled from Chapters 3 and 4 that the funders of the project were conscious of the importance of organising UK Biobank as a resource belonging primarily to the public domain; to inspire public confidence and maintain public trust. This was no doubt informed by the experience of the Icelandic database and controversies surrounding commercialisation in privately owned biobanks, and the impossibility of specific consent in long-term, large-scale population databases that are created without specific research purposes in mind.[1031]

On the other hand, analysis in Chapters 3 and 4 has illustrated that the decision to incorporate UK Biobank Ltd as a private charitable company was also made to safeguard and justify the significant public and private financial investment in the project, as well as to emphasise Biobank's independence from its funders (public and private) via its separate legal personality.

However, UK Biobank collects samples and data from the public, stores both, and allows access by public and private bodies on the grounds of the public good.[1032] Whether and to what extent these factors prove UK Biobank to be 'public' will now be considered for the purpose of 1) public law and judicial review; and 2) human rights.

8.2.1 The changing face of a 'public body'

Judicial review is only actionable against public bodies or, more broadly, bodies exercising public functions. Part 54.1(2)(a) of the Civil Procedure Rules defines a claim for judicial review as a claim to review the lawfulness of: (i) an enactment or (ii) a decision, action or failure to act in relation to the *exercise of a public function*. Additionally, section 6(1) of the HRA states that it is unlawful for a public authority to act incompatibly with the Convention rights and section 6 (3)(b) includes within

[1030] 'UK Biobank will ensure that only those who are bona fide researchers working on health related research in the *public interest* get access to the valuable information and data.' UK Biobank 'UK Biobank in the news' (*UK Biobank*) <http://www.ukbiobank.ac.uk/2012/04/uk-biobank-in-the-news-2/> accessed 1 January 2015

[1031] As described in Chapter 2 of this thesis

[1032] Capps B, Campbell V and Meulen R, 'Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good' (Commissioned Report, UK Biobank 2008) < http://egcukbiobank.org.uk/meetingsandreports> accessed 26 January 2016, 24: For the authors this is proof that UK Biobank certainly isn't acting for private interests: 'it is fairly certain that UK Biobank is not performing a private function.'

its scope 'any person certain of whose functions are functions of a public nature.'[1033] In practice, these provisions have created 'hybrid' categories of partly private, partly public organisations, for reasons that will be explored herein. Beyond this, however, there is not yet a definitive legal test as to what constitutes a public body or public functions, and an incremental and contextual approach has pervaded. This drift of public law into the private arena has occurred because the focus of administrative law has shifted from controlling the institutions of government, to controlling the exercise of functions of governance, and now '[t]he boundaries of administrative law are set by a messy combination of functional and institutional markers.'[1034]

Traditionally, administrative law was understood institutionally;[1035] in terms of the organs and agencies of central and local government. So, administrative law was seen as being concerned with judicial control of government decision-making.[1036] Through the 1970's and early 1980's administrative law developed and formalised a 'new' remedy in judicial review.[1037] A clear divide was drawn between public and private law via Order 53 of the Rules of the Supreme Court 1977. In effect, this meant that from this point, a public law claim had to be brought via judicial review. This was confirmed in s. 31 of the Senior Courts Act and emphasised in *O'Reilly v Mackman,*[1038] in which Lord Denning M.R stated that an Order 53 application 'should be the normal recourse in all cases of public law where a private person is challenging the conduct of a public authority or a public body, or of anyone acting in the exercise of a public duty.'[1039] Applicants could not originate their action under the general civil law procedure because that would allow them to avoid the procedural safeguards that are afforded to public authorities by the judicial review procedure (i.e. sufficient interest, time and permission).

[1033] Although s. 6(5) states; 'in relation to a particular act: a person is not a public authority by virtue only of s.6 (3)(b) if the nature of the act is private.'
[1034] Cane P, *Administrative Law* (4th edn, OUP 2004), 26
[1035] Ibid.
[1036] Ibid. 4-5
[1037] It is arguable whether judicial review existed before Order 53 of the Rules of the Supreme Court 1977: Williams D, 'Administrative Law in England: The Emergence of a New Remedy' (1986) 27 Wm & Mary L Rev 715.
[1038] *O'Reilly v Mackman* [1983] 2 AC 237 (1982)
[1039] Ibid [256]

Shortly after this time of procedural change, a notably functional[1040] approach was taken to the question of whose decisions ought to be reviewable in the *GCHQ* case.[1041] This case ruled that the reviewability of decisions should depend not on the source of the power to make the decision, but instead on the substance or *nature* of that decision.[1042] Therefore, decisions of central government were reviewable by the courts according to the principles of administrative law, regardless of whether the power to make the decision was given by statue or Royal Prerogative. *R v. Panel on Takeovers and Mergers, ex p. Datafin Plc*[1043] followed this approach. The Panel was a body established by the Stock Exchange but the court held that decisions of the Panel were subject to judicial review, on the basis that the Panel was performing regulatory functions of public importance that significantly affected the interests of individuals, and because its activities were embedded in a framework of statutory regulation of the financial services industry. If the Panel had not existed it was likely that the government would have established a statutory body to do its work instead. Therefore, the Panel was a public body for the purpose of judicial review.

8.2.2 Regulatory functions for judicial review

Focussing on the regulatory functions of the Panel, the Court of Appeal held that this 'governmental' private body's decisions should be reviewable because it was engaged in 'self-regulation' of financial activities and the court was concerned with the 'monopolistic regulation of an industry'.[1044] In so doing, the court rejected the suggestion that judicial review was only available in respect of statutory or prerogative powers and extended protection to self-regulatory bodies exercising public discretion:

> Self-regulation is an emotive term. It is also ambiguous. An individual who voluntarily regulates his life… [is] practising self-regulation. But it can… [also] connote a system whereby a group of people… use their collective power to force

[1040] Cane P, *Administrative Law* (4th edn, OUP 2004), 26

[1041] *Council of Civil Service Unions v Minister for the Civil Service (GCHQ case)* [1985] AC 374, [1984] 3 WLR 1174
The case reached the House of Lords and then later was appealed to the Court of Appeal whose functions were changed by the 'Bowman Review': Jacob JM, 'The Bowman Review of the Court of Appeal' (1998) 61 MLR 390.

[1042] Ibid.

[1043] *R v Panel on Take-overs and Mergers, ex parte Datafin plc.* [1987] QB 815, [1987] WLR 699, [1987] 1 All ER 564

[1044] Garton J, 'The judicial review of the decisions of charity trustees' (2006) 20 Trust Law International 160.

> themselves and others to comply with a code of conduct of their own devising. This is not necessarily morally wrong or contrary to the public interest, unlawful or even undesirable. But it is very different.[1045]

The Court noted the 'abundance' of 'invisible' legal support the Panel received and deemed the Panel to be performing a 'public function' that was therefore reviewable under Part 54.4 of the CPR:

> The panel is… performing its function without visible means of legal support. But the operative word is 'visible'… invisible or indirect support there is in abundance… As an act of government it was decided that… there should be a central self-regulatory body which would be supported and sustained by a periphery of statutory powers.[1046]

Potentially, UK Biobank's Ethics and Governance Framework is evidence that UK Biobank is exercising the kind of self-regulation that the courts had in mind in *Datafin*. Although the Framework operates within UK Biobank's multi-faceted regulatory environment, this thesis has illustrated that UK Biobank Ltd still has wide-ranging discretionary powers to manage the resource. The Framework was established by the funders of UK Biobank[1047] (including the WT, the MRC and the DH) who were aware that the project raised a number of ethical concerns as a 'living', self-regulatory governance tool; to ensure that safeguards are in place for scientifically and ethically approved research and to assist in the day-to-day management of UK Biobank by outlining Biobank's relationship with i) participants; ii) researchers; and iii) society. The Framework was also a means of inspiring public trust in the governance of UK Biobank, by instilling confidence in Biobank participants that the resource made up of their samples would not be used in a manner contrary to their interests and consent.

A common concern of the court in *Datafin* was preventing abuse of the wide discretionary powers that the Panel possessed:

> Is… this remarkable body… above the law… I do not doubt… that it is intended to and does operate in the public interest and the enormously wide discretion which it

[1045] *R v Panel on Take-overs and Mergers, ex parte Datafin plc*. [1987] QB 815, [1987] WLR 699, [1987] 1 All ER 564, [824] *per* Sir John Donaldson MR
[1046] Ibid.
[1047] UK Biobank 'Ethics' (UK Biobank) <http://www.ukbiobank.ac.uk/ethics/> accessed 27 February 2015

> arrogates to itself is necessary if it is to function efficiently and effectively… in the public interest. But that said, what is to happen if the panel goes off the rails? Suppose, perish the thought that it were to use its powers in a way which was manifestly unfair. What then?[1048]

In *Datafin*, the Counsel for the Panel submitted in response that the Panel would lose public support in the financial markets and would be unable to operate. Perhaps the same would be true of UK Biobank. Each participant possesses the right to withdraw at any time[1049] and in the unfortunate event of controversy participants may act on this right to the detriment of the project. No doubt, the EGC could act upon its power to make such a breach public, causing reputational damage to the project.[1050]

Furthermore, in *Datafin*, decisions of the Panel were subject to judicial review on the basis that their regulatory functions were of public importance and significantly affected the interests of individuals. 'Publicness' was further proven by its production of the Code on Takeovers and Mergers. The matters covered by the Code on Takeovers and Mergers were wide-ranging, and the public consequences of non-compliance with the Code were serious for members of the Stock Exchange, a vital national resource, albeit one privately owned. The Panel was therefore deemed to be performing a public duty; acting in the public interest and not their own or their members' interests when administering the Code.[1051]

The same form of argument can be made for UK Biobank, whose EGF explains its commitment as 'the steward of the resource, maintaining and building it for the public good in accordance with its purpose.'[1052] Crucially, in order to be incorporated as a charitable company, the purpose of UK Biobank Ltd had to benefit the public. UK Biobank Ltd's Memorandum of Association outlines its charitable purpose: to 'advance the health and welfare of human beings, and promote

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[1048] *R v Panel on Take-overs and Mergers, ex parte Datafin plc*. [1987] QB 815, [1987] WLR 699, [1987] 1 All ER 564, [824] *per* Sir John Donaldson MR

[1049] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) I.B.6 <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016

[1050] Ibid.

[1051] Oliver D, 'The frontiers of the State: public authorities and public functions under the Human Rights Act' [2000] PL 476, 8. Generally, public bodies are regarded as being under duties to act only in the public interest, as they perceive it to be; 'Above all, they are not regarded as having self-serving interests.'

[1052] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) II. <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016 'Relationship with Research Users; A Stewardship of Data and Samples'.

knowledge and education,'[1053] which falls under s.3(d) of the Charities Act 2011: 'the advancement of health or the saving of lives'. This limits the powers of the Board of Directors, who are 'company directors under company law and charity trustees under UK charity law'[1054] to ensure their discretion is exercised in accordance with UK Biobank's public good mission.[1055]

A separate but related question to the regulatory functions of a public body has subsequently emerged: 'but – for' the existence of the body in question, the functions would have to be performed by a governmental body. Thus, 'but – for' the existence of UK Biobank Ltd, would the government step in and fulfil the role of governing the UK Biobank resource? This was one of the arguments made in the subsequent case of *R v Disciplinary Committee of the Jockey Club, ex p Aga Khan.*[1056] The appellant argued that if the Jockey Club or other private body did not perform its functions, then the government would be obliged to create a body to perform those functions.[1057] The problems with this question are well documented, not least due to the lack of consensus on the normative question of what functions the government should perform.[1058] Therefore, judge's conclusions are often 'ad hoc and unprincipled'; requiring judges to 'rely on their own conceptions of the appropriate role of the government.'[1059] Nonetheless, Beloff and Kerr argue 'the but-for test,

[1053] <www.ukbiobank.ac.uk> accessed 22 February 2015
[1054] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) III.A <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016 'Management and Accountability Board of Directors'. Furthermore, UK Biobank Ltd's 2011 Report and Financial Statements recognised that '...the Directors of the Charity are its Trustees for the purpose of charity law and throughout this report are collectively referred to as the Directors...' UK Biobank Ltd, 'Report and consolidated financial statements' (UK Biobank, 30th Sept 2011), 4 <www.ukbiobank.ac.uk/wp-content/uploads/2011/12/UK-Biobank-Limited-Signed-2011-Report-and-Financial-Statements.pdf> accessed 06 Jan 2016.
[1055] However, 'Factors such as delegation from, or supervision by, a State body, public funding, the public interest in the relevant function or service being provided and the pursuit of the public interest as opposed to a pure commercial interest in profit are not in themselves likely to establish public authority status'; Joint Committee on Human Rights, *The Meaning of Public Authority under the Human Rights Act* (*ninth report)* (2006–07, HL 77, HC 410), 16. Cited in Capps B, Campbell V and Meulen R, 'Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good' (Commissioned Report, UK Biobank 2008), 24 <http://egcukbiobank.org.uk/meetingsandreports> accessed 26 January 2016
[1056] *R v Disciplinary Committee of the Jockey Club, ex parte Aga Khan* [1993] 1 WLR 909
[1057] The appellant was successful in persuading the Court on this particular point, although ultimately the Appeal was dismissed on the grounds that the Jockey Club was not 'in its origin, its history, its constitution or (least of all) its membership a public body' per the Master of the Rolls; and 'the remedies in private law available to the Aga Khan seem to me entirely adequate' *per* Lord Hoffman
[1058] Campbell C, 'The Nature of Power as Public in English Judicial Review' (2009) 68 Cambridge Law Journal, 93
[1059] Ibid.

properly understood, presupposes that no private body would be prepared to undertake the function in question.'[1060] For Campbell:

> It is only by having regard to how the government would act in those circumstances that it can be ascertained whether a function – and power exercised pursuant to the function – is genuinely public.[1061]

Applied to UK Biobank, across Europe many different regulatory approaches have been taken to the governance of large-scale population biobanks. This was the topic of discussion in Part 1 of this thesis. There is debate as to which approach is more or less effective, with many academics concluding that it is not possible to adopt a 'one size fits all' system.[1062] In some instances, countries have found it necessary to establish publically owned biobanks via statutory legislation, such as Estonia and the Human Genes Research Act.[1063] Arguably, a court could be influenced by the statutory alternative and conclude that government intervention is necessary in the absence of UK Biobank Ltd. This is especially conceivable because UK Biobank receives joint funding from a number of institutions that are classified as public bodies, including the Department of Health and the Medical Research Council. Accordingly, it has been argued that UK Biobank is carrying out a duty that the Department of Health or some other government institution would normally do.[1064] Given the public interest mission of the Biobank, it is arguably more difficult to consider the alternative model for UK Biobank; handing over to a commercial company. This is particularly so given the Icelandic database controversy and the

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[1060] Beloff M and Kerr T, 'Why Aga Khan is Wrong' (1996) 1 Judicial Review 30, 30-31

[1061] Campbell C, 'The Nature of Power as Public in English Judicial Review' (2009) 68 Cambridge Law Journal, 95:
'Accordingly, it would be a mistake to hold, purportedly pursuant to the but-for test, that a function was not public, on the basis that the government would not invariably undertake the function, because of the preparedness of a private body other than the respondent to undertake the function. It can hardly be thought that the 'adventitious availability' of a non-governmental body willing to exercise a function would preclude that function being public, especially given that the whole point of the but-for-test is to ascertain whether functions which are exercised by non-governmental bodies may be public.'
Citing Beloff M and Kerr T, 'Why Aga Khan is Wrong' (1996) 1 Judicial Review 30, 31

[1062] As discussed in Chapter 1 of this thesis

[1063] Human Genes Research Act 2000

[1064] Furthermore, UK Biobank is situated within, and works closely with, UK Universities and the Research Ethics Committees that vet the individual projects prior to application to UK Biobank are also firmly within the public realm. Capps B, Campbell V and Meulen R, 'Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good' (Commissioned Report, UK Biobank 2008) < http://egcukbiobank.org.uk/meetingsandreports> accessed 26 January 2016.

concerns that deCODE's private structure raised about the agenda of the functioning of the company.[1065]

This international precedent could be evidence that UK Biobank is performing a regulatory function that is in the public interest, and that 'but-for' its existence the resource may have been managed governmentally. However, there are also important factors that might lead to the conclusion that UK Biobank Ltd is not judicially reviewable. In particular, it could be decided that there are adequate remedies available in private law and therefore, as a residual remedy, public law redress is not necessary. This was the conclusion that was reached in the *Aga Khan* case via breach of contract:

> The Club has an implied obligation under contract to conduct its disciplinary proceedings fairly. If it has not done so, *Aga Khan* can obtain a declaration that the decision was ineffective… and, if necessary, an injunction to restrain the Club from doing anything to implement it. No injustice is therefore likely to be caused in the present case by the denial of a public law remedy.[1066]

As previously mentioned, UK Biobank Ltd's discretionary powers are significantly limited by UK company and charity law, because the Board of Directors act as charity trustees and company directors. Charity law duties owed to the public are enforceable by the State via the Charity Commission, A-G and others as persons interested in charity proceedings.[1067] The Board of Directors owe statutory and fiduciary duties to the company and the charity under charity and company law, and breach of these duties is regarded as a breach of trust, since the relationship between Directors (exercising all the rights of the Company) and the resource is one of fiduciaries over a jointly held resource managed for the public beneficiaries. Charity proceedings may be brought in relation to the administration of a trust for charitable purposes,[1068] but litigants may not rely on charity proceedings to enforce a personal right[1069] such as an action in tort[1070] or for breach of contract or another other right at

[1065] Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80.
[1066] Lord Hoffman in *Aga Khan*
[1067] Ibid.
[1068] Charities Act 2011 s.115(8)
[1069] In *Rooke v Dawson* [1895] 1 CH 480: Here the trust deed provided for the award of a scholarship to the pupil achieving the best performance in an examination. The trustees declined to award the scholarship to the plaintiff, who had obtained the highest mark and who sought a declaration that he was entitled and an order directing the trustees to make him the award. Chitty J decided that, there

common law or equity.[1071] Therefore, an action brought against a Board member (trustee) for breach of their fiduciary duty (perhaps a conflict of interest) during decision-making is likely to fall within the definition of charity proceedings.[1072]

Additionally, the preceding chapter has demonstrated the potential for a negligence claim for failure to disclose incidental findings to a Biobank participant. If an individual has been aggrieved by a decision not to feedback and consequently suffered personal harm, it may be the case that the tort of negligence is a more appropriate means of compensating the individual with damages. In this situation, judicial review would only be a means of inviting the decision maker to retake their decision which, once the harm has been done to the claimant, may not be satisfactory or appropriate. On the other hand, if the claim was to review the policy in its entirety, then it is submitted that public law would be an excellent means of inviting UK Biobank to justify or review its policy; to be dealt with in more detail in the next section of this chapter.

Therefore, depending on the nature of the claim in question, judicial review may not be the appropriate avenue for challenge. Charity and company law supervise the decisions made by the Board regarding access requests etc. and the tort law of negligence could be a means of challenging UK Biobank's feedback policy if causation of harm could be proven. However, in other instances judicial review may offer the only realistic means of challenging the issue in question. In sum, it would be down to the court to decide whether a private law remedy is available and adequate for the purpose of the challenge.

8.2.3 Summary

Politically, *Datafin* was heard at a time of constitutional and institutional reform. The aim was to reduce direct government participation in social and economic life, and encourage 'new public management.' Accordingly, functions that had once been

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being no contract between the plaintiff and the trustees, the formers action was not to enforce a personal right, but rather to enforce the administration of the trusts of the charitable deed. As the Charity Commissioners certificate had not been obtained under the Charitable Trusts Act 1853, s.17, his Lordship held that the action could not proceed, as discussed in Chapter 6 of this thesis.

[1070] *British Diabetic Association v Diabetic Society of Great Britain* [1995] 4 All ER 812, [1996] FSR 1.

[1071] In *Rendall v Blair* [1890] 45 ChD 139 [160], Fry LJ expressed the view that an action to enforce 'an individual equitable right, not relating to the administration of the trusts of the charity' would be outside the Charitable Trusts Act 1853, s.17

[1072] *Construction Industry Training Board v A-G* [1973] Ch 173, [1972] 3 WLR 187.

the province of central and local government were now being performed by private, non-governmental entities;[1073] changing 'the shape of the state.'[1074] This trend has continued to this day and has problematized the definitional boundaries of 'public' and 'private'. Although the basic position is that the judicial process is confined to disputes in public law,[1075] over time, the application of administrative law rules and principles[1076] has expanded due to changes in 'the way the state does its business.'[1077]

Today, reforms on local government,[1078] education,[1079] healthcare[1080] and public services[1081] have continued under the Coalition government[1082] and important questions of the scope of the courts' powers to control the performance of functions by such entities persist.[1083] This is especially reflected in the drafting of section 6 (3)(b) of the HRA, which identifies and brings within the scope of the Act 'hybrid'

[1073] Reform included privatisation of state-owned enterprise such as the gas and electricity industries, and assets such as council houses, promotion and increased regulation of industry self-regulation, for example in the financial services sector, and contracting out of the provision of public services such as waste collection etc.

[1074] Bamforth N, 'Public Law in a Multi-Layered Constitution' (2003) 8 Judicial Review 157: 'Since 1979, the United Kingdom has witnessed privatisation, regulation, deregulation, new public management, the creation of next steps agencies, contracting in the public sector, compulsory competition tendering in local government, public private partnerships, the citizen's charter, and health service reorganisation (to name but a few of the most prevalent initiatives). The tangled interactions between public and private bodies involved in these mechanisms have been further complicated by the operation of divergent patterns of contracting-out and regulation at different constitutional layers. There are increasingly dense networks of accountability within which power is exercised, with state institutions being tied into relationships with the business sector and voluntary and consumer groups in many different ways.'

[1075] Forsyth C, 'The Scope of Judicial Review: 'Public Duty' not 'Source of Power'' [1987] PL 356

[1076] Public law values can be seen in the 'Seven Principles of Public Life' identified by Lord Nolan's Committee on Standards in Public Life: Selflessness; integrity; objectivity; accountability; openness; honesty; leadership: Committee on Standards in Public Life, 'The 7 principles of public life' (the 'Nolan principles', Cabinet Office 1995) <www.gov.uk/government/publications/the-7-principles-of-public-life/the-7-principles-of-public-life—2> accessed 17 September 2014.

[1077] Feldman D, 'Changes in Human Rights' in Adler M (ed), *Administrative Justice in Context* (Hart 2010), 109

[1078] Cabinet Office, 'Building the Big Society' (Cabinet Office 2010) <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/78979/building-big-society_0.pdf> accessed 26 January 2016.

[1079] The 'Free Schools' policy; cited in Carolan E, 'The legitimacy of public service reform: democracy; accountability and experimentalism in the Big Society' [2013] Public Law 240.

[1080] Health and Social Care Act 2012

[1081] Cabinet Office, *Open Public Services* (White Paper, Cm 8145, 2011).

[1082] Carolan E, 'The legitimacy of public service reform: democracy; accountability and experimentalism in the Big Society' [2013] Public Law 240, 1

[1083] For more detailed discussion see Gamble A and Thomas R, 'The Changing Context of Governance: Implications for Administration and Justice' In Alder M, *Administrative Justice in Context* (Hart 2010), 3-23

authorities i.e. authorities which exercise both public and private functions;[1084] thereby adopting a similarly functional approach.[1085]

Consequently, a series of cases brought under the HRA on the implications of this provision have challenged the basic understanding that the judicial review process is confined to disputes in public law. As will be demonstrated, the definition of 'public body' is subtly different under the HRA than the judicial review definition outlined above. However, in the case of *Weaver*[1086] Lord Justice Richards implied that in many cases the answer will be the same whether the case is brought under judicial review or the HRA:

> In so far as a function of [the body in this case] is a public function which makes it a public authority for the purpose of the Human Rights Act 1998, then it seems to me that it should equally be amenable to judicial review on conventional public law grounds in respect of its performance of that function. It would be strange if a function had a public character to engage the application of the 1998 Act yet insufficient to engage the court's normal public law jurisdiction.[1087]

8.3 Section 6 HRA: Public functions; Private acts

Under HRA jurisprudence there are two types of public body; 'core' and hybrid 'functional'[1088] public bodies. These were distinguished in *Aston Cantlow PCC v. Wallbank*[1089] in which Lord Nicholls identified examples of specific authorities 'known' to be public, including: the police, the army, government departments and local authorities.[1090] Core public bodies are public for all purposes and would be

[1084] Although there is academic debate that we have 'witnessed an apparent reiteration of the divisions between public and private institutions at UK level due to the obligations imposed specifically on public authorities by the HRA 1998.' Bamforth N, 'Public Law in a Multi-Layered Constitution' (2003) 8 Judicial Review 157. For discussion of the potential inconsistency between domestic law and the Convention, see: Bamforth N, 'The Application of the Human Rights Act 1998 to Public Authorities and Private Bodies' (1999) 58 Cambridge Law Journal 159.

[1085] The then Home Secretary, Jack Straw, stated that in drafting s.6 of the HRA the Government decided that 'the best approach would be by reference to the concept of a public function.' HC Deb 17 June 1998, vol 314, col 409; cited in Palmer E, 'The Liability of 'Functional Public Authorities' for Breach of ECHR Rights: The House of Lords Endorses a Palpable Gap in Human Rights Protection' (2008) 16 Med LR 141.

[1086] *Weaver v London and Quadrant Housing Trust* [2008] EWHC 1377 (Admin) [2009] 1 All ER 17

[1087] Ibid. [64]

[1088] Mead D, 'The Continuing Mystery of "Publicness" within Section 6 of the HRA' (UK Const Law Assoc Blog, 17th October 2013) <http://ukconstitutionallaw.org > accessed 31 Jan 2016.

[1089] *Aston Cantlow and Wilmcote with Billesley Parochial Church Council v Wallbank* [2003] UKHL 37, [2004] 1 AC 546 (HL) Hereafter *Aston Cantlow*

[1090] Mead D, 'The Continuing Mystery of "Publicness" within Section 6 of the HRA' (UK Const Law Assoc Blog, 17th October 2013) <http://ukconstitutionallaw.org > accessed 31 Jan 2016.

considered public bodies in judicial review as well. Core public bodies must comply with Convention rights at all times, and do not have any Convention rights of their own.[1091] This is because to be a rights-holder one must be a 'victim' under s. 7(1) HRA, which in turn requires one to be a 'person, non-governmental organisation or group of individuals' under Article 34 ECHR (s. 7(7) HRA).

Core public bodies contrast with hybrid authorities, which have both public and private sides and are defined in section 6 (3)(b) as:

> b) Any person certain of whose functions are of a public nature.

In *Aston Cantlow*, the wider reach of the Convention intended in section 6(3)(b) was integral to the decision that the Church was not a core but a hybrid public body. The consequential issue was whether this hybrid possessed, as well as fell subject to, Convention rights.[1092] Lord Nicholls and Lord Hope emphasised that when considering whether bodies fall within the terms of section 6(3)(b), the approach should be more generous than when identifying 'core' public bodies:

> Giving a generously wide scope to the expression 'public function' in s 6(3)(b) will further the statutory aim of promoting the observance of human rights values without depriving the bodies in question of the ability themselves to rely on Convention rights when necessary.[1093]

Certainly, earlier analysis in this chapter points to the conclusion that UK Biobank Ltd does not qualify as a 'core' public body. It is funded by public and private money, it is not created or controlled solely by government, and it is not definitive

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[1091] Recently, the question of whether hybrid public authorities can possess Convention rights was raised in *Olympic Delivery Authority v Persons Unknown* [2012] EWHC 1012 (Ch), [2012] EWCA 1012 in which Arnold J ruled in the affirmative.

[1092]This has been a matter of intense debate in academia as well as in the Court: Mead D, 'The Continuing Mystery of "Publicness" within Section 6 of the HRA' (UK Const Law Assoc Blog, 17th October 2013) <http://ukconstitutionallaw.org > accessed 31 Jan 2016; Williams D, 'Administrative Law in England: The Emergence of a New Remedy' (1986) 27 Wm & Mary L Rev 715.

[1093] At [11]. Indeed, the Joint Committee on Human Rights has since argued that this wide interpretation is necessary to prevent the United Kingdom breaching its own obligations under the Convention: Joint Committee on Human Rights, *The Meaning of Public Authority under the Human Rights Act* 2006–07, HL 77, HC 410). The extent to which the entrenchment of human rights into UK law diminishes the value in a public/private distinction will be commented on in the last section of this chapter. Four of the Law Lords in *Aston Cantlow* seemed to equate the notion of 'public' with 'governmental' (at least in relation to core public authorities) on the basis that the United Kingdom is responsible in Strasbourg for acts of governmental organisations. See [7], [10] (*per* Lord Nicholls), [46–47], [59] (*per* Lord Hope), [87–90] (*per* Lord Hobhouse), [156], [166], [170] (*per* Lord Roger). See also discussion in Palmer E, Public functions and private services: A gap in human rights protection (2008) 6 Int J Constitutional Law 585.

that UK Biobank does not possess its own Convention Rights. In fact, according to the EGF UK Biobank Ltd as the legal owner of the database and sample collection has certain rights, including 'the right to take legal action against unauthorised use or abuse of the database or samples'.[1094] So, the more relevant legal question is whether UK Biobank Ltd is a 'hybrid' public body with both public and private facets.

The problem that has emerged, however, is that the test for hybridity under section 6(3)(b) 'leaves[s] a great deal of open ground.'[1095] For example, there is uncertainty regarding the relationship between section 6(3)(b) and section 6(5); questions of whether either provision carries more weight than the other;[1096] and problems distinguishing between functions and acts.[1097] Policy considerations have been used to justify contrasting approaches between judges, evidenced in bare majority decisions with powerful dissenting arguments and rendering it difficult to know how the courts will decide in the future.[1098] Conceptually, two jurisprudential approaches have emerged and both are demonstrated in the judgments of the leading case of *YL v. Birmingham City Council.*[1099] These are the professed 'severability thesis' and the 'continuum thesis'. These will now be critiqued and applied to evaluate how UK Biobank would be treated in court. Analysis will conclude that if either approach is followed, UK Biobank may fall subject to the heightened administrative and human rights obligations of a public body.

[1094] UK Biobank, *Ethics and Governance Framework* (Version 3.0, UK Biobank 2007) II.A <http://www.ukbiobank.ac.uk/resources/> accessed 26 January 2016. Arguably, a parallel can be drawn with the recent case of *Olympic Delivery Authority v Persons Unknown* [2012] EWHC 1012 (Ch), [2012] EWCA 1012

[1095] [36] *per* Lord Hope.

[1096] Mead D, 'The Continuing Mystery of "Publicness" within Section 6 of the HRA' (UK Const Law Assoc Blog, 17th October 2013) <http://ukconstitutionallaw.org > accessed 31 Jan 2016; Williams A, 'The Scope of Section 6 HRA Revisited' UK Const. L. Blog (*UK Const Law Assoc Blog,* 28th October 2013) <https://ukconstitutionallaw.org/2013/10/28/alexander-williams-the-scope-of-section-6-hra-revisited/> accessed 06 Feb 2016; Mac Amhlaigh C, 'Once More Unto the (Public/Private) Breach …: s. 6 of the Human Rights Act 1998 and the Severability Thesis' (UK Const Law Assoc Blog, 13th December 2013) <http://ukconstitutionallaw.org/2013/12/13/cormac-mac-amhlaigh-once-more-unto-the-publicprivate-breach-s-6-of-the-human-rights-act-1998-and-the-severability-thesis/> accessed 31 Jan 2016.

[1097] See *YL v Birmingham City Council* (Secretary of State for Constitutional Affairs intervening) [2007] UKHL 27 [2008] 1 AC 95 and *R (Weaver) v London & Quadrant Housing Trust (Equality and Human Rights Commission intervening)* [2009] EWCA Civ 587 (CA), [2010] 1 WLR 363 for contrasting approaches

[1098] Ibid.

[1099] See *YL v Birmingham City Council* (Secretary of State for Constitutional Affairs intervening) [2007] UKHL 27 [2008] 1 AC 95

8.3.1 The 'severability thesis': Public functions and private acts

In *YL* the issue was whether a private company operating a care home for profit, Southern Cross Healthcare Ltd, was a hybrid public authority[1100] and whether a decision to evict a tenant from the care home was a public or private act. Southern Cross provided accommodation and care to Mrs YL under arrangements made with Birmingham City Council; the Council had a statutory duty to provide these services. When threatened with eviction, Mrs YL brought proceedings on the basis of her right to respect for private and family life under Article 8 ECHR. She argued that Southern Cross would owe a duty directly to her if the company was exercising a public function, which required clarification of what the relevant 'function' was.

With two Lords strongly dissenting,[1101] their Lordships decided in a bare 3:2 majority that Southern Cross was not performing 'functions of a public nature' for the purpose of section 6(3)(b) so that it was not a 'public authority' obliged to act compatibly with Convention rights. They held that providing care and accommodation was not inherently a public function and that in housing Mrs YL, Southern Cross was acting as a profit-making company governed by private not public law, rather than carrying out functions of a public nature.[1102] Evicting the tenant was a private act and so Mrs YL could not assert her Convention rights against Southern Cross.[1103]

To reach this conclusion, the majority followed the reasoning of earlier cases *Poplar Housing*[1104] and *Leonard Cheshire;* also concerned with the question of whether a private act performed by a private body (the private care home's enforcement of its

[1100] It being accepted that it was not a core public authority.
[1101] Lord Bingham and Baroness Hale
[1102] See *YL v Birmingham City Council* (Secretary of State for Constitutional Affairs intervening) [2007] UKHL 27 [2008] 1 AC 95 Lord Scott [31]; Lord Manse [116]; Lord Neuberger [130]
[1103] The Court considered itself bound by the earlier decision in *R (Heather) v Leonard Cheshire Foundation* [2002] EWCA Civ 366, [2002] 2 All ER 936 (hereafter *Leonard Cheshire*) in which the Court of Appeal held that state-funded patients in a privately-operated care home could not sue the private care home under the HRA, because the provision of care was not a 'public function' under s.6(3)(b) HRA. The Court of Appeal concluded that a private body carrying out a public function on behalf of a public body would only be a 'public authority' under the HRA if it could be shown that the function itself has a 'public flavour'. Because accommodation in a care home was something that could be done by a private provider, it could not be said that the provision of care was necessarily a 'public function' under s.6(3)(b) HRA, even though the local authority in Leonard Cheshire was under a statutory duty to provide care to its patients.
[1104] *Teresa Donoghue v Poplar Housing and Regeneration Community Association Ltd (Respondent) & Secretary of State for the Environment, Transport and The Regions (Interested Party)* [2001] EWCA Civ 595, [2002] QB 48 hereafter '*Poplar Housing'.*

own contract with its residents) became a function of a public nature because the private body was assisting a public body in the discharge of the latter's public functions.[1105] The Court of Appeal in *YL* considered itself bound by *Leonard Cheshire*[1106] and not *Aston Cantlow* because the latter, it justified, concerned a different matter of law; namely whether the Church Council had relinquished their ability to enforce their own Convention rights, as would be the case if it was considered a core public body. Appealing, the Secretary of State argued that in deciding that Southern Cross was not a public body the Divisional Court had wrongly decided on the basis of *Leonard Cheshire*; ignoring the generous reasoning of *Aston Cantlow*, which it felt had 'superseded' the restrictive *Leonard Cheshire*

[1105] In *Poplar Housing*, the defendant had been housed by a local authority, Tower Hamlets, which sought to evict the defendant from her flat following a decision that she was 'intentionally homeless'. It was then discovered that her home belonged to Poplar, a housing association that the local authority had set up and to which it had transferred much of its housing stock. Poplar sought an order to evict the defendant, and her defence was that Poplar was a functional public authority, and that it was a breach of her Article 8 rights under the Convention for Poplar to evict her. The Court of Appeal held that Poplar was a functional public authority because of its *close relation* with Tower Hamlets, which meant that its relation with the tenant was 'enmeshed' in the local authority's discharge of its own public function. There was however no breach of Article 8 because the interests of other homeless people justified the system for obtaining possession of a flat rented to a particular person (Article 8(2) ECHR). Focus on the historic ties between the institutions was later criticised and undermined by the subsequent 'functional' approach adopted in *R (Heather) v Leonard Cheshire Foundation* [2002] EWCA Civ 366, [2002] 2 All ER 936

[1106] In *Leonard Cheshire* the court found against the foundation performing a public function, but failed to provide detailed analysis of when a function would be public. Instead, it was suggested that if, in performing a function, a non-public body is 'standing in the shoes' of a public body, then the function may be public. However, guidance was not provided as to how this should be decided except that according to the Court of Appeal, there was no special characteristic of the relationship between the local authority and the charity that would suggest that it should be considered a hybrid public authority. Lord Woolf CJ emphasised that the Foundation's functions were private, even though the local authority would have been regarded performing a public function had it delivered the services itself: [15].

For Williams 'The resulting incongruity and arbitrariness is concerning. Vulnerable service users can plead their Convention rights against the service provider if the local authority decides to deliver the services in-house, but not if it decides- which is completely beyond the service user's control – to contract them out'

Williams D, 'Administrative Law in England: The Emergence of a New Remedy' (1986) 27 Wm & Mary L Rev 715, 765

approach.[1107] The appeal was rejected on the grounds that the facts of *Leonard Cheshire* bound the Court in *YL*, not the distinguishable facts of *Aston Cantlow*.[1108]

In so ruling, the Court of Appeal clearly focussed on the distinction between 'functions' for the purpose of section 6(3)(b) and 'acts' for the purpose of section 6(5).[1109] This brought 'the perplexing conceptual question of how 'functions' and 'acts' differ to the fore.'[1110] On this point Lord Neuberger reasoned:

> In my view, both as a matter of ordinary language and on a fair reading of [s. 6], there is a difference between 'functions', the word used in s. 6(3)(b) and 'act[s]', the word used in section 6(2) and (5) […]. The former has a more conceptual, and perhaps less specific, meaning than the latter. A number of different acts can be involved in the performance of a single function. So, if this appeal succeeds, a proprietor … would be performing a 'function', which, while 'of a public nature', would involve a multitude of acts, many of which would be private … a hybrid public authority is only bound by section 6(1) in relation to an act which is (a) is not private in nature and (b) is pursuant to or in connection with a function which is public in nature.**[1111]**

The majority took a two-step approach leading to the conclusion that the act of terminating the tenancy and evicting the tenant was private because it was contractual in nature. In particular, Lord Scott argued that:

> The effect of [s.6 HRA] is that an act (or an omission) of a private person or company that is incompatible with a Convention right is not unlawful under the 1998 Act… unless the person or company has at least some 'functions of a public

[1107] *R (Johnson) v London Borough of Havering; R (YL) v Birmingham City Council* (2007) EWCA Civ 26, [2007] 2 WLR 1097: 'But it was strongly submitted to us, as it had been to the judges in the courts below, that a series of general observations in the *Aston Cantlow* case as to the proper approach to section 6(3)(b) of the 1998 Act, to which observations respectful attention must of course be given, showed that this court had not properly applied the law in the Leonard Cheshire Foundation case. Indeed, to quote Mr Sales's skeleton, that the approach of the House in the Aston Cantlow case was 'in stark contrast' to the approach of this court in the Donoghue case [2002] QB 48 and the Leonard Cheshire Foundation case.' (Buxton LJ, [41]).

[1108] Arguably, the continuum thesis underpinned the reasoning of the *Aston Cantlow* case; discussed in this Chapter.

[1109] See Lord Hobhouse in *Aston Cantlow* and Lords Scott and Neuberger in *YL v Birmingham City Council (Secretary of State for Constitutional Affairs intervening)* [2007] UKHL 27 [2008] 1 AC 95. Williams argues that these later cases 'saw something of a judicial awakening in this respect' as compared with earlier institutional approaches demonstrated in *Poplar*: Williams D, 'Administrative Law in England: The Emergence of a New Remedy' (1986) 27 Wm & Mary L Rev 715.

[1110] Ibid.

[1111] At [129]

> nature'; but even if that condition is satisfied the private person or company will not have any liability under the 1998 Act if the nature of the act complained of was private.[1112]

Arguably, in so doing the Court of Appeal placed emphasis on section 6(5) as the 'centre' of the hybridity test because even if functions of a public nature were found, an authority would be precluded from being subject to Convention rights if the nature of the particular act in question was private. This has, therefore, been argued to be an example in the judiciary of the 'severability thesis' described by academics such as Mac Amhlaigh:

> The two-stage test to determine the liabilities of 'hybrid bodies' is clear from this latter judicial endorsement of the severability thesis; firstly it must be ascertained whether the function being discharged was a 'public' one within the meaning of s. 6(3)(b), and secondly, it must be determined that the impugned act which gave rise to the alleged human rights violation was not private.[1113]

Following this two-step approach, even if UK Biobank was characterised as a hybrid public body, the act in question would still need to be proven to be public to be reviewable under s.6 HRA. Many of the challengeable acts might be 'regulatory' decisions and policies that may fall into the public bracket, for example the decision to have a no feedback policy (Chapter 7). Alternatively, other decisions might be argued to be of a contractual nature, for example between a researcher and UK Biobank regarding access to samples, and therefore 'private'.

8.3.2 The 'continuum thesis'

The narrow approach of the severability thesis was 'vigorously' contested by the minority in *YL* who took a broader, functional approach focusing on section 6(3)(b) and the fundamental purposes of the HRA; to give effective protection to ECHR rights in the UK courts.[1114] Lord Bingham argued that there could be no 'single test

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[1112] At [23]

[1113] Mac Amhlaigh C, 'Once More Unto the (Public/Private) Breach …: s. 6 of the Human Rights Act 1998 and the Severability Thesis' (UK Const Law Assoc Blog, 13th December 2013) <http://ukconstitutionallaw.org/2013/12/13/cormac-mac-amhlaigh-once-more-unto-the-publicprivate-breach-s-6-of-the-human-rights-act-1998-and-the-severability-thesis/> accessed 31 Jan 2016.

[1114] As section 6 is a provision in a domestic statute whose meaning 'is not to be found in the Convention but rather is 'a measure intended to give effective domestic protection of Convention rights' and so a generously wide approach ought to be given to the expression public function in section 6(3)(b). Lord Bingham at [4]; Baroness Hale at [60] cited in Palmer E, 'The Liability of

of uniform application to determine whether a function is of a public nature.'[1115] He therefore concluded that 'tempting though it may be' to try and formulate a general test, 'the draftsmen had been wise, to leave it to the courts to decide on the facts of particular cases where the dividing line should be drawn.'[1116] Therefore, the courts should consider a range of factors, including whether or not the state has assumed responsibility for the performance of the task in question, and 'the nature and extent of the public interest in the function in question'.[1117] Accordingly, a function remains public where the state makes arrangements for the function to be performed by a private body, and this is the underpinning of the continuum thesis:[1118]

> [i]t is artificial and legalistic to draw a distinction between meeting those needs and the task of addressing and arranging them, when the state has assumed responsibility for seeing that both are done.[1119]

Citing the factor-based approach of Lord Nicholls in *Aston Cantlow*, Lord Bingham and Baroness Hale also agreed that, 'although not itself determinative', the extent of the state's involvement in the funding of a service is an important indicator that a private body is performing a public function.[1120] The minority were evidently influenced by Lord Nicholls' conclusion that while there could be 'no single test of application' in relation to the definition of a public function, the relevant factors for the claimants, at least, included the extent to which the body: was exercising statutory powers; was taking the place of central government or local authority in providing the function; or was providing a public service.[1121]

It is perhaps surprising that the severability approach of the majority in *YL* was not directly followed in the subsequent and recent case of *R (Weaver) v London & Quadrant Housing Trust (Equality and Human Rights Commission intervening).*[1122]

'Functional Public Authorities' for Breach of ECHR Rights: The House of Lords Endorses a Palpable Gap in Human Rights Protection' (2008) 16 Med LR 141.

[1115] *YL v Birmingham City Council (Secretary of State for Constitutional Affairs intervening) [2007] UKHL 27* [2008] 1 AC 95 [5].

[1116] Ibid.

[1117] Ibid. [7] So, the minority are using the nature of the act question as one question that must be answered alongside many others, with the others drawn in through the nature of the function clause. As a result, we come to much the same position as under JR.

[1118] Ibid. [65]

[1119] Ibid.[66]

[1120] *Aston Cantlow* Lord Bingham [11], Baroness Hale [69].

[1121] Ibid. [12]

[1122] *R (Weaver) v London & Quadrant Housing Trust (Equality and Human Rights Commission intervening)* [2009] EWCA Civ 587 (CA), [2010] 1 WLR 363

In fact, there is evidence of both the severability thesis and the factor based 'continuum thesis' that had underpinned the judgments of Lord Bingham and Baroness Hale.[1123] This is further evidence of the difficulties that surround the legal question of what constitutes a public body.

Weaver questioned the status of the London Quadrant Housing Trust (LQHT) under s. 6, who, in contrast to *Poplar* had not been created by government, but rather as a non-profit charity. Mrs Weaver had defaulted on a number of rent payments and after a number of failed payment programmes, LQHT enforced a mandatory ground for possession and eviction under the Housing Act 1988.[1124] Mrs Weaver had no defence to LQHT's possession claim but sought to challenge LQHT's decision to take possession proceedings; arguing that LQHT was in breach of a legitimate expectation by failing to pursue 'all reasonable alternatives' before resorting to possession. She also contended that possession was a breach of her rights under Article 8 of the Convention. To be able to pursue this line of argument, Mrs Weaver had to first establish that LQHT was amenable to judicial review and that it was a 'public authority' within the meaning of s. 6(3)(b) of the HRA.

On judicial review amenability, the Divisional Court held that LQHT was a public authority:

> Insofar as a function of LQHT is a public function which makes it a public authority for the purposes of the Human Rights Act 1998, then … it should equally be amenable to judicial review on conventional public law grounds in respect of its performance of that function.[1125]

Therefore, LQHT was a public body for the purpose of judicial review, and a hybrid for the purpose of the HRA. When LQHT challenged this,[1126] the Court of Appeal

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[1123] Williams A, 'A Fresh Perspective on Hybrid Public Authorities under the Human Rights Act: Private Contractors, Rights-Stripping and "Chameleonic" Horizontal Effect' (2011) 139 Public Law 51

[1124] Schedule 2; Ground 8. In contrast to Ground 10 and 11 which are discretionary; meaning that the ground must not just be proven but the Court must also be satisfied that it is reasonable to make a possession order, the enforcement of which the Court can suspend or postpone.

[1125] *R (Weaver) v London & Quadrant Housing Trust (Equality and Human Rights Commission intervening)* [2009] EWCA Civ 587 (CA), [2010] 1 WLR 363 [64] (Richards LJ)

[1126] The Divisional Court rejected Mrs Weaver's substantive grounds of challenge. It held that there had been no legitimate expectation and, even if there had been one, it had not been breached and that there was no infringement of her Convention rights. Mrs Weaver was subsequently evicted and from that point on was no longer involved in the case. However, LQHT decided to appeal the finding that it

decided 2-1 (Lord Justice Elias and Lord Justice Lawrence Collins in the majority with Lord Justice Rix dissenting) to dismiss the appeal, upholding the decision that the LQHT was a hybrid authority exercising functions of a public nature. Elias LJ delivering the leading judgment took a notably wide approach to the question of the relationship between HRA and JR and commented that although they were not the same, 'in this case' they were most likely to be determined in the same way, as the Divisional Court had done.[1127] This contrasted the approach in *YL* and *Aston Cantlow* and the uncertain implications of the relationship between judicial review and human rights in the future have been noted.[1128]

To decide whether LQHT was exercising a public function for the purpose of the Act, Elias LJ[1129] in a conflicted judgment began by severing the assessment of public function and act, following *YL*. For Elias LJ, the focus of the Divisional Court on the nature of the function of housing management, rather than the nature of the act of terminating a tenancy, did not: 'satisfactorily encapsulate the real issue in this case which is whether the termination of this tenancy was a private act within section 6(5).'[1130]

> … [O]nce it is determined that the body concerned is a hybrid authority – in other words that it exercises functions at least some of which are of a public nature – the only relevant question is whether the act in question is a private act. Even if the particular act under consideration is connected in some way with the exercise of a public function, it may nonetheless be a private one. Not all acts concerned with carrying out a public function will be public acts. Conversely, it is also logically possible for an act not to be a private act notwithstanding that the function with

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was a public authority for the purposes of the termination of Mrs Weaver's tenancy and the Divisional Court gave permission to appeal.

[1127] *R (Weaver) v London & Quadrant Housing Trust (Equality and Human Rights Commission intervening)* [2009] EWCA Civ 587 (CA), [2010] 1 WLR 363, [83]

[1128] Alderson I, 'R (Weaver) v. London and Quadrant Housing Trust' (2013) 16 The Charity Law & Practice Review 129.

[1129] Mead D, 'The Continuing Mystery of "Publicness" within Section 6 of the HRA' (UK Const Law Assoc Blog, 17th October 2013) <http://ukconstitutionallaw.org > accessed 31 Jan 2016; Williams A, 'The Scope of Section 6 HRA Revisited' UK Const. L. Blog (*UK Const Law Assoc Blog*, 28th October 2013) <https://ukconstitutionallaw.org/2013/10/28/alexander-williams-the-scope-of-section-6-hra-revisited/> accessed 06th Feb 2016; Mac Amhlaigh C, 'Once More Unto the (Public/Private) Breach …: s. 6 of the Human Rights Act 1998 and the Severability Thesis' (UK Const Law Assoc Blog, 13th December 2013) <http://ukconstitutionallaw.org/2013/12/13/cormac-mac-amhlaigh-once-more-unto-the-publicprivate-breach-s-6-of-the-human-rights-act-1998-and-the-severability-thesis/> accessed 31 Jan 2016.

[1130] At [6]

> which it is most closely connected is a private function, although it is difficult to envisage such a case. Such situations are likely to be extremely rare.[1131]

Following the severability thesis, the subsequent consideration would be whether the relevant act in question under s. 6 (5) was a 'private' act so as to negate the finding that LQHT's functions were public for the purpose of s. 6(3)(b). However, at this point, Elias LJ retreated from the severable approach and, like Lord Justice Rix (dissenting), took a broader, 'relational'[1132] approach to the relationship between s. 6(3)(b) and section 6(5):

> When considering how to characterise the nature of the act, it is in my view important to focus on the context in which the act occurs; the act cannot be considered in isolation simply asking whether it involves the exercise of a private law power or not.[1133]

> In my judgment, the act of termination is *so bound up* with the provision of social housing that once the latter is seen, in the context of this particular body, as the exercise of a public function, then acts which are necessarily involved in the regulation of the function must also be public acts. The grant of a tenancy and its subsequent termination are part and parcel of determining who should be allowed to take advantage of this public benefit. This is not an act which is purely incidental or supplementary to the principle function.[1134] (Emphasis added)

The majority therefore concluded that between *YL* and *Aston Cantlow* a 'broad or generous' 'factor-based approach'[1135] had emerged. Accordingly there was 'no single test of universal application.'[1136] Instead, 'a number of factors may be relevant, but none is likely to be determinative on its own and the weight of different factors will vary from case to case.'[1137] The factors derived from *Aston Cantlow* and *YL* that influenced the majority included:

[1131] At [28]
[1132] Mac Amhlaigh C, 'Once More Unto the (Public/Private) Breach …: s. 6 of the Human Rights Act 1998 and the Severability Thesis' (UK Const Law Assoc Blog, 13th December 2013) <http://ukconstitutionallaw.org/2013/12/13/cormac-mac-amhlaigh-once-more-unto-the-publicprivate-breach-s-6-of-the-human-rights-act-1998-and-the-severability-thesis/> accessed 31 Jan 2016.
[1133] *Weaver* [66] Elias LJ
[1134] Ibid. [76] Elias LJ
[1135] Elias LJ in *Weaver* at [35]
[1136] *per* Lord Nicholls in *Aston Cantlow* at [12]
[1137] *per* Lord Bingham in *YL* at [5]

- where the body performs a governmental function, which would otherwise have been exercised by a central or local governmental body, or is acting on behalf of such a body for that purpose;[1138]
- where the body is funded or subsidised by a governmental body out of public funds;[1139] where the body provides a service to the public, or one which it is in the public interest to have provided;[1140]
- if the decision is amenable to judicial review; and where a failure to exercise the function properly would give rise to a significant risk to Convention rights.[1141]

Furthermore, the exercise of statutory powers 'may be a factor supporting the conclusion that the body is exercising public functions' and can 'often be determinative'.[1142] Providing a public service should not be confused with performing functions that are in the public interest or for the public benefit.[1143] On the other hand, some factors will have little weight, and the fact that a function is one which is carried out by a public body does not mean that it is a public function when carried out by a potentially hybrid body.[1144] Hence, '…it will often be of no real relevance that the functions are subject to detailed statutory regulation.'[1145]

Applying these principles, Lord Justice Elias held that LQHT was a public authority because: LQHT had a 'significant reliance on public finance' through subsidy rather than a contractual arrangement in which it was paid for providing services of public benefit; when allocating housing, LQHT 'operated in very close harmony' with local authorities to assist them in meeting their statutory duties; providing subsidised housing (as opposed to proving housing generally) is a governmental function;

[1138] *per* Lord Nicholls in *Aston Cantlow* at [10]
[1139] Ibid. [12]
[1140] Ibid.
[1141] *per* Lord Bingham in *YL* at [8]
[1142] *per* Elias LJ in Weaver [35], derived from the speeches of Lord Mance and Lord Neuberger in *YL*. This may be why LQHT conceded that it was a hybrid authority.
[1143] Elias LJ referred to Lord Mance's observations in *YL* at [105]: 'the self-interested endeavours of individuals usually works to the general benefit of society.'
[1144] Elias LJ in *Weaver* at [36]
[1145] Ibid. Lord Neuberger observed in *YL* [134] that otherwise companies providing financial services and running restaurants, both of which are subject to detailed regulatory control, could be said to be public authorities.

LQHT is a charity and as such acts in the public interest rather than for profit; and LQHT is subject to detailed regulation. [1146]

In so ruling, despite endorsing principles from *YL*, *Weaver* went some way beyond the restrictive conclusions of this case and towards the broader analysis that had been prominent in *Aston Cantlow*. There has not been a subsequent case discussing *Weaver's* impact and the Supreme Court has since re-refused leave to appeal *Weaver*. However, the Supreme Court have recently expressed in their revised Order on Appeal that this issue is clearly one for the Supreme Court to consider, and that they would fast track a more suitable case, indicating that the question is still contentious and unsettled.[1147]

8.3.3 UK Biobank Ltd: Public functions for the purpose of s.6 HRA

A number of factors have therefore emerged from *YL* and *Weaver* that help determine whether or not UK Biobank Ltd would be deemed public for the purpose of s.6. Most significantly, UK Biobank has received substantial public support: from government for its creation in the first instance, who saw UK Biobank as an opportunity for the UK Government to put the UK at the forefront of genomics research;[1148] from public and private bodies which are part of UK Biobank's constitution, namely the MRC and the WT as Members of UK Biobank Ltd as a charitable company; from the taxpayer who, in conjunction with the WT continues to fund the endeavour;[1149] and finally from the public who participated in the project in good faith.

In terms of funding, *YL* highlighted that public funding takes various forms[1150] and Lord Neuberger argued:

> It seems to me much easier to invoke public funding to support the notion that a service is a function of 'a public nature' *where the funding effectively subsidises, in*

[1146] Ibid. [68]-[71]
[1147] Arden Chambers, 'eflash No.366 R (on the application of Weaver) v London and Quadrant' (Arden Chambers, November 2009) <www.ardenchambers.com/uploads/File/pdf/eflash%20366.pdf> accessed 31 Jan 2016
[1148] As highlighted in Chapter 3 of this thesis.
[1149] It has also had funding from the Welsh Assembly Government, the British Heart Foundation and Diabetes UK: <http://www.ukbiobank.ac.uk/about-biobank-uk/> accessed 1 September 2014
[1150] 'The injection of capital or subsidy into an organisation *in return for undertaking a non-commercial role or activity of general public interest* may be one thing; payment for services under a contractual arrangement with a company aiming to profit commercially thereby is potentially quite another.' [Emphasis added] Lord Mance at [105].

> *whole or in part, the cost of the service as a whole*, rather than consisting of paying for the provision of that service to a specific person. [Emphasis added] [1151]

To date, UK Biobank Ltd funding totals £93 million, with £25 million granted in 2011 for the following 5 years.[1152] The resource has not reached the stage where it is self-sufficient from money generated by access fees, although the intention is that this revenue will be put back into the resource to guarantee its longevity.[1153] UK Biobank's annual returns are available through the Charity Commission website and the most recent financial report (to 30th September 2014) shows that the WT and the MRC are providing equal levels of funding for the resource. There is also an agreement from January 2014 whereby UK Biobank has entered into a contract with both the MRC and the WT for funding of up to £58M over 8 years.[1154]

In terms of power, in *YL* it was held that the reason for which powers have been conferred will go some way towards proving that an authority functions in a public manner:

> [The] existence of wide ranging and intrusive set of statutory powers …is a very powerful factor in favour of the function falling within section 6(3)(b).'[1155]

UK Biobank Ltd has permission to grant access to the NHS medical records of all participants. Participants consent to donating their material to UK Biobank, who declares itself the 'legal owner of the samples'.[1156] Participants 'relinquish all rights to these samples which I am donating to UK Biobank'[1157] on the understanding that UK Biobank Ltd will only make access grants to bona fide researchers acting in the

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[1151] [165]

[1152] <http://www.ukbiobank.ac.uk/about-biobank-uk/> accessed 1 September 2014

[1153] UK Biobank 'Can commercial research organisations use the Resource?' (UK Biobank) <http://www.ukbiobank.ac.uk/all-faqs/> accessed 1 September 2014.
According to the Charities Commission webpage, UK Biobanks Annual Return for 2013 shows an income of £1,320 in 'Trading to raise funds':
<http://apps.charitycommission.gov.uk/Showcharity/RegisterOfCharities/CharityWithPartB.aspx?RegisteredCharityNumber=1101332&SubsidiaryNumber=0> accessed 30 January 2016

[1154] UK Biobank Ltd, 'Report and consolidated financial statements' (UK Biobank, 30th Sept 2014) <www.ukbiobank.ac.uk/wp-content/uploads/2011/03/2014-UK-Biobank-Limited-Signed-2014-Report-and-Financial-Statements.pdf> accessed 6 Jan 2016.

[1155] Lord Neuberger at [167].

[1156] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) Section II A. 'Stewardship of Data and Samples' <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016.

[1157] UK Biobank, 'Consent form: UK Biobank' Version: 20061124: <http://www.ukbiobank.ac.uk/wp-content/uploads/2011/06/Consent_form.pdf?phpMyAdmin=trmKQlYdjjnQIgJ%2CfAzikMhEnx6> accessed 2 June 2014

public interest.[1158] This power is also derived from UK Biobank Ltd's incorporation as a charitable company, in pursuit of its charitable objects, as identified in Chapter 4 and analysed in depth in Chapter 6. As we have seen, UK Biobank has also created its own self-governing instrument (the EGF). Arguably this significant power, although not statute-based, indicates that UK Biobank is exercising public functions for our purposes.

If we accept that UK Biobank is exercising public functions under section 6(3)(b), the final hurdle is to prove that the nature of the act in question was public. The extent to which this is problematic depends, as we have seen, on whether the approach of the majority in *YL* or the minority in *YL* and the *Weaver* approach is followed. For example, UK Biobank policies could be considered by the court as inextricably bound with its purpose of providing a research resource for the benefit of society. This is not least in light of UK Biobank's power to devise its own self-governing instrument on the issue of incidental findings which is, as yet, unregulated in the UK.

On the other hand this may not be true, for example, of a breach in the contractual MTA between a researcher and UK Biobank if the *YL* severability thesis is followed. As in *YL*, this would be the kind of private law scenario that concerns the exercise of private rights between a researcher and UK Biobank Ltd in its capacity as an incorporated charity company. The latter would therefore be more likely to be deemed a breach of contract and hence perhaps more readily characterised as a 'private act' for the purpose of s.6(5).

8.3.4 Summary

Overall, the disagreement between the majority and the minority of the Court in *YL* demonstrates just how subjective the test for hybridity is. Indeed, it might be argued

[1158] Not stated on the consent form, but the UK Biobank participant information leaflet states: 'The purpose of UK Biobank is to set up a resource that can support a diverse range of research intended to improve the prevention, diagnosis and treatment of illness, and the promotion of health throughout society… UK Biobank is a not-for-profit charitable company set up to act as the legal owner and guardian of the database and sample collection. In signing the consent form, participants transfer all property and intellectual property rights in their samples and data to UK Biobank. The charity's role is to protect this valuable resource so that scientists can do a wide range of health related research in the future.' UK Biobank, 'Participant Information Leaflet' (UK Biobank April 2010), 10 <http://www.ukbiobank.ac.uk/wp-content/uploads/2011/06/Participant_information_leaflet.pdf?phpMyAdmin=trmKQlYdjjnQIgJ%2CfAzikMhEnx6> accessed 2 June 2014

that had a different judiciary been in bench, an entirely different outcome could have been reached. In particular, there is confusion as to whether the s.6(3)(b) test arrives at a different result under the HRA as to ordinary judicial review outlined above,[1159] and the severability or continuity of s.6(3)(b) and s.6(5) is yet to be resolved.

But what does this mean for UK Biobank? Evidently, the vulnerability of UK Biobank to an HRA action depends not only on whether the charitable company is proven to be public, but also the nature of the challenge brought against UK Biobank and whether it relates to an act which encourages the court to separate the act from UK Biobank's function, as was the case in *YL*, or whether the continuum thesis is followed such that Biobank's functions and acts are relational. On this basis, this chapter will now briefly analyse a few hypothetical examples of public law challenge to which UK Biobank may be subject.

8.4 Grounds for Judicial Review

8.4.1 Procedural Impropriety, Legitimate Expectations and UK Biobank Ltd's Access Decisions

From the above analysis, it may be submitted that there is a plausible argument that UK Biobank is a hybrid public body for legal purposes. In this section, the analysis turns to the grounds on which a challenge could be brought against it.

In the case of *Council of Civil Service Unions V Minister for the Civil Service*[1160] *(GCHQ* case*)* Lord Diplock set out a framework for understanding the grounds for judicial review, summarising them under the headings illegality, irrationality and procedural impropriety. This analysis section will consider the potential for challenge on the grounds of procedural impropriety (fairness), as it is submitted that this is a plausible ground for review of UK Biobank Ltd's decisions.

Within administrative law it is understood that good administration requires decisions to be made according to processes that appropriately require the decision-maker to take into account all the relevant considerations before acting. Such processes are captured within the umbrella term procedural impropriety. Procedural impropriety is closely linked to other heads of review. For example, judicial review

[1159] *Aston Cantlow* and *YL* cf. *Weaver*.
[1160] [1985] AC 374

can also be used for instances where a public body has disregarded a relevant consideration, or taken into account an irrelevant consideration when reaching its decision, but only it can be proven that if the relevant matter had been considered or the irrelevant one ignored, a different decision might have been made.[1161]

As a ground for review, procedural impropriety includes a number of different procedural expectations. For instance: parties to a dispute must be given an opportunity to be heard;[1162] there are rules against bias;[1163] consultations must be conducted 'properly;'[1164] and adequate reasons for decisions must be provided[1165] which are proper, adequate and intelligible and enable the person affected to know why they have won or lost.[1166] This branch of administrative law has expanded over the years. One result is that it is now possible to argue that when a body by its conduct creates a legitimate expectation that it will act in a particular way, it has an obligation to take that expectation into account in deciding what to do.[1167] There is also scope for argument that a public functionary has a duty to give reasons once a decision has been made. For example, there could be a duty to give reasons where a body has, by words or conduct, generated a legitimate expectation that reasons will be given.[1168] The principle of unfairness inherent in public law 'implies not only that decisions must be reasoned but also that any reason given for a decision must be properly related to the purposes for which the power was given.'[1169] In the absence

[1161] Elliot M and Thomas R, *Public Law* OUP: 2011
[1162] *R v Deputy Industrial Injuries Commissioner, ex p Moore* [1965] 1 QB 456
[1163] *Magill v Porter* [2001] UKHL 67, [2002] 2 AC 357, *per* Lord Hope at [103]: 'The question is whether the fair minded observer, having considered the facts, would conclude that there was a real possibility that the tribunal was biased.'
[1164] *R v North and East Devon Health Authority, ex p Coughlan* [2001] QB 213 held that to be 'proper', consultation must be undertaken at a time when proposals are still at a formative stage; it must include sufficient reasons for particular proposals to allow those consulted to give intelligent consideration and an intelligent response; adequate time must be given for this purpose; and the product of consultation must be consciously taken into account when the ultimate decision is taken.
[1165] A 'duty' to give reasons was considered in the case of *R v Ministry of Defence, ex p Murray* [1998] COD 134 which held against an express duty, but recognised that there was a trend in the courts towards an insistence on greater openness in the making of administrative decisions.
[1166] *R v Brent London Borough Council ex p Baruwa* [1997] HLR 915
[1167] Cane P, *Administrative Law* (4th edn, OUP 2004), 221
[1168] *R v Civil Service Board ex p Cunningham* [1991] 4 All ER 310
[1169] Cane P, *Administrative Law* (4th edn, OUP 2004), 205: *British Oxygen Co Ltd v Minister of Technology* [1971] AC 610, [1970] 3 All ER 165.

of such expectation, reasons may be required if the claimant's interest in the decision is sufficiently 'weighty.'[1170]

The doctrine of legitimate expectation is perhaps the most significant development in this area of law. The doctrine addresses circumstances in which a decision maker may have operated a practice or made a promise that raised expectations that it would be unfair or unreasonable to dishonour. The question of whether a legitimate expectation has arisen depends on the interaction of a number of factors which may or may not be individually relevant depending on the context, including: whether the words or conduct which gave rise to the expectation were clear and unequivocal;[1171] whether the person who promised the benefit had the legal power to grant it (or whether he was acting ultra vires); and whether the recipient of the promise took action in reliance upon it to their detriment.[1172] There are also related cases in which public authorities have been held to have acted unfairly in not following relevant past practices adopted by the authority.[1173] In these cases it may be said that by consistently following a particular practice, the authority impliedly represents that the practice will be followed in the future.[1174] However, the principle creates the risk of unduly constraining the freedom of public authorities either to change their policies or to tailor them to take account of the facts of individual cases.[1175] For this reason courts are wary of reading promises or representations to individuals into general statements of policy.[1176]

Considering such grounds with regard to UK Biobank, there may be a number of possible scenarios that could give rise to a legal action. For instance, it may be the case that in the future, once a higher volume of access requests have been granted, unsuccessful research applicants wish to challenge the decision of the Board and Committee on the grounds that they had a legitimate expectation that their request

[1170] *R v Secretary of State for the Home Department, ex p. Doody* [1994] 1 AC 531; *R v Corporation of the City of London, ex p Matson* [1997] 1 WLR 765; *R v Ministry of Defence, ex p Murray* [1998] COD 134.
[1171] *Association of British Civilian Internees – Far Eastern Region v Secretary of State for Defence* [2003] EWCA Civ 473, [2003] QB 1397.
[1172] *R v Department of Education and Employment, ex p Begbie* [2000] 1 WLR 1115.
[1173] *R v Inland Revenue Commissioners, ex p Unilever Plc* [1996] 68 TC 205; *HTV v Price Commission* [1976] ICR 170; *Council of Civil Service Unions v Minister for the Civil Service* (*GCHQ* case) [1985] AC 374 [1984] 3 WLR 1174.
[1174] Cane P, *Administrative Law* (4th edn, OUP 2004), 211.
[1175] Ibid.
[1176] E.g. *Ministry of Defence, ex p. Walker* [2000] 1 WLR 806, [2000] 5 LRC 49.

would be approved. To date, there have been 57 successful access grants.[1177] UK Biobank's Ethics and Governance Framework commits UK Biobank to explaining to participants and the public the policies and procedures for research access[1178] as laid down in Biobank's Access Procedures.[1179] According to the UK Biobank Access Procedures,[1180] access to the resource is subject to recommendation by the Principal Investigator and Co-ordinating Centre and ultimate approval by the UK Biobank Board of Directors and Access Sub-Committee. If an access request is denied it will be for the court to analyse whether similar projects had previously been successful, whether inadequate reasons were given as explanation for the decision, and whether the Committee and Board considered all relevant factors before making its decision. Could there have been a bias in the decision making process in light of the membership of the Board?

What if UK Biobank grants a contentious access approval to a company with possible commercial intentions that are not necessarily in the public benefit, for example, a company with links to the tobacco industry?[1181] It has been argued that participants who freely give their data to a biobank to further public interests do not truly consent if it turns out that the institution in question are essentially serving private or third party interests.[1182] This is because their willingness to participate often entails a large degree of trust that the future of the biobank's resources will remain as stated from the outset. Ethically, biobanks should respect the participants'

[1177] Listed on the UK Biobank website: UK Biobank, 'Approved research' (UK Biobank) <http://www.ukbiobank.ac.uk/approved-research-2/> accessed 2 September 2014

[1178] UK Biobank, Ltd. 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) II.B.2 <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016.

[1179] UK Biobank Ltd., *Access Procedures: Application and review procedures for Access to the UK Biobank Resource Version 1.0* (UK Biobank 2011) <www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Access-Procedures-2011.pdf> 14 January 2013

[1180] Ibid.

[1181] Although on the website UK Biobank reassures the public that this would be unlikely to be the case: 'Previous research into the effects of smoking saves many millions of lives around the world every year. The UK Biobank Resource is well placed to provide more health information to tackle smoking-related diseases. Researchers using the Resource will have to show that they are bona fide health research scientists and that their work is for the public good. It is virtually impossible to see that an application by the tobacco industry to use the Resource would fulfil these requirements and be approved. Likewise applications by researchers funded by the tobacco industry (directly or indirectly) would be similarly unlikely to be approved. (In addition to the tobacco industry, there may be other sources of research applications not considered acceptable because their activities are not in the public interest.)' UK Biobank 'Will tobacco industry researchers be able to use the Resource?' (UK Biobank) <http://www.ukbiobank.ac.uk/all-faqs/> accessed 4 September 2014

[1182] Capps B, Campbell V and Meulen R, 'Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good' (Commissioned Report, UK Biobank 2008) < http://egcukbiobank.org.uk/meetingsandreports> accessed 26 January 2016.

consents to maintain trust in the project (Chapter 1). Legally, however, they should respect the terms of consent because a number of stakeholders have a legitimate expectation that such consent will be honoured.

In UK Biobank's case, participants, researchers, NGO's, and the EGC may all have standing to initiate a challenge if they can prove 'sufficient interest'. Participants broadly consented to future uses of their samples and information in confidence, on the understanding that access to their material would only be granted 'to all bona fide researchers for all types of health related research that is in the public interest.'[1183] This is not to say that all ties with industry should be resisted to further the public interest. In fact, it is important to bear in mind that the social value of research (or public interest) may also include work with or by private actors.[1184] Indeed, research has indicated a degree of tolerance for commercial involvement so long as there is also a commitment to benefit sharing and that the prospect of profit is not one of excessive or obscene profit.[1185] However, it may be the case that access requests from private industry require a transparent and heightened justification as to why the research is in the public interest, which may not be so high for a not-for-profit publically funded researcher.

Overall, it remains to be seen whether the Administrative Court would respond favourably to an accusation that a decision was not in the public interest, especially given the estimation of UK Biobank worldwide. Indeed, UK Biobank has strived to inspire confidence and trust in the project via consultations, transparency (via its website) and governance arrangements including the independent Ethics and Governance Council (EGC) and EGF.[1186] For now, what is important is that if UK Biobank is proven to be a public body there may exist another layer of accountability of decision making and protecting participant interests which strengthens UK

[1183] UK Biobank, *Access Procedures: Application and review procedures for Access to the UK Biobank Resource Version 1.0* (UK Biobank 2011) <www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Access-Procedures-2011.pdf> accessed 24 Jan 2014.
[1184] Laurie G and others, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315; Taylor MJ and Townend D, 'Issues in protecting Privacy in Medical Research Using Genetic Information and Biobanking: The Privileged Project' (2010) 10 Med Law Int 253.
[1185] Davidson S, McLean C, Treanor S and others, 'Public Acceptability of Data Sharing Between the Public, Private and Third Sectors for Research Purposes' (Scottish Government, DPPAS 14736, 2013).
[1186] Capps B, Campbell V and Meulen R, 'Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good' (Commissioned Report, UK Biobank 2008) < http://egcukbiobank.org.uk/meetingsandreports> accessed 26 January 2016

Biobank's legitimacy, and goes some way to meeting its promise of being run for the public good.

8.4.2 Human Rights and UK Biobank Ltd's No-Feedback Policy

Alternatively, could a participant contest a decision not to feedback a research finding which had serious implications for their health on the grounds that it breaches the Article 8 right to private and family life, or even the Article 2 right to life? Furthermore, could they (or a person with 'sufficient interest') challenge Biobank's no feedback policy in its entirety, on the same grounds? Even if UK Biobank was characterised as a hybrid public body, and the act in question accepted as a public function and not a private act, this would still leave the fundamental question of whether or not failure to feedback results is a breach of human rights.

The issue of incidental findings in the context of biobanking research is a matter of intense academic debate which, as yet, has not reached a legislative conclusion. There has also not been any jurisprudence directly on the matter (Chapter 7). It is therefore not within the scope of this chapter to contribute originally to this ongoing debate. However, an argument has been made[1187] that there could be a positive obligation on UK Biobank to safeguard the lives of its participants (Article 2) and warn of potential health risks that are discovered in the course of research.[1188] Otherwise, a participant may claim that not knowing valuable information about their health and genetics is an infringement of their Article 8 right to private and family life.[1189]

[1187] This argument is raised by Johnston and Kaye in Johnston C and Kaye J, 'Does the UK Biobank have a Legal Obligation to Feedback Individual Findings to Participants?' (2004) 12 Medical Law Review 239, 262. Article 2 ECHR states; 'Everyone's right to life shall be protected at law. No one shall be deprived of his life intentionally...'

[1188] The authors argue on the basis of *Osman v UK* (23452/94) [1999] 1 FLR 193, [2000] 29 EHRR 245. In this case the European Court of Human Rights (ECtHR) considered the failure of the State to protect the lives of individuals from a threat. It was argued that the police had failed to act on information that could have averted the risk to an individual who was murdered. The ECtHR held that the State must take appropriate steps to safeguard the lives of those within its jurisdiction. However, no breach of Article 2 was found because to establish this positive obligation it is necessary to show that the authority knew or ought to have known at the time of existence of a real or immediate risk to the life of an individual or individuals from the criminal acts of third parties and that they failed to take measures within the scope of their powers which, judged reasonably, might have been expected to avoid that risk.

[1189] Capps B 'The Third Party Interest, Public Goods, and Third-Party Access to UK Biobank' (2012) Public Health Ethics 2; Chico V, *Genomic Negligence: An Interest in Autonomy as the Basis for Novel Negligence Claims Generated by Genetic Technology* (Routledge, 2011).

In *Venables v News Group Newspapers*[1190] a challenge under s. 6 HRA allowed the court to develop the common law to provide private sphere protection for Article 8 privacy rights.[1191] The conclusion reached in this case means that even if the Court did not characterise UK Biobank as a public body for the purpose of review, there may still be scope to challenge its decisions. Arguably, cases such as this have extended the scope of human rights protection beyond the public/private dichotomy potential 'horizontal effect'[1192] of public law in due course. This will inform opinion on whether, and on what grounds, UK Biobank ought to be held higher standard of accountability, regardless of its characterisation as public or private for legal purposes. As a concluding remark, it is posited that UK Biobank may be a timely example of a more modern concept of governance which potentially transcends the traditional public/private divide because of the nature of the interests it was created to further and protect.[1193]

8.4.3 Summary

Analysis so far has concluded that there is a strong argument that UK Biobank Ltd could be treated as a public body for the purpose of public and human rights law. If this were the case, UK Biobank participants could directly challenge UK Biobank Ltd decision making if they were granted the necessary legal standing. By extension, this legal analysis raises an additional theoretical question as to whether or not UK Biobank Ltd should be a public body for legal purposes. This question goes to the heart of an extensive body of literature debating the appropriateness of the public/private law divide in law, which will now be briefly discussed in the biobank context. It is submitted that this is as yet an unexplored research question and as such is a topic worthy of further future research.

Discussion will now briefly consider this debate, which theorises the purposes of public law. Discussion will raise the possibility of following old common law standards to impose principles of good administration on UK Biobank even if it is a

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[1190] [2001] 1 All ER 908

[1191] See also *Campbell v Mirror Group Newspapers Ltd* [2004] UKHL 22, [2004] 2 AC 457; *Douglas and others v Hello! Ltd and others (No. 3)* [2005] EWCA Civ 595, [2006] QB 125 (CA). As will be discussed next in this Chapter, Oliver argues this is evidence of 'indirect horizontal effect' of administrative justice principles: Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 234.

[1192] Ibid. 229

[1193] As will be discussed in the last section of this chapter.

private body, exercising private functions, as a matter of public policy. This 'horizontal' approach has pervaded human rights cases concerning the right to privacy (but not in cases of contracting out). There is also a line of precedent that suggests principles of good administration ought to be extended to private decision-making. I will critically consider the arguments for and against the expansion of administrative law to cover public-private biobanks, and how far such legal development might be regarded to be for the public benefit.

8.5 Biobanking beyond boundaries: Extending judicial review towards administrative justice

A growing body of literature has raised a number of arguments as to the relationship between private law and public values and the extent to which division between public and private law in this way is desirable or appropriate. First, it has been argued that the leading case of *O'Reilly* introduced a procedural distinction between public and private cases that has since wrongly been interpreted substantively.[1194] Second, and relatedly, a line of case law pre *O'Reilly* shows the court imposing administrative duties on bodies exercising power and discretion despite their legal status.[1195] Third, the Human Rights Act was specifically designed to 'bring rights home' and accordingly, a broad interpretation was intended by the drafters to catch hybrid bodies that exercise public functions.[1196] Evidence such as this leads Oliver to the conclusion that there is no such thing as a public/private dichotomy,[1197] and is the basis of Campbell's argument that monopoly power ought to be accountable regardless of legal status.[1198]

If these assertions are defensible, then it might be submitted that UK Biobank Ltd ought to be subject to public administrative duties because of the wide-reaching discretion it exercises, and the nature of the range of interests it serves to protect.

[1194] Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010).
[1195] Ibid
[1196] Joint Committee on Human Rights, *Bringing rights home for everyone: The problem* (1998, HC Deb 314) 409-410; Joint Committee on Human Rights, *The Meaning of Public Authority Under the Human Rights Act* (2003-4, HL 39, HC 382).
[1197] Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 243
[1198] A body is exercising public power if it is the only body providing that 'service' so is the only way for a decision to be made: Campbell C, 'The Nature of Power as Public in English Judicial Review' (2009) 68 Cambridge Law Journal.

Consequently, private individuals (i.e. participants) would be able to challenge UK Biobank Ltd, thereby adding a further layer of accountability to UK Biobank's legal model as a charitable company. This is a welcome conclusion: if UK Biobank is not in a private legal relationship with its participants, which is true if the nature of their consent is not contractual,[1199] there is no pre-existing tortious relationship (Chapter 7), and participants and the EGC are not empowered within the legal structure of UK Biobank Ltd (Chapter 6); arguably the governance model of UK Biobank is such that protecting participants is not, by itself, a quid pro quo of the public interest that UK Biobank Ltd was created to serve. Therefore, if public law could create a legal relationship between the participant and UK Biobank, this would strengthen the accountability of the public-private mixed model and facilitate forms of individual redress that would be available if UK Biobank Ltd was a statutory body. This relationship would also empower wider stakeholders of UK Biobank, such as the donors, members of the public and the EGC, thereby demonstrating the kind of 'good governance' that is debated in the socio-legal biobanking literature (Chapters 1, 4 and 5).

8.5.1 Procedural and substantive distinctions between public and private and good administration

> These [bodies] control the destinies of thousands; they have quite as much power as the statutory bodies… They can make or mar a man by their decisions…[1200]

Jurisprudential problems with the question 'what constitutes a public body' are demonstrative of the uncertainty that exists between the definitional boundaries of public and private in law. This question is embroiled in a much broader, theoretical and normative debate as to the role of the State in the exercise of public power.[1201]

This thesis has critiqued the extent to which UK Biobank Ltd could be considered both a private and a public body in law, in light of the 'publicness' of its decision-

[1199] In fact samples are donated as a gift of which UK Biobank Ltd is the legal owner: as discussed in Chapters 3 and 6.
[1200] *Breen v Amalgamated Engineering Union* [1971] 2 QB 175, [1971] 1 All ER 1148 [1154]
[1201] Although it is not within the scope of this thesis to analyse constitutional relationships with the State and the role of law in the regulation of this relationship, nor the theoretical relationship of UK Biobank with the State, but there is scope for significant novel research on this question and contribution to a developed body of literature including: Black J, 'Constitutionalising Self-Regulation' (1996) 59 MLR 24.

making, and despite its incorporation as a charitable company. However, separating analysis in this way begs the question of whether a public/private divide should exist in law at all. This is the topic of a much wider academic debate which questions '… whether, when and how good administration standards of the kinds applied in judicial review can or should be applied to purely private-horizontal decision making.'[1202] So, when a private body like UK Biobank Ltd has the power to make decisions that can adversely affect individuals and their interests, to what extent should this discretion be limited in law? Academic debate has highlighted three arguments that point to the conclusion that this should be the case, based on either: an extension of public duties to private bodies and vice versa;[1203] abolishing the public/private divide in law altogether;[1204] and the evolving role of the Human Rights Act in protecting public and private interests.[1205]

Some commentators have argued for the extension of the scope of judicial review to include anybody performing a public function in providing public services. This 'public function test' would be satisfied where bodies are set up to 'achieve some collective benefit for the public or a section of the public and is accepted by the public or that section of the public as having the authority to do so.'[1206] Justifications for judicial control would include the impact of decisions on the interests of individual citizen, and their significance for the interests of the public at large.[1207] Accordingly, such bodies would be under duties to observe standards of legality, reasonableness and procedural fairness in decision-making.[1208]

[1202] Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 237

[1203] For example see Craig P, 'Contracting Out, The Human Rights Act And the Scope of Judicial Review (2002) 118 LQT 351; Palmer E, 'Should Public Health be a Private Concern? Developing a Public Service Paradigm in English Law' (2002) 22 OJLS 663; Woolf H, 'Public Law- Private Law: Why the Divide?' [1986] Public Law 57; Vincent-Jones P, 'Citizen Redress in Public Contracting for Human Services' (2005) 68 Modern Law Review 887, 901.

[1204] Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 237; Oliver D, 'Lord Denning and the Public/Private Divide' (1999) 14 Denning Law Journal 79; Oliver D, *Common Values and the Public-Private Divide* (Butterworths 1999), 227

[1205] Oliver D, 'Functions of a Public Nature under the Human Rights Act' [2004] PL 329; cited in Vincent-Jones P, 'Citizen Redress in Public Contracting for Human Services' (2005) 68 Modern Law Review 887, 905.

[1206] DeSmith SA, Lord Woolf and Jowell J, *Judicial Review of Administrative Action* (5th edn, Sweet & Maxwell 1995),167

[1207] Palmer E, Public functions and private services: A gap in human rights protection (2008) 6 Int J Constitutional Law 585, Vincent-Jones P, 'Citizen Redress in Public Contracting for Human Services' (2005) 68 Modern Law Review 887, 902.

[1208] Ibid.

More broadly, arguments have been made to transcend the public/private divide as the basis for defining the application of judicial review and instead focus on of the power that such bodies can wield:

> … the role of judicial review is to regulate all forms of power; any exercise of power, public or private, by state or companies should be subject to principles of 'liberty, fair dealing and good administration'.[1209]

This argument for 'publicness' based on power can be further subdivided into those focussing on the amount of power exercised by a body, compared to those that focus on the exercise of monopoly power and the extent of the bodies association with the state.[1210] For example, Oliver (who advocates that there is no substantive public/private divide in administrative law) argues that instead of consideration as a branch of public law, administrative law should be perceived as a 'technique for controlling exercises of power on both sides of the public/private divide:'[1211]

> My view, as I guess many may know, is that there is no public-private divide… I am saying that public and private law cannot be divided from one another in any categorical, significant or meaningful way and thus that an integrated approach to the substantive law of decision making is wise.[1212]

As evidence, Oliver describes the 'ample case law' that exists 'to lay the foundations for common law and equitable development … in certain situations and relationships' on the principle of power. Oliver argues that there is a line of cases pre-dating *O'Reilly v Mackman*[1213] in which the courts elaborated principles under which duties of good administration could be imposed on decision making in the private sphere. Indeed, before *O'Reilly*, Administrative law was not understood to be a sub-species of public law.[1214] Subsequently, Oliver argues that 'quite illogically',

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[1209] Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 237. Citing: Borrie G, 'The Regulation of Public and Private Power' [1989] Public Law 552, 559. See also: Woolf H, 'Public Law- Private Law: Why the Divide?' [1986] Public Law 57; Oliver D, 'Is the Ultra Vires Rule the Basis of Judicial Review?' [1987] Public Law 543

[1210] Pannick D, 'Who is Subject to Judicial Review and in Respect of What?' [1992] PL 1; Cane P, 'Self-Regulation and Judicial Review (1987) 6 CJQ 324. Cited in Black J, 'Constitutionalising Self-Regulation' (1996) 59 MLR 24

[1211] Oliver D, 'Lord Denning and the Public/Private Divide' (1999) 14 Denning Law Journal, 79

[1212] Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 243

[1213] [1983] 2 AC 237

[1214] Oliver cites Lord Denning in *Breen v Amalgamated Engineering Union* [1971] 2 QB 175, [1971] 1 All ER 1148 [1153]: 'it may truly be said that we have developed a system of administrative law.

while the *O'Reilly* decision introduced the doctrine of *procedural* exclusivity,[1215] this has since been understood to change '*substantive* public law'. This ruling has led to the differentiation of public and private on the basis of the procedures by which they might be protected rather than their substance.[1216] It has followed that administrative law is part of public law, and so in principle only cases involving duties of fairness and rationality outside of contract should be brought by way of judicial review.[1217] This precedent has, in Oliver's view:

> …[s]tifled healthy incremental common law development of substantive decision-making principle, which was not limited to public law and did not entail a substantive as opposed to procedural and remedial public/private divide.[1218]

Examples of pre-*O'Reilly* cases include *Breen v Amalgamated Engineering Union,*[1219] where Lord Denning held that duties of fairness and rationality might apply to decisions of private tribunals, categorising them as administrative law duties. The reason for imposing such duties was that private exercises of power (in the context of Unions) needed to be controlled:[1220]

> Does all this apply to a domestic body? I think it does… All these delegate power to committees. These committees control the destinies of thousands; they have quite as much power as the statutory bodies of which I have been speaking. They can make or mar a man by their decisions… Often their rules are framed to give them discretion. They then claim that it is an unfettered discretion with which the courts have no right to interfere… They claim too much… their rules are said to be a contract between the members and the union. So be it. If they are a contract, there is an implied term that the discretion should be exercised fairly. But the rules are in reality more than a contract. They are a legislative code laid down by the council of the union to be obeyed by the members. This code should be subject to control by the courts just as much as the code laid down by Parliament itself. If the rules set up

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These developments have been most marked in the review of decisions of statutory bodies: but they apply also to domestic bodies.'

[1215] Requiring public law cases to be brought under the Civil Procedure Rules, Part 54

[1216] *Shearson Lehman Hutton Inc. v Maclaine Watson and Co Ltd* [1989] 2 Lloyds Rep 570 [625].

[1217] Oliver D, 'Lord Denning and the Public/Private Divide' (1999) 14 Denning Law Journal, 79

[1218] Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 239

[1219] [1971] 1 All ER 1148

[1220] Oliver D, 'Lord Denning and the Public/Private Divide' (1999) 14 Denning Law Journal, 72
Therefore, Oliver is one of the academics who frames the public/private divide according to the power that an authority exercises- not the amount of power, but the relationship or association between the state and the authority (in particular, whether or not the body exercises monopoly power)

> a domestic body and give it discretion, it is to be implied that body must exercise its discretion fairly.[1221]

Therefore, in this case, and in others around this time,[1222] duties of good administration were imposed on the basis of wider grounds of public policy. This was because private legislators are under a duty, as exercisers of power, to exercise their discretion with due regard for the impact of their decisions on those affected by them.[1223] Arguably, this approach has founded the more recent common law developments in relation to sporting bodies. In particular, the *Jockey Club* cases[1224] can be used to support the argument that the jurisdiction of the court to grant declaratory relief does not depend on the existence of a contract, but rather on the impact of the decision on those affected.[1225]

For example, Richards J in *Bradley* stated:

> [37] That brings me to the nature of the courts' supervisory jurisdiction over such a decision. The most important point, it seems to me, is that it is *supervisory*. The function of the court is not to take the primary decision but to ensure that the primary decision-maker has operated within lawful limits. It is a review function, very similar to that of the court on judicial review. Indeed, given the difficulties that sometimes arise in drawing the precise boundary between the two, I would consider it surprising and unsatisfactory if a private law claim in relation to the decision of a domestic body required the court to adopt a materially different approach from a judicial review claim in relation to the decision of a public body. In each case the essential concern should be with the lawfulness of the decision taken: whether the procedure was fair, whether there was any error of law, whether any exercise of judgment or discretion fell within the limits open to the decision maker and so forth…

[1221] *Breen v Amalgamated Engineering Union* [1971] 2 QB 175, [1971] 1 All ER 1148 [1154]
[1222] *Nagel v Feilden* [1966] 1 All ER 689. In this case, the plaintiff's case was pleased on the basis that the practice of the defendants was 'in restraint of trade and contrary to public policy.' Lord Denning did not use the phrase 'restraint of trade' and instead dealt with the case on public policy grounds stating: 'a man's right to work at his trade or profession is just as important to him as, perhaps more important than, his right to property. Just as the courts will intervene to protect his rights of property, so they will also intervene to protect his right to work.' [694]
[1223] Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 239; Oliver D, 'Lord Denning and the Public/Private Divide' (1999) 14 Denning Law Journal, 77
[1224] *Bradley v Jockey Club* [2005] EWCA Civ 1056, [2006] ISLR SLR-1; *R (Mullins) v Jockey Club* [2006] EWHC 986 (QB), [2006] ACD 2
[1225] Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 239

On this basis, it has been argued that duties of fairness and rationality may be non-contractual and imposed, for instance, in equity or as a matter of public policy.[1226]

Furthermore, Campbell uses the case of *Datafin*[1227] as evidence that the exercise of monopoly power ought to constitute proof of 'publicness' to warrant judicial review, in spite of the public/private status of the body in question. In *Datafin*, the Panel on Take-overs and Mergers was the sole body responsible for the regulation of mergers and acquisitions in the City:

> …One possibility would be to regard as public, power that is exercised by a person or body in the carrying out of a particular function, where *only* that person or body performs that function. In these circumstances, someone who might be adversely affected by the exercise of power in the carrying out of the function in question would be unable to choose to deal with an alternative decision – maker.[1228]

Rather than justifying review on the grounds of the source of the power, Campbell contends that the monopoly power such bodies are given to 'grant permission to a person to engage in an activity… in the absence of such permission would be illegal' could be just reason for review. For Campbell, this test is consistent with results of the courts 'in the bulk of past judicial review cases,' where applicants for review submitted 'that the power sought to be impugned is public because of its nature.'[1229] Therefore, it is argued that the adoption of the monopoly test would not significantly disrupt existing precedent.

Conversely, arguments have been made against the extension of judicial review, including, briefly: the pragmatic 'flood-gates argument';[1230] the technical jurisdictional argument concerned with ensuring that only appropriate cases are brought under Part 54 CPR;[1231] and the conceptual argument of the strain on the coherence of the principles of judicial review if they are extended and the desire to

[1226] Ibid. 243
[1227] *R v Panel on Take-overs and Mergers, ex parte Datafin plc.* [1987] QB 815, [1987] WLR 699, [1987] 1 All ER 564
[1228] Campbell C, 'The Nature of Power as Public in English Judicial Review' (2009) 68 Cambridge Law Journal, 116.
[1229] Ibid.
[1230] Which is the pressure of an increased case load: Black J, 'Constitutionalising Self-Regulation' (1996) 59 MLR 24, 31
[1231] Ibid.

protect the body's autonomy from court or state interference.[1232] Other weaknesses have been raised by Vincent-Jones such as the need for legislation if such reform is considered to be beyond judicial interpretation and development.[1233]

8.5.2 Human Rights

In addition to the debate for the extension of public law to private bodies and the abolition of this distinction in law, there have also been arguments to the effect that human rights are now so entrenched in UK law that this has rendered the public/private divide meaningless. This argument is based on the substantive values promoted by the Human Rights Act, rather than procedural norms: 'with the content and effect of decisions as well as the process of decision making, and ultimately with justifiability and proportionality rather than reasonableness.'[1234] For example, the Human Rights Act specifically provides for hybrids via section 6 (3)(b), to capture 'private' bodies exercising 'public functions' (Chapter 8.3). Indeed, the Joint Committee on Human Rights has suggested that the intention was for this provision to be widely construed, so as to 'bring rights home'.[1235] This is in contrast to the narrow interpretation of the judiciary, which has been highlighted in this chapter.

That said, in some cases such as *Venables* and *Campbell*[1236] the courts have considered themselves able to extend the scope of the Act to develop private rights to privacy.[1237] So, while Convention rights do not have direct horizontal effect, the courts may develop the common law in such a way that individual's rights will be

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[1232] Arthurs H, 'Rethinking Administrative Law: A Slightly Dicey Business' (1970) 17 OHLJ 1. Cited in Ibid.

[1233] Vincent-Jones P, 'Citizen Redress in Public Contracting for Human Services' (2005) 68 Modern Law Review 887, 901. Vincent- Jones notes that there is disagreement amongst public lawyers as to how far the governance issue raised by contractualisation amount to a crisis in administrative law: 'One argument is that the 'court-centered focus' of the common law has vested too much importance in the position of the judiciary within the structure of governance. The increasingly ineffectual role of the courts is regarded here as a reflection of the failure of the legal order to respond to new challenges of social complexity, resulting in the displacing of law as an active regulatory mechanism over great areas of public life.' Citing Loughlin M, 'Courts and Governance' in Birks P (ed) *The Frontiers of Liability* (OUP 1994).

[1234] Elliott MC, *The Constitutional Foundations of Judicial Review* (Hart 2001). Cited in Vincent-Jones P, 'Citizen Redress in Public Contracting for Human Services' (2005) 68 Modern Law Review 887, 904.

[1235] Joint Committee on Human Rights, *The Meaning of Public Authority Under the Human Rights Act* (2003-4, HL 39, HC 382).

[1236] *Campbell v Mirror Group Newspapers Ltd* [2004] UKHL 22, [2004] 2 AC 457

[1237] For Oliver, this was because broader 'polycentric' issues of contracting out were not raised: Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 244

protected.[1238] In these cases, the principle of proportionality[1239] meant that the rights and interests of the parties were weighed and a decision for the individual was reached.[1240]

On the other hand, it has been argued that the Human Rights Act in fact reinforces the public/private divide. This is in light of the severability of section 6(3)(b) and section 6(5) between public functions and private acts,[1241] as evidenced in the approach of the majority in the leading case of *YL* (which has been analysed in depth in this chapter).

8.5.3 UK Biobank Ltd

So, what does this mean for UK Biobank Ltd? In practice, perhaps very little; the implications would depend on a judicial review claim being brought against UK Biobank and the courts once again wrestling with a decision on the 'publicness' of this body corporate.

As Chapter 6 of this thesis has demonstrated, it cannot certainly be said that the current Board of Directors and Members of the company are accountable to the public when performing all of their constitutional and legal duties under 'private' charity and company law,[1242] which casts doubt on the robustness of the chosen model for its public good purpose. If the 'public' nature of UK Biobank Ltd's power was called into question, the proposed 'public function test' may well justify judicial control in light of the impact of UK Biobank Ltd decision making on the interests of participants, as well as the promised significance of UK Biobank for the benefit of the public. Alternatively, the common law approach illustrated above and advocated by Oliver might be used as evidence that this question ought to be decided on the basis of the court's substantive duty to control the abuse of power. If this was the

[1238] Ibid.
[1239] Previously, in the case of *Daly v Sec of State for the Home Office* [2001] UKHL 26, [2001] 2 AC 532 the courts articulated a series of questions to ascertain proportionate and lawful infringements including: 'is the measure adopted sensibly directed at the aim? Could aims be achieved in a less restrictive way?'
[1240] However, Oliver cautions that extending Human Rights protection in this way is not as straightforward as extending principles of good administration, since it allows the courts to 'substitute their own views for those of private decision makers.' Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010), 246
[1241] Hunt M, 'The "horizontal effect" of the Human Rights Act' [1998] PL 423.
[1242] Although it is noted that this is not the case for *all* duties which are accountable to the Charity Commission, for example the alteration of UK Biobank Ltd's constitutional documents: see Chapter 4.

case, then UK Biobank Ltd's considerable discretion over the sensitive personal information stored in the resource, combined with the far-reaching implications of its misuse, may be convincing evidence for scrutiny. On the other hand, endorsing Campbell's argument would require UK Biobank Ltd to be the sole controller of UK Biobank's activities which, given the role of the Charity Commission and the potential for EGC legal standing to oversee certain activities, as discussed in Chapter 6, might be difficult to sustain.

Or, if the claim referred to a breach of a Convention right, for example privacy, then the courts might not necessarily be restricted by considerations of public function under section 6. Instead, in light of *Campbell* and *Venables*, perhaps the more pressing challenge for the court would be balancing the rights of the individual against the benefits of biobank research for society. Given the popularity of UK Biobank and success to date, in this instance the scales may well tip in UK Biobank's favour.

8.6 Conclusion

This chapter has considered, on the basis of public law and human rights jurisprudence, the extent to which UK Biobank might be considered a public body for the purpose of protecting donors and holding UK Biobank to account. An important conclusion of this chapter is that there are strong legal arguments to be made, backed by good precedent, that UK Biobank Ltd could be characterised as a public body and therefore is vulnerable to judicial review challenge. Analysis has highlighted precedent that could be used as evidence that UK Biobank Ltd is a 'hybrid' public body performing functions of a public nature for the purpose of Part 54.4 CPR and s.6 HRA 1998. Such a challenge could either be on made on the grounds of traditional administrative principles or breach of Convention rights. It is conceivable that an aggrieved researcher with a legitimate expectation of access to the resource might challenge an unsuccessful application. In light of current academic debate and the uncertain, unregulated environment surrounding feedback of incidental findings, an interested individual may claim that UK Biobank's no feedback policy is inconsistent with their Article 8 right to private and family life, or indeed, their Article 2 right to life.

Public law analysis potentially adds another dimension of accountability to UK Biobank's multi-faceted legal framework, which may go some way to legitimising UK Biobank's significant discretion and non-statutory footing. In the absence of a pre-existing private relationship between UK Biobank and its participants, judicial review is therefore a potential means by which a private individual may seek to challenge exercises of UK Biobank Ltd's power that may have adversely affected them. However, the limits of the judicial review remedy are notable. The scope of judicial review raises questions as to who could prove legal standing to bring an action against UK Biobank, and on what grounds. Furthermore, as a reactive process, the judicial review remedy would be reliant on a case actually being brought against UK Biobank in the future, and this remains to be seen.

Furthermore this conclusion has, somewhat inevitably, begged the question of whether Biobank should be a public body and consequently opened the door to the wider theoretical debate of the appropriateness of the traditional public/private divide today. In conjunction with Chapters 5 and 6 of this thesis (regarding the theoretical and legal basis of UK Biobank as a corporation), this chapter shows how UK Biobank could be seen to be a 'private' corporation protecting 'public' values which may well require the application of stricter public responsibilities to UK Biobank's discretion. This chapter highlights the potential for UK Biobank to be analysed as a timely example of such a corporation, which would contribute to an existing debate regarding the role of corporations as 'social institutions.'[1243] Furthermore, emerging tensions between 'private' law and 'public' values (as defined herein) have inspired a growing debate as to the relationship between public and private law, and whether a divide between the two is necessary and/or desirable. As such, UK Biobank could be used as a lens to normatively re-examine the relationship between public and private, to illuminate the deficiencies of such a distinction.[1244]

[1243] Low C, 'A framework for the governance of social enterprise' (2006) 33 International Journal of Social Economics 376.
[1244] Barker K, 'Private law: Key encounters with public law' in Barker K and Jensen D, *Private Law: Key Encounters with Public Law* (CUP 2013), 3

Conclusion

Thesis summary and key findings

UK Biobank Ltd has been established as a charitable company limited by guarantee to manage the operation of UK Biobank; one of the world's most comprehensive population biobanks. The establishment of UK Biobank was driven by the UK government and the Wellcome Trust following heavy involvement in the success of the Human Genome Project in the late 1990's, and in response to pressure from the scientific community for a large-scale epidemiological resource to combine patient medical information with human tissue samples and investigate the linkages between lifestyle, genes and environment. Around the same time (late 1990's) the NHS was undergoing considerable reform and early forecasts suggested the development of the electronic health record, as well as governmental investment in new genetics research partnerships between the NHS and industry. This infrastructure and investment meant that the UK was in a unique position to be able to fund and facilitate a world-leading resource comprised of 500,000 participants' human tissue and medical records.

The host of associated ethical challenges that are raised by population biobanks have attracted worldwide academic attention and have been intensely debated in socio-legal scholarship. Early lessons for population biobanking were learnt from the Icelandic National Health Database; whose controversial opt-out approach to participant consent and exclusive licensing to the private company deCODE Genetics, put consent and commercialisation at the top of the list of ethical challenges. In so doing, a central concern of population biobanking was exemplified: how to uphold the interests of individual donors in the use of their biological

materials and health records while at the same time furthering the public's interest in maximising research use of the biobank resource. The crucial challenge is therefore to manage these diverse interests in a way that is consistent with donor expectations and the purpose of the biobank to inspire and maintain trust to ensure long-term biobank sustainability. As we have seen, there is no one way of doing this and a range of approaches to biobank governance have therefore emerged, which vary according to the type of biobank concerned (Chapters 1 and 2).

At the time of UK Biobank's development, between 1999 and 2004, Estonia and Iceland were two suitably comparative examples of models to regulate and govern a population biobank. In an attempt to balance these interests, which are not necessarily incompatible,[1245] both Iceland and Estonia's biobanks were created by the legislature and were made publically accountable via specific biobanking legislation that regulated access to, and use of the biobanks. In Iceland, an exclusive licence to for-profit company deCODE for access to the database ultimately led to the demise of the national health sector database, which was never built. Similarly, in Estonia, an exclusive licence also threatened the success of the biobank, before it was bought-out by the Estonian State in 2007. Combined, the Estonian and Icelandic experiences highlight the difference in priorities between public and private investors in genomics research, and between research and development in the drugs industry compared with research for the public benefit. Ultimately, the combination of regulation and biobank business models did not strike the right balance and this lack of equilibrium either threatened or thwarted the successful development of these population biobanks.

In the UK, in the absence of specific biobanking legislation but within a general nexus of regulation applicable to human specimen research, the decision was made to establish UK Biobank as an independent legal entity in its own right; a charitable

[1245] In fact, it has come to be accepted that there are public interests in protecting both the privacy of individuals *and* promoting scientifically sound and ethically robust health research: Another relevant case-study for the use of the public interest as a guiding principle to the governance of research is within the Scottish Health Informatics Programme's (SHIP) Good Governance Framework which also served as the basis of the Scottish Government's strategy in its Guiding Principles for Data Linkage: Information Governance Working Group, SHIP Guiding Principles and Best Practices (SHIP 2010) <www.scot-ship.ac.uk/sites/default/files/Reports/Guiding_Principles_and_Best_Practices_221010.pdf> accessed 24 Jan 2014.See also: Laurie G and Sethi N, 'Towards Principles-Based Approaches to Governance of Health-related Research using Personal Data' (2013) 4 The European Journal of Risk Regulation 43.

company limited by guarantee. According to traditional definitions of private law, this is a 'private' legal structure.[1246] Although the initial proposal was to build the biobank on a statutory footing (Chapter 3), the UK government ultimately opted for this structure at the behest of funders, notably the WT (Chapters 3 and 4).

Chapters 4, 5 and 6 have examined the legal basis of this dual model in private[1247] charity and company law and the theoretical underpinnings of the model to understand clearly the legal scope and limits of the discretion vested in the Directors and Members of UK Biobank. By virtue of this private legal model, UK Biobank Ltd is not directly accountable to the public, which would be the case had UK Biobank been created as a public authority (like the HFEA) accountable to Parliament, as originally envisaged (Chapter 3). This observation raises the question of the extent to which UK Biobank's charity-corporate model is fit for its public purpose and whether the structure adequately protects the private interests of the donors. On the basis of UK Biobank's traditionally 'private' structure, but in light of UK Biobank's potentially 'public' nature and the public values which it promotes (Introduction), Chapters 6, 7 and 8 explored the implications for individual redress and lines of accountability of UK Biobank Ltd in both private and public law. The conclusions of these chapters will now be outlined, highlighting the limitations and scope of each remedy in relation to the research questions of this thesis.

Private Law avenues for holding UK Biobank Ltd to account

Critical examination of company and charity law and UK Biobank Ltd's constitutional documents has revealed a series of inherent tensions in the charitable company legal structure (Chapter 6). These conflicts point to weaknesses in UK Biobank because it falls to the management of UK Biobank, i.e. the Board of Directors and the Members of the company (WT and MRC) to make decisions[1248] that strike the right balance between the public good mission of UK Biobank and the protection of private interests. Contrary to what one might reasonably expect, and indeed to what donors and the public might expect, there are no representatives of

[1246] Barker K, 'Private law: Key encounters with public law' in Barker K and Jensen D, *Private Law: Key Encounters with Public Law* (CUP 2013), 3

[1247] As defined in the Introduction of this thesis.

[1248] Or delegate responsibility to committees to make such decisions, i.e. the Access Sub Committee: UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007), II.B.2 <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016 'Decisions on access and use'

the EGC or the donors on the Board. Perhaps even more surprisingly, there appears to be no legal requirement for Members to appoint Board Directors in pursuit of UK Biobank's public mission,[1249] possibly explaining why the composition of the Board does not currently include direct representation of the EGC or the donors.[1250] This is particularly problematic in the light of the strictly advisory role of the EGC.[1251]

Structuring UK Biobank Ltd in this way gives rise to the risk that donors and members of the EGC have limited legal means to hold decision makers to UK Biobank's public mission. Instead, by virtue of the dual legal basis of UK Biobank Ltd in charity and company law the Board of Directors owe a confusing and overlapping web of statutory and fiduciary duties; to both the Company and its Members, and the public as beneficiaries of the charity. This complicates the lines of accountability within the private corporate legal structure, making it unclear who may enforce the duties of the Directors and via what means. Yet, under UK company law, UK Biobank Members operate with significant discretion and have the right to enforce the duties of Directors and vitiate breaches. There is uncertainty as to what extent the Members must exercise these rights in the public interest and there are limited legal qualifications on the exercise of Members' administrative and voting rights.

On the other hand, one of the key consequences of incorporating UK Biobank as a charity is that UK Biobank Ltd is legally subject to oversight via the Charity

[1249] However, according to UK Biobank Ltd's most recent 'Report and consolidated financial statements' the Directors' Report states:
'Under UK Biobank Limited's Articles, Directors may be appointed either by the Members or by the Board. Under the terms of a contract entered into by the Charity the Members are entitled to appoint one Director each and they are jointly entitled to appoint additional Directors. The Secretary of State for Health, the Scottish Ministers and the University of Manchester are entitled to appoint one Director each.'
UK Biobank Ltd, 'Report and consolidated financial statements' (UK Biobank, 30th Sept 2014) <www.ukbiobank.ac.uk/wp-content/uploads/2011/03/2014-UK-Biobank-Limited-Signed-2014-Report-and-Financial-Statements.pdf> accessed 06th Jan 2016.
It is not certain which contract this Report is referring to, but the exact statement can also be found in the 2013 Report. If it is referring to the joint venture agreement that has been signed by the WT/MRC, access to this agreement could provide valuable evidence as to the basis of this provision, and potentially, the justification for not granting the EGC a similar entitlement. UK Biobank Ltd., 'Report and consolidated financial statements' (UK Biobank, 30th Sept 2013) <www.ukbiobank.ac.uk/wp-content/uploads/2014/03/2013-UK-Biobank-Limited-Signed-2013-Report-and-Financial-Statements.pdf> accessed 06th Jan 2016.

[1250] Which one might expect if the Board was elected to be representative of the stakeholders of UK Biobank and run in the interests of the public.

[1251] As identified in Chapters 1 and 3,which is contrary to the original suggestions in the DH White Paper: Department of Health, *Our Inheritance, Our Future: Realising the Potential of Genetics in the NHS* (White Paper, CM 5791-II, 2003).

Commission and potentially via charity proceedings. Duties owed by the Board of Directors under charity law, for example the application of resources towards UK Biobank's charitable purpose, may be scrutinised by the Charity Commission. Importantly, Chapter 6 has shown that legally standing does not need to be proven to report issues to the Charity Commission, which means that the Chair of the EGC, members of the public, donors or even an investigative journalist could potentially raise a concern. If the Charity Commission were to find that UK Biobank is in breach of its charitable mission, this may constitute evidence of misconduct or mismanagement for the purpose of charity proceedings involving court action. As a prerequisite, the Charity Commission must be satisfied they cannot resolve the matter outside such proceedings. Even then, charity proceedings are only open to those who can prove legal standing, namely either the Charity Commission, the A-G or 'persons interested.'

The case law suggests that there is uncertainty as to who would satisfy the requirements for legal standing, and 'persons interested' are typically private individuals. Whether the EGC would qualify as 'persons interested' is a moot point. Precisely in whose name would the action be filed? Would it be matter for the EGC Chair? Would the whole Committee or the majority of the Committee have to agree? Could individual members of the EGC file an action? What pressures within UK Biobank might be deployed to prevent or dissuade a member of the EGC from this course of action? What is the likelihood of such an action? These are difficult legal questions that do not readily admit a clear answer and illustrate the legal complexities of holding UK Biobank to account in its existing legal form.

Overall, the charity-corporate legal structure of UK Biobank only opens limited and uncertain avenues of accountability for the furtherance of the biobank's public good mission, which do not extend to protecting the private interests of the donors from, for example, misuse of their donated biological samples and/or personal injury.

As a potential means of redressing personal harm, Chapter 7 has explored additional avenues of redress in the English common law of negligence using the specific example of failure to feedback individual results. The chapter highlights the absence of clear precedent and the multiple burdensome hurdles that donors would need to overcome to prove that UK Biobank owes a duty of care to them and are in breach of

this duty in the adoption of a negative policy on feedback. This would be a novel duty scenario; case law suggests that the likely classification of this duty as a failure to warn (an omission), coupled with the potentially public nature of UK Biobank as the defendant, may mean that the courts could find that it is not 'fair just and reasonable' to impose such a duty on UK Biobank. Paradoxically, the 'public good' dimension of UK Biobank's mission may make it more difficult for individual donors to establish a duty of care owed to them in the law of negligence. However, the fast evolving environment of genetics research and the increasing availability of resources to feedback such results raises questions as to how far UK Biobank's no feedback policy will be sustainable in the future.

Public Law avenues for holding UK Biobank Ltd to account

Considering the identification of UK Biobank's potentially public character in Chapter 7, and to explore how legal avenues within public law may be available to assert the aforementioned interests and hold UK Biobank to account, Chapter 8 considered the extent to which UK Biobank discretion is 'public' for the purpose of judicial review.

Chapter 8 has shown that there is a strong case to be made that UK Biobank Ltd may be deemed to be a public body for the purpose of public law, such that all UK Biobank Ltd decisions (i.e. on feedback of individual research results in the future) would lie in the public realm. If UK Biobank can be proven to be a public body for the purposes of public law, Chapter 8 has highlighted a range of public law duties that UK Biobank Ltd potentially owes when exercising their discretion, which conceivably includes policies for feedback of individual results. In depth jurisprudential analysis concludes that it is at least arguable that UK Biobank Ltd indeed functions as a public body for the purpose of judicial review and administrative law, and for the purpose of the Human Rights Act. There is convincing precedent that could be used as evidence that UK Biobank Ltd is a 'hybrid' public body performing functions of a public nature for the purpose of Part 54.4 CPR and s.6 HRA 1998.

Potentially, this layer of accountability goes some way to legitimising UK Biobank's significant discretion and non-statutory legal basis. In the absence of a pre-existing private relationship between UK Biobank and its participants (Chapter 7), and

governance processes through which participants can have a say in the running of the resource (Chapters 4 and 5), judicial review is a potential means by which a private individual may seek to challenge exercises of UK Biobank Ltd's power that may have adversely affected them. The limits of this remedy have been noted in this thesis; judicial review would only require UK Biobank Ltd to review procedural decisions not to provide a remedy or compensation to individuals whose samples have been (mis)used. So far a restrictive approach has been taken to substantive review of public acts under the Human Rights Act (against the intention of the Joint Human Rights Committee) to provide a remedy.[1252] Another limitation of judicial review is of course its reactive nature. It remains to be seen whether a case will be brought against UK Biobank, and by whom (perhaps a researcher denied access to the recourse, or an opaque decision to grant access on the part of UK Biobank challenged by a member of the EGC?) Even if judicial review is a powerful remedy, it cannot be relied upon unless a case is brought against UK Biobank. That said, in the face of future uncertainty and rapid developments in the biobanking arena this is an important conclusion, and a significant contribution of this thesis to the scholarly literature on UK Biobank.

Together Chapters 6, 7 and 8 show how UK Biobank's legal structure straddles the public/private divide in law and the multiple layers of law that UK Biobank is subject to by virtue of its charity-corporate legal structure. As such, this thesis raises novel questions as to the adequacy of the charity-company legal structure for biobanking, and the implications of the public/private law divide in this context.

Before concluding with final remarks and future directions of this research, there are a number of observable limitations of this research, which will now be briefly discussed.

Limitations of research

This thesis has explored some of the avenues of accountability that may arise by virtue of UK Biobank Ltd's legal structure to protect donors' interests and pursue UK Biobank's public mission, mainly in respect of the biobank's use of donor biological materials and tissue samples. However, space has precluded an exhaustive

[1252] Joint Committee on Human Rights, *The Meaning of Public Authority under the Human Rights Act* (*ninth report)* (2006–07, HL 77, HC 410).

review of all the legal avenues and a number of additional routes may have been analysed. For example, this thesis notes the applicability of data protection law to the running of UK Biobank, by virtue of the materials and data contained therein. But this thesis has not aimed to critically analyse the ways in which the Data Protection Act,[1253] overseen by the Information Commission, operates to protect health data and the privacy interests of individuals who have taken part in research. This important area of research is already being rigorously considered.[1254]

It is noted that the new EU Data Protection Regulation includes provisions for research access to genetic data, which is now explicitly considered 'personal data'.[1255] It is also currently uncertain whether there will be an exception to the 'right to be forgotten' that is enshrined in the Regulation in the case of scientific research. If so, this principle would uphold the privacy interests of UK Biobank donors with implications for UK Biobank practices in terms of the destruction of data in the event of donor withdrawal. However, it seems that Member States will be able to decide whether or not this applies in research[1256] and 'broad consent' to research purposes has survived the Regulation, such that further processing of personal data for 'scientific research' purposes is considered to be a compatible lawful basis for sharing.[1257]

Furthermore, this thesis has not extensively considered the potential contractual obligations of UK Biobank with regard to granting access to researchers, as well as the potentially quasi-contractual nature of the relationship with UK Biobank donors by virtue of their signing the consent form. For example, it is at least worth considering whether UK Biobank is acting within its statutory obligations in excluding liability for feedback individual research results? Is it arguable that the no-feedback policy could be an unfair contract term?[1258] On the other hand, construing

[1253] Which implements EU data protection law in the UK
[1254] Taylor MJ, 'Legal bases for disclosing confidential patient information for public health: Distinguishing between health protection and health improvement' (2015) 23 Med Law Rev 348; Taylor MJ, 'Health Research, Data Protection and the Public Interest in Notification' (2011) 19 Med Law Rev 267; Taylor MJ and Grace J, 'Disclosure of Confidential Patient Information and the Duty to Consult: The Role of the Health and Social Care Information Centre' (2013) 21 Med Law Rev 415.
[1255] Art 4(10) final (unofficial) draft of General Data Protection Regulation: draft available: <http://www.haerting.de/sites/default/files/pdfs/proposal-eudatap-regulation-final-compromise-151216.pdf> accessed 20 January 2016
[1256] Ibid. Art 83(2)
[1257] Ibid. Art 5(1)(b)
[1258] The Unfair Contract Terms Act 1977 and Unfair Terms in Consumer Contracts Regulations 1999 were recently consolidated within the Consumer Rights Act 2015

the relationship between donors, researchers and biobanks in contract carries negative implications for the 'trust' model that is often presented as ideal in the literature on biobanking.[1259] This might be an important area of further research in the context of UK Biobank in the future.

Finally, as a general observation, the difficulties expressed by Langan in obtaining archival evidence from the WT that may have enabled a more detailed and balanced understanding of the origins of UK Biobank, also points to the limitations in the levels of public scrutiny relating to a private company by contrast to a public body. Were the WT (or UK Biobank) listed in Schedule 1 of the FOI Act[1260] this would enable any member of the public to obtain information as to the operation of the organisation. This avenue is particularly desirable when bearing in mind the recent changes to the remit of the EGC in reviewing applications for access, as if UK Biobank were listed as a Scheduled public body this might enable access to information in the extreme circumstance that UK Biobank refuse to provide evidence of the reasons behind their decision.

Concluding remarks and future directions

Throughout this thesis there have been a series of overlapping themes that have been returned to regularly. One such issue is the ongoing debate as to the adequacy of UK Biobank's legal structure and the theoretical model that should ideally underpin it. Regarding the theoretical conceptualisation of UK Biobank as a shareholder or stakeholder model of governance, in depth analysis of the legal framework and the composition of UK Biobank Ltd in this thesis suggest that UK Biobank Ltd is not so obviously conformant to either the stakeholder or shareholder models, for a number of reasons. First, part of the Board's functional responsibility is to negotiate access to the resource to maximise use of the resource and optimum public benefit outputs. In pursuit of this objective it is arguable that expertise, rather than democratic representation, fuelled the election of the UK Biobank Board of Directors, corresponding with a traditional shareholder approach to corporate governance. However, because of the lack of share capital and the membership structure of UK

[1259] Winickoff DE and Winickoff RN, 'The Charitable Trust as a Model for Genomic Biobanks' (2003) 349 N Engl J Med 1180; Winickoff DE and Neumann L, 'Towards a Social Contract for Genomics: Property and the Public in the 'Biotrust' Model' (2005) 1 Genomics Society and Policy 8.
[1260] Sch. 1 Freedom of Information Act 2000: 'Public Authorities'

Biobank, and the wider–reaching range of interests that are affected by UK Biobank's objectives beyond the charities 'shareholders', it is arguable that Winickoff's shareholder model is not appropriate for UK Biobank Ltd's charity mission either. In fact, the Board of Directors is under a statutory duty to consider wider stakeholders by virtue of the 'enlightened shareholder value' provision of the Companies Act 2006, and in this regard it may be more fitting to view UK Biobank governance as being underpinned by a stakeholder perspective of governance. However, this is not necessarily fully realised because the Board of Directors are not democratically elected to represent this full range of stakeholders. Donors and members of the public are absent from the governance model; as are members of the EGC who are supposedly responsible for safeguarding the interests of the public in the running of UK Biobank.[1261]

Indeed, based on conclusions in this thesis, it may be more accurate to conceptualise UK Biobank as a social institution because of UK Biobank Ltd's charitable incorporation, potentially public character and mission to benefit the health of future generations on the one hand, and the self-professed role of the Board of Directors as 'stewards' of the UK Biobank resource on the other.[1262] Further research into the public and private law implications of social institutions generally, and in relation to UK Biobank in particular, is an opportunity for novel contribution to an emerging debate regarding the role of social institutions in society.[1263]

Looking ahead, proposals have been made in the socio-legal literature for governance solutions that would go some way to giving a voice to underrepresented interests in biobanking. However, these proposals arguably do not go far enough in terms of accountability to the public mission of endeavours such as UK Biobank Ltd, and are based on a limited understanding of the existing legal structure. Within the existing legal structure, while representation or involvement of members of the donor, public and EGC might enable these constituencies to have a voice in the

[1261] UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016.
[1262] Mason C, Kirkbride J and Bryde DJ, 'From stakeholders to institutions: the changing face of social enterprise governance theory' (2007) 45 Management Decision 284, 290: there must be a 'culture of trust between the principal (or primary stakeholder) and managers to support this approach. To achieve this, it is typical for managers to be members of the defined community that the enterprise serves to ensure that managerial decision making closely aligns with the required needs of that community. In so doing, the organisation 'aligns with the ethos of the social enterprise'.
[1263] Low C, 'A framework for the governance of social enterprise' (2006) 33 International Journal of Social Economics 376.

governance of UK Biobank, this does not ensure that all the legitimate voices are heard and accounted for. Based on the doctrinal, socio-legal and comparative legal analysis in this thesis, it is debatable how far the private and the public interest are served by the legal structure of UK Biobank Ltd, which may not have been the case if UK Biobank had been established on a statutory basis as a public body accountable to Parliament. Public law accountability has been reduced following corporatisation. Thus, there is prima facie a case for redressing this loss, whether by administrative law or other means.[1264]

A key finding of this thesis is that one avenue for reform of the UK Biobank legal structure that deserves further consideration following the Charities Act 2011 is to convert UK Biobank Ltd from a charity company into a Charitable Incorporated Organisation (CIO). Potentially, the benefits of such reform would be to empower a wider UK Biobank constituency to have a say in organisational decision making and the running of the resource (Chapter 6). Conversion could facilitate involvement of members of the EGC, as well as donors and participants, by virtue of the wider membership and voting rights, which are facilitated by both the 'foundation' and the 'association' model made available by the Charity Commission so far.[1265] This new legal structure would also make UK Biobank Ltd wholly accountable to the Charity Commission and by extension, increase public oversight. However, further research is needed to understand the practical implications of such conversion and how feasible this is as a short or long-term solution for UK Biobank. Moreover, even if UK Biobank was converted to this new legal form, it is observable that this structure would arguably do little more than the charity corporation structure to protect donors

[1264] Vincent-Jones P, 'Citizen Redress in Public Contracting for Human Services' (2005) 68 Modern Law Review 887, 901.

[1265] Charity Commission, 'How to write your charity's governing document' (CC22b, Charity Commission, 2nd June 2014) <https://www.gov.uk/guidance/how-to-write-your-charitys-governing-document> accessed 07th Feb 2016:
'We have produced two model constitutions for CIOs:
• The 'foundation' model is for charities whose only voting Members will be the charity trustees
• The 'association' model (this model) is for charities that will have a wider membership, including voting Members other than the charity trustees.
In practice a CIO using the 'foundation' model will be like an incorporated charitable trust, run by a small group of people (the charity trustees) who make all key decisions. Charity trustees may be appointed for an unlimited time and they will probably appoint new charity trustees. A CIO using the 'association' model will have a wider voting membership who must make certain decisions (such as amending the constitution), will usually appoint some or all of the charity trustees (who will serve for fixed terms), and may be involved in the work of the CIO. There are not two different forms of CIO. A CIO with the 'foundation' model could change to the 'association' model if it wanted a wider voting membership. (This could also happen the other way around, but Members who were not trustees would be giving up their membership.) Some of the changes would need our approval.'

from personal harm. Therefore, wider common law avenues of redress or legislative solutions would still be required to ensure that appropriate redress is available to individual donors for misuse of their biological samples (or data).

Moving forward, analysis of the multi-dimensional structure of UK Biobank Ltd to run UK Biobank has raised a number of questions for future research. Theoretical questions have arisen regarding the legal underpinnings and level of scrutiny of public and private discretion in large-scale organisations that are created (partly) with public funds and established for the public good, but are privately structured by virtue of operating as a body corporate. This thesis suggests that there is scope to review the legal structure of biobanks in the context of population health services and research, such that organisations responsible for delivering a public good, using public funds, are subject to appropriate levels of public scrutiny and administrative responsibility as well as clear obligations in private law to provide compensation and redress to donors. In light of an apparently continuing trend for public health endeavours to be organised outside the traditional public law confines,[1266] and in view of the private interests at stake and the public interest in accountability and transparency of ethically sensitive activities, the legal implications for donors and the public of the shift to private corporate models of governance requires further research.

Overall, there is significant scope for novel research into how best to link corporations, including biobanks like UK Biobank Ltd, with the general public and society. There is a risk that the increasing privatisation of public mission organisations and the resultant reduction in public law accountability will not protect the full range of interests that are concerned and instead will grant management significant, and in some instances unlimited, discretion with no adequate public oversight. Such research would add to emerging debates as to the evolving role of the corporation in the 21st Century and the potentially 'public' aspects of 'private' corporations, which may invite application of stricter public standards in the future. This research would have important implications not only for future public health initiatives established at arms-length from the government, but also public

[1266] For example, Genomics England, which is a wholly owned Department of Health Company: Genomics England 'About Genomics England' (Genomics England) <http://www.genomicsengland.co.uk/about-genomics-england/> accessed 5 February 2016

mission/private structured organisations in wider contexts, and would contribute to a long held debate as to the role and division of public and private law in society.

Reports, Policies, Consultations and UK Biobank Resources

Article 29 Data Protection Working Party, 'Working Document on Genetic Data' (European Commission 12178/03/EN, WP 91, 2004).

Bioethics Advisory Committee Singapore, 'Human Tissue Research' (Bioethics Advisory Committee Singapore, 2nd Report 2002) <www.bioethics-singapore.org/images/uploadfile/2002-11%20-%20Human%20Tissue%20Research.pdf> accessed 06 Jan 2016.

Cabinet Office and Office of Science and Technology, *The advisory and regulatory framework for biotechnology: report from the government's review* (Stationary Office 1999).

Cabinet Office Strategy Unit, 'Private Action, Public Benefit: Charitable Incorporated Organisation' (Background Paper, Cabinet Office, September 2002) Pg 4 <http://webarchive.nationalarchives.gov.uk/+/http://www.cabinetoffice.gov.uk/media/cabinetoffice/strategy/assets/inc.pdf> accessed on 22nd October 2012

Cabinet Office, 'Building the Big Society' (Cabinet Office 2010) <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/78979/building-big-society_0.pdf> accessed 26 January 2016.

Cabinet Office, *Open Public Services* (White Paper, Cm 8145, 2011).

Capps B, Campbell V and Meulen R, 'Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good' (Commissioned Report, UK Biobank 2008) < http://egcukbiobank.org.uk/meetingsandreports> accessed 26 January 2016.

Charity Commission, 'How to write your charity's governing document' (CC22b, Charity Commission, 2nd June 2014) <https://www.gov.uk/guidance/how-to-write-your-charitys-governing-document> accessed 07th Feb 2016.

Charity Commission, 'Our regulatory approach to protecting the public's interest in charity—how we assess and manage risks' (Risk Framework, Charity Commission, June 2012) <www.gov.uk/government/uploads/system/uploads/attachment_data/file/313453/risk-framework-our-regulatory-approach-to-protecting-the-public_s-interest-in-charity.pdf> accessed 7th Feb 2016.

Charity Commission, *Where the Charity Commission investigates charities* (Policy paper, Charity Commission, 23rd May 2013) <www.gov.uk/government/publications/where-the-charity-commission-investigates-charities> accessed 7th Feb 2016.

Charity Commission, *Report of the Charity Commissioners for England and Wales for the year 1990* (HMSO 1991) 77.

Charity Commission, *Setting up and running a charity—guidance* (updated 11 December 2014) < www.gov.uk/guidance/how-to-write-your-charitys-governing-document> accessed 26 January 2016.

Charity Commission, *Setting up and running a charity—guidance* (updated 11 December 2014) <www.gov.uk/topic/running-charity/setting-up> accessed 26 January 2016.

Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57).

Committee on Standards in Public Life, 'The 7 principles of public life' (the 'Nolan principles', Cabinet Office 1995) <www.gov.uk/government/publications/the-7-principles-of-public-life/the-7-principles-of-public-life—2> accessed 17 September 2014.

Committee on the Financial Aspects of Corporate Governance (the Cadbury Committee), *Report of the Committee on the Financial Aspects of Corporate Governance* (Gee 1992). *Company Directors: Regulating Conflicts of Interest and Formulating a Statement of Duties* (Law Com No 261, 1999).

Council for International Organisations of Medical Science (CIOMS) and World health Organisation (WHO), *International Ethical Guidelines for Epidemiological Studies* (CIOMS 2009) < www.cioms.ch/index.php/publications/printablev3/541/view_bl/65/bioethics-and-health-policy-guidelines-and-other-normative-documents/47/international-ethical-guidelines-for-epidemiological-studies?tab=getmybooksTab&is_show_data=1> accessed 06 Feb 2016.

Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS 2002) < http://www.cioms.ch/publications/layout_guide2002.pdf> accessed 26 January 2016.

Cragg Ross Dawson Ltd., *Public Perceptions of the Collection of Human Biological Samples—Report Prepared for the Wellcome Trust and Medical Research Council* (Wellcome and MRC 2000) <www.ukbiobank.ac.uk/wp-content/uploads/2011/07/Public-Perceptions-Collection-Human-Biological-Samples.pdf> accessed 26 January 2016.

Davidson S, McLean C, Treanor S and others, 'Public Acceptability of Data Sharing Between the Public, Private and Third Sectors for Research Purposes' (Scottish Government, DPPAS 14736, 2013).

Department of Health, *Government response to the report from the House of Lords Select Committee on Science and Technology inquiry on human genetic databases: challenges and opportunities* (Cmd 5236, 2001).

Department of Health, *Our Inheritance, Our Future: Realising the Potential of Genetics in the NHS* (White Paper, CM 5791-II, 2003).

Department of Health, *The new NHS: Modern; Dependable* (White Paper, Cm 3807, 1997).

Department of Health, *The NHS Plan: a plan for investment, a plan for reform* (Cm 4818-I, 2000).

Department of Trade and Industry, *Modern Company Law for a Competitive Economy: Developing the Framework* (URN 00/656, 2000).

Financial Reporting Council, *The UK Corporate Governance Code* (FRC 2014) <www.frc.org.uk/Our-Work/Publications/Corporate-Governance/UK-Corporate-Governance-Code-2014.pdf> accessed 06 Jan 2016.

HM Government and Association of British Insurers, *The Concordat and Moratorium on Genetics and Insurance* (ABI 2014) <www.abi.org.uk/Insurance-and-savings/Topics-and-issues/Genetics/Genetic-testing> accessed 19 March 2015.

House of Lords Science and Technology Committee, *Genomic Medicine* (HL 2008-09, 107-I).

Human Genetics Commission, *Inside Information: Balancing interests in the use of personal genetic data* (Department of Health 2002) <http://webarchive.nationalarchives.gov.uk/20061023110946/http:/www.hgc.gov.uk/UploadDocs/DocPub/Document/insideinformation_summary.pdf> accessed 31 Jan 2016.

Human Genetics Commission, *Whose hands on your genes?* (Department of Health 2000).

Human Genome Organisation (HUGO), 'Ethics Committee: Statement on human genomic databases' 2002 14 J Int Bioethique 207.

Human Tissue Authority, *Code of Practice 1: Consent* (Version 14.0, HTA July 2014) < www.hta.gov.uk/sites/default/files/Code_of_practice_1_-_Consent.pdf> accessed 31 Jan 2016.

Information Governance Working Group, *SHIP Guiding Principles and Best Practices* (SHIP 2010) <www.scot-ship.ac.uk/sites/default/files/Reports/Guiding_Principles_and_Best_Practices_221010.pdf> accessed 24 Jan 2014.

Interim Advisory Group on Ethics and Governance, 'UK Biobank Ethics and Governance Framework Background Document' (Wellcome Trust, 10th October 2003) <www.wellcome.ac.uk/about-us/publications/reports/biomedical-ethics/wtd003284.htm> accessed 06 Jan 2016.

Joint Committee on Human Rights, *The Meaning of Public Authority Under the Human Rights Act* (2003-4, HL 39, HC 382).

Joint Committee on Human Rights, *The Meaning of Public Authority under the Human Rights Act* (*ninth report)* (2006–07, HL 77, HC 410).

Law Commission and Scottish Law Commission, Law Commission, *Administrative Redress: Public Bodies and the Citizen* (Law Com No 322, 2010).

Medical Research Council and Wellcome Trust, *Framework on the feedback of health-related findings in research* (MRC, March 2014) <www.mrc.ac.uk/documents/pdf/mrc-wellcome-trust-framework-on-the-feedback-of-health-related-findings-in-researchpdf/> accessed 09 July 2015.

Medical Research Council, 'Human Tissues and Biological Samples for Use in Research: Operational and ethical guidelines' (Medical Research Council 2001).

Ministry of Justice, *Judicial Review: Proposals for further reform* (White Paper, Cm 8703, 2013).

NHS England, *NHS Five Year Forward View* (NHS England 2014) <www.england.nhs.uk/ourwork/futurenhs/> accessed 31 Jan 2016.

NHS Executive, *Information for Health: an information strategy for the modern NHS 1998-2005* (Department of Health 1998).

Nuffield Council on Bioethics, *The collection, linking and use of data in biomedical research and health care: ethical issues* (Nuffield Council 2015) < http://nuffieldbioethics.org/project/biological-health-data/> accessed 05th Feb 2016.

OECD Corporate Governance Committee, *Principles of Corporate Governance* (OECD 2015) <www.oecd.org/daf/ca/Corporate-Governance-Principles-ENG.pdf> accessed 31 Jan 2016.

People Science and Policy Ltd, *UK Biobank Consultation on the Ethical and Governance Framework—Report prepared for the Wellcome Trust and The Medical Research Council* (People Science & Policy Ltd 2003) <www.ukbiobank.ac.uk/wp-content/uploads/2011/07/EGF-Consultation.pdf?

People Science and Policy Ltd., *Biobank UK; A Question of Trust: A consultation exploring and addressing questions of public trust* (People Science & Policy Ltd 2002) <www.ukbiobank.ac.uk/wp-content/uploads/2011/07/A-Question-of-Trust.pdf?phpMyAdmin=trmKQlYdjjnQIgJ%2CfAzikMhEnx6> accessed 21st Jan 2013.

Presidential Commission for the Study of Bioethical Issues, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts* (Presidential Commission for the Study of Bioethical Issues 2013) <http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf> accessed 14th March 2015.

Research and Development Council (Estonia), 'Knowledge-based Estonia: Estonian Research and Development Strategy 2002-2006' (Research and Development Council, December 18 2001) <www.akadeemia.ee/_repository/File/ALUSDOKUD/Knowledge-basedEstonia.pdf> accessed 08th Feb 2016.

Scottish Government, 'Joined-Up Data For Better Decisions: Guiding Principles For Data Linkage' (Strategy Document, DPPAS 13570, 2012).

Select Committee on Science and Technology, *The Work of the Medical Research Council* (HC 2002-3, 132).

The Charity Commission, (RS7) *Membership of Charities* (Charity Commission 2004) < www.gov.uk/government/uploads/system/uploads/attachment_data/file/284722/rs7text.pdf> accessed 30 Jan 2016.

The Royal College of Radiologists (RCR) and the Scottish Imaging Network: A Platform for Scientific Excellence (SINAPSE), *Management of Incidental Findings Detected During Research Imaging* (The Royal College of Radiologists 2011) <www.rcr.ac.uk/docs/radiology/pdf/BFCR(11)8_Ethics.pdf> accessed 19 Dec 2015.

UK Better Regulation Taskforce, 'Alternatives to State Regulation' (Cabinet Office 2000)

UK Biobank Ltd., 'Memorandum and Articles of Association of UK Biobank Limited' (Incorporated 28 November 2003) available at Companies House, company no. 04978912 <https://beta.companieshouse.gov.uk/company/04978912/filing-history> accessed 8 Feb 2016.

UK Biobank Ltd., 'Report and consolidated financial statements' (UK Biobank, 30th Sept 2014) <www.ukbiobank.ac.uk/wp-content/uploads/2011/03/2014-UK-Biobank-Limited-Signed-2014-Report-and-Financial-Statements.pdf> accessed 06th Jan 2016.

UK Biobank Ltd., 'Report and consolidated financial statements' (UK Biobank, 30th Sept 2013) <www.ukbiobank.ac.uk/wp-content/uploads/2014/03/2013-UK-Biobank-Limited-Signed-2013-Report-and-Financial-Statements.pdf> accessed 06th Jan 2016.

UK Biobank Ltd., 'Report and consolidated financial statements' (UK Biobank, 30th Sept 2011) <www.ukbiobank.ac.uk/wp-content/uploads/2011/12/UK-Biobank-Limited-Signed-2011-Report-and-Financial-Statements.pdf> accessed 06th Jan 2016.

UK Biobank Ltd., 'Material Transfer Agreement' <www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Material-Transfer-Agreement.pdf> accessed 27 July 2014.

UK Biobank Ltd., 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016.

UK Biobank Ltd., 'UK Biobank—Summary Information Return 2013' (Charity Commission Online, submitted 10 April 2014) <http://apps.charitycommission.gov.uk/SIR/ENDS32/0001101332_SIR_20130930_E.PDF> accessed 08 February 2016.

UK Biobank Ltd., 'Access Procedures: Application and review procedures for Access to the UK Biobank Resource Version 1.0' (UK Biobank, 2011 <www.ukbiobank.ac.uk/wp-content/uploads/2012/09/Access-Procedures-2011.pdf> accessed 24 Jan 2014.

UK Biobank Ltd., 'Consent Form: UK Biobank' (UK Biobank 2006) <www.ukbiobank.ac.uk/wp-content/uploads/2011/06/Consent_form.pdf?phpMyAdmin=trmKQlYdjjnQIgJ%2CfAzikMhEnx6> accessed 31 Jan 2016.

Wakeford T and Hale F, Generation Scotland: Towards Participatory Models of Consultation (University of Newcastle, Policy Ethics and Life Sciences Research Institute (PEALS) 2004) <www.generationscotland.org/images/stories/GS_-_towards_participatory_models_of_Consultation.pdf> accessed 06 Feb 2016.

Wallace H, *Bioscience for Life?—Appendix A; The history of UK Biobank, electronic medical records in the NHS, and the proposal for data-sharing without consent* (Genewatch UK 2009) < www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/UK_Biobank_fin_2.pdf> accessed 31 Jan 2016.

World Health Organisation, Governance for Health in the 21st Century: a study conducted for the WHO Regional Office for Europe (WHO 2011) EUR/RC61/Inf.Doc./6.

World Medical Association, *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects* (WMA 1964, Helsinki, Latest revision Fortaleza, 2013).

Bibliography

Adalsteinsson R, 'The Constitutionality of the Icelandic Act on a Health Sector Database' in Sandor J, *Society and Genetic Information: Codes and Laws in the Genetic Era* (CEU Press 2003).

Alderson I, 'R (Weaver) v. London and Quadrant Housing Trust' (2013) 16 The Charity Law & Practice Review 129.

Allen NE, Sudlow C, Peakman T and Collins R, 'UK Biobank Data: Come and Get It' (2014) 6 Sci Transl Med 224ed4.

Allison JWFA, *Continental Distinction in the Common Law* (revised edn, Oxford 2000).

Andrews L and Nelkin D, 'Whose body is it anyway? Disputes over body tissue in a biotechnology age' (1998) 351 The Lancet 53.

Andriof J, Waddock S, Husted B and Rahman R, *Unfolding Stakeholder Thinking: Theory, Responsibility and Engagement* (Greenleaf 2002).

Appelbaum PS, Roth LH, Lidz CW, Benson P and Winslade W, 'False hopes and best data: consent to research and the therapeutic misconception' (1987) 17 Hastings Cent Rep 20.

Arendt H, *The human condition* (2nd edition, University Chicago Press 1958).

Arnardottir O and others, 'The Icelandic Health Sector Database' (1999) 6 European Journal of Health 307.

Arthurs H, 'Rethinking Administrative Law: A Slightly Dicey Business' (1970) 17 OHLJ 1.

Article 29 Data Protection Working Party, 'Working Document on Genetic Data' (European Commission 12178/03/EN, WP 91, 2004).

Association of British Civilian Internees – Far Eastern Region v. Secretary of State for Defence [2003] QB 1397

Baldwin R, 'Better Regulation: The Search and The Struggle', In Baldwin R, Cave M and Lodge M (eds) *The Oxford Handbook of Regulation* (OUP 2010).

Bamforth N, 'Public Law in a Multi-Layered Constitution' (2003) 8 Judicial Review 157.

Bamforth N, 'The Application of the Human Rights Act 1998 to Public Authorities and Private Bodies' (1999) 58 Cambridge Law Journal 159.

Banakar R and Travers M (eds) *Theory and Method in Socio-Legal Research* (Hart 2005).

Bankas S, 'Voluntary Assumption of Tort Liability in English Law: A Paradox?' (2009) 4 InDret <www.raco.cat/index.php/InDret/article/view/141377> accessed 26 Jan 2016.

Barbour V, 'UK Biobank: a project in search of a protocol?' (2003) 361 The Lancet 1734.

Barker K, 'Private law: Key encounters with public law' in Barker K and Jensen D, *Private Law: Key Encounters with Public Law* (CUP 2013).

Bedard K, Wallace S, Lazor S and Knoppers BM, 'Potential Conflicts in Governance Mechanisms used in Population Biobanks' in Kaye J and Stranger M (eds) *Principles and practice in biobank governance* (Ashgate 2009).

Beloff M and Kerr T, 'Why Aga Khan is Wrong' (1996) 1 Judicial Review 30.

Berlin I, 'Two concepts of liberty' in Berlin I, *Four essays on liberty* (OUP 1969).

Beskow LM and Burke W, 'Offering individual genetic research results: Context matters' (2010) 2 Sci Trans Med 38cm20.

Beskow LM, Khoury MJ, Baker TG and Thrasher JF, 'The integration of genomics into public health research, policy and practice in the United States' (2001) 4 Common Genetics 2.

Beyleveld D and Brownsword R, 'Law as a Moral Judgment vs. Law as the Rules of the Powerful' (1983) 28 American Journal of Jurisprudence 79.

Beyleveld D and Brownsword R, 'My body, my body parts, my property?' (2000) 8 Health Care Anal 87.

Beyleveld D, 'Data Protection and Genetics: Medical Research and the Public Good' (2007) 18 King's Law Journal 275.

Black J, 'Constitutionalising Self-Regulation' (1996) 59 MLR 24

Black J, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World' (2001) 54 CLP 103.

Borrie G, 'The Regulation of Public and Private Power' [1989] Public Law 552.

Bovenberg J, 'Whose tissue is it anyway?' (2005) 29 Nature Biotechnology 929.

Bovenberg JA, Meulenkamp T, Smets EM and Gevers JKM 'Your Biobank, Your Doctor? The right to full disclosure of population biobank findings.' (2009) 5 Genomics Society and Policy 55.

Briceño Moraia L, Kaye J, Tasse AM and others, 'A Comparative Analysis of the Requirements for the Use of Data in Biobanks Based in Finland, Germany, the Netherlands, Norway, and the United Kingdom' (2014) 14 Med Law Int 187.

Brownsword R and Goodwin M, *Law and the Technologies of the Twenty-First Century: Texts and Materials* (Cambridge University Press 2012).

Brownsword R, 'An Introduction to Legal Research' (2006) <http://eprints.uwe.ac.uk/18856/1/TPA%20Smith%20-%20'The%20Zealous%20Advocate%20in%20the%2021st%20Century'.pdf> accessed 27 January 2012.

Brownsword R, 'Genetic Databases: One for All and All for One?' (2007) 18 King's Law Journal 247.

Brownsword R, 'The Ancillary Care Responsibilities of Researchers: Reasonable but not Great Expectations' (2007) 35 JLME 679.

Brownsword R and Yeung K, (eds) *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart 2008).

Bunton R and Petersen A, *Genetic Governance* (Routledge 2004).

Burton PR, Hansell AL, Fortier I and others, 'Size matters: just how big is BIG? Quantifying realistic sample size requirements for human genome epidemiology' (2009) 38 International Journal of Epidemiology 263.

Cambon-Thomsen A, Rial Sebbag E, Knoppers BM, 'Trends in ethical and legal frameworks for the use of human biobanks' (2007) 30 ERJ 373.

Campbell AV, 'The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust' (2007) 18 King's Law Journal 227.

Campbell C, 'The Nature of Power as Public in English Judicial Review' (2009) 68 Cambridge Law Journal.

Cane P, *Administrative Law* (4th edn, OUP 2004).

Cane P, 'Self-Regulation and Judicial Review (1987) 6 CJQ 324.

Capps B, 'The Public Interest, Public Goods and Third-Party Access to UK Biobank' (2012) 5 Public Health Ethics 240.

Capps B, Campbell V and Meulen R, 'Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good' (Commissioned Report, UK Biobank 2008) < http://egcukbiobank.org.uk/meetingsandreports> accessed 26 January 2016.

Carolan E, 'The legitimacy of public service reform: democracy; accountability and experimentalism in the Big Society' [2013] PL 240.

Caulfield T and Kaye J, 'Broad consent in biobanking: reflections on seemingly insurmountable dilemmas' (2009) 10 Med Law Int 85.

Caulfield T and others, 'A review of the key issues associated with the commercialisation of biobanks' 2014 1 Journal of Law and the Biosciences 94.

Cave M and Lodge M, 'Introduction: Regulation—The Field and The Developing Agenda' in Baldwin R, Cave M and Lodge M (eds), *The Oxford Handbook of Regulation* (OUP 2010).

Cave M and Lodge M, *Understanding Regulation: Theory, Strategy and Practice* (2nd edn, OUP 2011).

Chalmers D, 'Genetic Research and Biobanks' in Dilner J (ed), *Methods in Biobanking* (Springer 2010).

Chan TW, 'The Closure of the National Bio-bank in Singapore' (2012) 16 Asia-Pacific Biotech News Journal 40.

Chang A, 'National Biobank to Close' (04th June 2011) The Straits Times S.D6-7.

Chico V, *Genomic Negligence: An Interest in Autonomy as the Basis for Novel Negligence Claims Generated by Genetic Technology* (Routledge, 2011).

Chico V, ‘Saviour Siblings: Trauma and Tort Law’ (2006) 14 Medical Law Review 187.

Chih-Hsing H, ‘Socio-legal perspectives on biobanking: the case of Taiwan’ (PhD thesis, The London School of Economics and Political Science 2012) <http://etheses.lse.ac.uk/501/> accessed 04 July 2015.

Cho MK, ‘Understanding Incidental Findings in the Context of Genetics and Genomics.’ (2008) 36 JLME 280.

Collins R, ‘What makes UK Biobank special?’ (2012) 379 The Lancet 1173.

Conaghan J, ‘Tort Law and Feminist Critique’ (2003) 56 Current Legal Problems 175.

Cownie F, *Legal Academics: Culture and Identities* (Hart 2004).

Craig P, ‘Contracting Out, The Human Rights Act And the Scope of Judicial Review (2002) 118 LQT 351.

Cross SR, ‘New legal forms for charities in the United Kingdom’ [2008] Journal of Business Law 662.

Daniels M, ‘Accountability for reasonableness: Establishing a fair process for priority setting is easier than agreeing on principles’ (2000) 321 BMJ 1300.

Davies G, Frow E and Leonelli S, ‘Bigger, faster, better? Rhetorics and practices of large-scale research in contemporary bioscience’ (2013) 8 BioSocieties 386.

Davies PL, Gower and Davies’ Principles of Modern Company Law (8th edn, Sweet and Maxwell 2008)

Deschenes M and Sallee C, ‘Accountability in Population Biobanking: Comparative Approaches’ (2007) 33 JLME 46

DeSmith SA, Lord Woolf and Jowell J, *Judicial Review of Administrative Action* (5th edn, Sweet & Maxwell 1995).

Dickenson D, ‘Consent, Commodification and Benefit Sharing in Genetic Research’ (2004) 4 Developing World Bioethics 109.

Donaldson L and Preston M, ‘The stakeholder theory of the corporation: concepts, evidence, and implications’ (1995) 20 Academy of Management Review 85.

Dorey E, ‘NextCODE to mine Icelandic genetic wealth’ (2014) 32 Nature Biotechnology 6.

Dove T, Laurie G, ‘Consent and anonymisation: beware binary constructions’ (2015) 350 BMJ http://dx.doi.org/10.1136/bmj.h1139.

Drury R, ‘The Relative Nature of a Shareholder’s Right to Enforce the Company Contract’ (1986) 45 CLJ 219

Dunn A, Riley CA, ‘Supporting the not-for-profit sector: the government’s review of charitable and social enterprise’ (2004) 67 MLR 632.

Edgar A, ‘Genetic information and public opinion’ in Widdows H and Mullen C, *The Governance of Genetic Information: Who Decides?* (CUP 2009).

Eensaar R, ‘Estonia: Ups and Downs of a biobank project’ in Gottweis H and Petersen A, *Biobanks: Governance in comparative perspective* (Routledge 2008).

Einsiedel E, *Whose Gene, Whose Safe, How Safe? Publics’ and Professionals’ Views of Biobanks* (Canadian Biotechnology Advisory Committee 2003).

Elliott MC, *The Constitutional Foundations of Judicial Review* (Hart 2001)

Elliot M and Thomas R, *Public Law* (OUP 2011).

Emma Jane Kirby, 'Iceland's DNA: The world's most precious genes?' (*BBC News*, 19 June 2014) <www.bbc.co.uk/news/magazine-27903831> accessed 31 Jan 2016. Karl Stefansson speaking to the BBC.

Epstein L and King G, 'The Rules of Inference' (2002) 69 University of Chicago Law Review 1.

Fan CT, Lin JC and Lee CH, 'Taiwan Biobank: a project aiming to aid Taiwan's transition into a biomedical island' (2008) 9 Pharmacogenomics 235.

Fears R and Poste G, 'Building Population Genetics Resources Using the U.K. NHS' (1999) 284 Science 267.

Feldman D, 'Changes in Human Rights' in Adler M (ed), *Administrative Justice in Context* (Hart 2010).

Ferriman A, 'House of Lords supports first UK genetic database' (2001) 322 BMJ 755.

Forsyth C, 'The Scope of Judicial Review: 'Public Duty' not 'Source of Power'' [1987] PL 356

Fortin S, Pathmasiri S, Grintuch R and Deschenes M, '"Access Arrangements" for Biobanks: a fine line between facilitating and hindering collaboration' (2011) 14 Public Health Genomics 104.

Fortun M, 'Towards Genomic Solidarity: Lessons from Iceland and Estonia.' (OpenDemocracy, 9 June 2003) <www.opendemocracy.net/theme_9-genes/article_1344.jsp> accessed 30th Jan 2016.

Freeman RE, 'The politics of stakeholder theory: some future directions' (1994) 4 Business Ethics Quarterly 409.

Freeman RE, *Strategic Management: A Stakeholder Approach* (CUP 1984).

French J, 'Something is Rotten in the State of Iceland: DeCODE Genetics, Population Research and Informed Consent' in Rimmer M, *Patent Law and Biological Inventions* (Elgar 2006).

Gamble A and Thomas R, 'The Changing Context of Governance: Implications for Administration and Justice' In Alder M, *Administrative Justice in Context* (Hart 2010).

Garton J, 'The judicial review of the decisions of charity trustees' (2006) 20 Trust Law International 160.

GeneWatch UK, (Press Release) 'UK Biobank based on fales assumptions and a waste of public money says GeneWatch' (*GeneWatch UK*, 15th March 2006) <www.genewatch.org/article.shtml?als[cid]=507674&als[itemid]=537742> accessed 12 April 2012.

GeneWatch UK, Memorandum submitted by Gene Watch UK (Appendix 2 to The Minutes of Evidence) in Select Committee on Science and Technology, *The Work of the Medical Research Council* (HC 2002-3, 132).

Gertz R, 'Withdrawing from participating in a biobank---a comparative study' (2008) 15 Eur J Health Law 381.

Gewirth A, *Community of Rights* (University of Chicago Press 1996).

Gewirth A, *Reason and Morality* (University of Chicago Press 1978).

Gibbons S and others, 'Governing Genetic Databases: Challenges Facing Research Regulation and Practice' (2007) 34 Journal of Law and Society 175.

Gibbons S, 'Are UK genetic databases governed adequately? A comparative legal analysis' (2008) 27 Legal Studies 317.

Gibbons S, 'Governance of Population Genetic Databases: A Comparative Analysis of Legal Regulation in Estonia, Iceland, Sweden and the UK' in Hayry M, Chadwick R, Arnason V and Arnason G (eds), *The Ethics and Governance of Human Genetic Databases Cambridge* (CUP 2007) 132.

Gibbons S, 'Lessons from European Population Genetic Databases: Comparing the Law in Estonia, Iceland, Sweden and the United Kingdom' (2005) 12 Eur J Health Law 114.

Gitter D, 'Ownership of human tissue: a proposal for federal recognition of human research participants' property rights in their biological material' (2004) 61 Washington & Lee Law Review 262.

Gliwa C and Berkman M, 'Do Researchers Have an Obligation to Actively Look for Genetic Incidental Findings?' (2013) 13 American Journal of Bioethics 41.

Godard B, Marshall J, Laberge C and Knoppers BM, 'Stategies for consulting with the community: the case of four large-scale genetic databases' (2004) 10 Science and Engineering Ethics 468.

Goodpaster K, 'Business ethics and stakeholder analysis' in Winkler E and Coombs J (eds), *Applied Ethics: A Reader* (Blackwell 1993) 229.

Gottweis H and Lauss G, 'Biobank governance: heterogeneous modes of ordering and democratization' (2012) 3 Journal of Community Genetics (2012) 72.

Gottweis H and Peteresen, *A Biobanks: Governance in Comparative Perspectives* (Routledge 2008).

Gottweis H, Kaye J, Bignami F and others, *Biobanks for Europe; A Challenge for Governance* Luxembourg (European Commission, 2012) doi:10.2777/68942.

Graham J, Amos B and Plumptre T, *Principles of good governance in the 21st Century—Policy Brief No. 15* (Institute on Governance 2003) <http://unpan1.un.org/intradoc/groups/public/documents/UNPAN/UNPAN011842.pdf> accessed 31 Jan 2016.

Greely HT, 'Human Genomics Research: new challenges for research ethics' (2001) 44 Perspectives in Biology and Medicine 221.

Greely HT, 'The Uneasy Ethical Underpinnings of Large-Scale Genomic Biobanks' (2007) 8 Annu Rev Genomics Hum Genet 343.

Green RC and others, 'ACMG recommendations for reporting of incidental findings in clinical exome and genome sequencing' (2013) 15 Genetics in Medicine 565.

Grosse SD and Khoury MJ, 'What is the clinical utility of genetic testing?' (2006) 8 Genetic Med 448.

Haddow G and others, 'Tackling community concerns about commercialisation and genetic research: A modest interdisciplinary proposal' (2007) 67 Social Science & Medicine 272.

Hancher L and Moran M, 'Organizing regulatory space', in L Hancher and M Moran (eds), Capitalism, Culture and Regulation (Clarendon Press 1989).

Hannigan B, *Company Law* (2nd ed, OUP 2009).

Harlow C, '"Public" and "Private" Law: Definition without Distinction' (1980) 43 MLR 241.

Hawkins N, 'Intellectual Property and Biobanks' in Mascalzoni D, *Ethics, Law and Governance of Biobanking: National, European and International Approaches* (Springer 2015).

Hillman AJ and Keim GD 'Shareholder value, stakeholder management, and social issues: what's the bottom line?' (2001) 22 Strategic Management Journal 126.

Holland S, 'Contested commodities at both ends of life: buying and selling gametes, embryos, and body tissues' (2001) 11 Kennedy Institute of Ethics Journal 263.

Holm S, 'Me, Myself, I- against narcissism in the governance of genetic information' in Widdows H and Mullen C, *The Governance of Genetic Information: Who Decides?* (CUP 2009).

Hood L, Rowen L, Galas DJ and Aitchison JD, 'Systems biology at the Institute for Systems biology and the future of medicine' (2011) 3 Wiley Interdisciplinary Review of Systems Biology Medicine 619.

Horsley K and Rackley E, *Tort Law* (2nd edn, OUP 2011).

Hunt M, 'The "horizontal effect" of the Human Rights Act' [1998] PL 423.

Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C (eds) *The Governance of Genetic Information: Who Decides?* (Cambridge University Press 2009).

Hunter K and Laurie G, 'Involving publics in biobank governance: moving beyond existing approaches' in Widdows H and Mullen C., *The Governance of Genetic Information: Who Decides?* (CUP 2009).

Hutton W, *The State We're In* (Jonathan Cape 1995).

Iecovich E, 'The profile of board membership in Israeli voluntary organisations' (2005) 16 Voluntas 161.

Illes J, Kirschen MP, Edwards E and others, 'Ethics: Incidental findings in brain imaging research' (2006) 311 Science 783.

International Human Genome Sequencing Consortium, 'Finishing the Euchromatic Sequence of the Human Genome' (2004) 431 Nature 931.

Ireland P, 'Company Law and the Myth of Shareholder Ownership' (1999) 62 MLR 32.

Jacob JM, 'The Bowman Review of the Court of Appeal' (1998) 61 MLR 390.

John Stuart Mill, *Utilitarianism* (Parker, Son and Bourn 1861).

Johnston C and Kaye J, 'Does the UK Biobank have a Legal Obligation to Feedback Individual Findings to Participants?' (2004) 12 Medical Law Review 239.

Jones M and Salter B, 'The governance of human genetics: policy discourse and constructions of public trust' (2003) 22 New Genetics and Society 21.

Kairie S, 'At crossroads: shareholder value, stakeholder value and enlightened shareholder value: which road should the United Kingdom take?' (2007) 17 International Company and Commercial Law 329.

Kaiser J, 'Agency Nixes deCODE's New Data Mining Plan' (2013) 340 Science 1389.

Kakabase NK, Rozeul C and Lee-Davies L, 'Corporate responsibility and stakeholder approach: a conceptual review (2005) 1 International Journal of Business Governance and Ethics 277.

Kattel R and Suurna M, 'The Rise and Fall of the Estonian Genome Project' (2008) 2 Studies in Ethics, Law, and Technology DOI: 10.2202/1941-6008.1050

Kaye J and Bell J, 'Biobank Governance' in *Introduction to Biobanking* (IPRI forthcoming)

Kaye J and others, 'Data Sharing in Genomics – Reshaping Scientific Practice' (2009) 10 Nat Rev Genet 331.

Kaye J, 'From single biobanks to international networks: developing e-governance' (2011) 130 Hum Gen 377.

Kaye J, 'Report may lead to population collection by the back door' (2001) 323 BMJ doi: http://dx.doi.org/10.1136/bmj.323.7313.632.

Kaye J, 'The Regulation of Human Genomics Research' in Kumar D and Eng C (eds) *Genomic Medicine: Principles and Practice* (2nd Edn, OUP 2014).

Kaye J, 'The Tension Between Data Sharing and the Protection of Privacy in Genomics Research' (2012) 13 Annu Rev Genomics Hum Genet 415.

Kaye J, Bell J, Briceño Moraia L and Mitchell C, 'Biobank Report: United Kingdom' (forthcoming) JLME

Kaye J, Boddington P, de Vries J, Gowans H, Hawkins N, Heeney C and Melham K, *Ethical, Legal and Social Issues Arising from the Use of GWAS in Medical Research* (Wellcome Trust 2009).

Kaye J, Gibbons S, Heeney C, Parker M and Smart A, *Governing Biobanks: Understanding the Interplay between Law and Practice* (Hart 2012).

Kaye J, Whitley EA, Lund D, Morrison M, Teare H and Melham K, 'Dynamic consent: A patient interface for twenty-first century research networks' (2014) 23 Eur J Hum Genet 141.

Keis A, 'The Estonian Genome Centre, University of Tartu' in Mascalzoni D (ed) *Ethics, Law and Governance of Biobanking* (Springer 2015).

Kennedy I and Grubb A, *Medical Law* (3rd edn, Butterworths 2000).

Kersbergen K and Waarden V, '"Governance" as a bridge between disciplines: Cross-disciplinary inspiration regarding shifts in governance and problems of governability, accountability and legitimacy' (2004) 43 European Journal of Political Research 143.

Knoppers BM and Dam A, 'Return of Results: Towards a Lexicon?' (2011) 39 JLME 577.

Knoppers BM and Kharaboyan L, '"Deconstructing" Biobank Communication of Results' (2009) 6 SCRIPTed 677.

Knoppers BM and others, 'Towards a data sharing Code of Conduct for international genomic research' (2011) 3 Genome Medicine 46.

Knoppers BM and Zawati MH, 'Biobanks' in Chadwick R (ed) *Encyclopaedia of Applied Ethics* (San Diego Academic Press 2012).

Knoppers BM, Joly Y and Simard J and Durocher F, 'The emergence of an ethical duty to disclose genetic research results: international perspectives' (2006) 14 European Journal of Human Genetics 1170.

Kohane IS, Mandl KD, Taylor PL, Holm IA, Nigrin DJ and Kunkel LM, 'Medicine; Re-establishing the researcher-patient compact' (2007) 316 Science 836.

Langan MA, 'A contemporary history of the origins and development of UK Biobank 1998-2005 (PhD thesis, University of Glasgow 2007).

Lansley J, 'Membership Participation and Ideology in Large Voluntary Organisations: The case of the National Trust' (1996) 7 Voluntas 221.

Laurie G and others,'Managing Access to Biobanks: How Can We Reconcile Individual Privacy and Public Interests in Genetic Research?' (2010) 10 Med Law Int 315.

Laurie G and Sethi N, 'Towards Principles-Based Approaches to Governance of Health-related Research using Personal Data' (2013) 4 The European Journal of Risk Regulation 43.

Laurie G, 'In Defence of Ignorance: Genetic Information and the Right Not to Know' (1999) 6 European Journal of Health Law 119.

Laurie G, 'Obligations Arising from Genetic Information: Negligence and the Protection of Familial Interests' (1999) 11 Child and Family Law Quarterly 109.

Laurie G, 'Managing Access to Biobanks: How Can We Reconcile Privacy and Public Interests in Genetic Research?' (2010) 10 Medical Law International 315.

Laurie G, 'Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law' (2011) 130 Hum Genet 347.

Laurie G, *Genetic Privacy: A Challenge to Medico-Legal Norms* (CUP 2002).

Lemmens T, Lori L and Hoy M, 'Genetic Information Access, a Legal Perspective: A Duty to Know or a Right Not to Know, and a Duty or Option to Warn?' in *Encyclopaedia of Life Sciences* (Wiley, 15th July 2008) DOI: 10.1002/9780470015902.a0005188.

Levitt M and Weldon S, 'A well placed trust?: Public perceptions of DNA databases.' (2005) 15 Critical Public Health 314.

Levitt M, 'UK Biobank: a model for public engagement?' (2005) 1 Genomics Society and Policy 78.

Logie J, 'Affirmative Action in the Law of Tort: The Case of the Duty to Warn' (1989) 48 CLJ 115.

Lord Woolf, 'Judicial Review: A Possible Programme for Reform' [1992] PL 221.

Loughlin M, 'Courts and Governance' in Birks P (ed) *The Frontiers of Liability* (OUP 1994).

Low C and Cowton C, 'Beyond stakeholder engagement: the challenges of stakeholder participation in corporate governance' (2004) 1 International Journal of Business Governance and Ethics 45.

Low C, 'A framework for the governance of social enterprise' (2006) 33 International Journal of Social Economics 376.

Lowrance WW and Collins FS, 'Identifiability in genomic research' (2007) 317 Science 600.

Luther L and Lemmens T, 'Human Genetic Data Banks: From Consent to Commercialization – An Overview of Current Concerns and Conundrums' in Doelle WH and DaSilva EJ (ed) *Biotechnology, Encyclopedia of Life Support Systems* (EOLSS 2007).

Luxton P, *The Law of Charities* (OUP 2001).

Lyall C and Tait J (eds), *New Modes of Governance; developing an Integrated Policy Approach to Science, Technology, Risk and the Environment* (Ashgate 2005).

M Burgess, O'Doherty K and Secko D, 'Biobanking in British Columbia: discussions of personalized medicine through deliberative public engagement' (2008) 5 Personalized Medicine 285.

Mac Amhlaigh C, 'Once More Unto the (Public/Private) Breach …: s. 6 of the Human Rights Act 1998 and the Severability Thesis' (UK Const Law Assoc Blog, 13th December 2013) <http://ukconstitutionallaw.org/2013/12/13/cormac-mac-amhlaigh-once-more-unto-the-publicprivate-breach-s-6-of-the-human-rights-act-1998-and-the-severability-thesis/> accessed 31 Jan 2016.

Malin B, Loukides G, Benitez K and Clayton EW, 'Identifiability in biobanks: models, measures, and mitigation strategies' (2011) 130 Human Genetics 383.

Manolio TA, Bailey-Wilson JE and Collins FS, 'Genes, environment and the value of prospective luthercohort studies' (2006) 10 Nature Review Genetics 812.

Manson N, 'The medium and the message: tissue samples, genetic information and data protection legislation' in Widdows H and Mullen C *The Governance of Genetic Information: Who Decides?* (CUP 2009).

Martin P and Kaye J, *The Use of Biological Sample Collections and Personal Medical Information in Human Genetics Research* (The Wellcome Trust 1999) <www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtd003283.pdf> accessed 31 Jan 2016.

Mason K and Laurie G, *Mason and McCall Smith's Law and Medical Ethics* (9th edn, OUP 2013).

Mason C, Kirkbride J and Bryde DJ, 'From stakeholders to institutions: the changing face of social enterprise governance theory' (2007) 45 Management Decision 284.

McIvor CM, *Liability in Tort for the acts of third parties; in search for coherence* (PhD Thesis, Durham University 2003).

Mead D, 'The Continuing Mystery of "Publicness" within Section 6 of the HRA' (UK Const Law Assoc Blog, 17th October 2013) <http://ukconstitutionallaw.org > accessed 31 Jan 2016.

Metcalf C, 'The stakeholder corporation' (1998) 7 Business Ethics 30.

Metspalu A and others, 'Cohort Profile: Estonian Biobank of the Estonian Genome Centre, University of Tartu' (2014) 1 International Journal of Epidemiology 11.

Meyer M, 'Icelandic Supreme Court holds that inclusion of an individual's genetic information in a national database infringes on the privacy interests of his child' (2004) 118 Harvard Law Review 810.

Middleton A and others, 'Attitudes of nearly 7000 health professionals, genomic researchers and publics toward the return of incidental results from sequencing research'(2016) 24 European Journal Human Genetics 21.

Miller FG, Mello MM and Joffe S, 'Incidental findings in genomic research: what do investigators owe research participants?' (2008) 36 JLME 271.

Morsing M and Shultz M, 'Corporate social responsibility communication: shareholder information, response and involvement strategies' (2006) 15 Business Ethics: A European Review 323.

Mulheron R, *Medical Negligence: Non-Patient and Third Party Claims* (Ashgate 2010).

Murphy J, Scott J, Kaufman D, Geller, G LeRoy L and Hudson K, 'Public expectations for return of results from large-cohort genetic research' (2008) 8 American Journal of Bioethics 36.

Nature Editorial, 'Careless.data' (2014) 507 Nature 7.

Nelkin D and Andrews L, 'Homo economicus: commercialisation of body tissue in the age of biotechnology' (1998) 28 Hasting's Centre Report 30.

Nelkin D and Lindee M, *The DNA Mystique: The gene as a cultural icon* (WH Freeman 1995).

Nicol D and Critchley C, 'Benefit Sharing and Biobanking in Australia' (2012) 21 Public Underst Sci 534.

Nobile H and Borry P, 'Why do participants enroll in population biobank studies? A systematic literature review' (2013) 13 Expert Rev Mol Diagn 35.

Nolan RC, 'Controlling fiduciary power' (2009) 68 CLJ 293.

Nuffield Council on Bioethics, *The collection, linking and use of data in biomedical research and health care: ethical issues* (Nuffield Council 2015) < http://nuffieldbioethics.org/project/biological-health-data/> accessed 05th Feb 2016.

O'Doherty and others, 'From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks.' (2011) 73 Social Science & Medicine 367.

O'Doherty KC, Burgess MM, Edwards K, Gallagher RP, Hawkins AK, Kaye J, McCaffrey V and Winickoff DE, 'From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks' (2011) 73 Social Science & Medicine 367.

Oliver D, 'Functions of a Public Nature under the Human Rights Act' [2004] PL 329.

Oliver D, 'Lord Denning and the Public/Private Divide' (1999) 14 Denning Law Journal 79.

Oliver D, 'The frontiers of the State: public authorities and public functions under the Human Rights Act' [2000] PL 476.

Oliver D, 'Towards Horizontal Effect of Administrative Justice Principles' in Alder M, *Administrative Justice in Context* (Hart 2010).

Oliver D, *Common Values and the Public-Private Divide* (Butterworths 1999).

Oliver D, 'Is the Ultra Vires Rule the Basis of Judicial Review?' [1987] Public Law 543

Opinion Leader, 'Accessing Public Attitudes to Health Related Findings in Research' (Wellcome Trust, April 2012) <www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtvm055196.pdf> accessed 19 Nov 2013.

Otlowski M, 'Developing an appropriate consent model for biobanks: in defence of 'broad' consent' in Kaye J and Stranger M (eds) *Principles and practice in biobank governance* (Ashgate 2009).

Palmer E, 'Should Public Health be a Private Concern? Developing a Public Service Paradigm in English Law' (2002) 22 OJLS 663.

Palmer E, 'The Liability of 'Functional Public Authorities' for Breach of ECHR Rights: The House of Lords Endorses a Palpable Gap in Human Rights Protection' (2008) 16 Med LR 141.

Palmer E, Public functions and private services: A gap in human rights protection (2008) 6 Int J Constitutional Law 585.

Pannick D, 'Who is Subject to Judicial Review and in Respect of What?' [1992] PL 1

Papaioannou T, 'Democratic governance of genomics: the case of UK Biobank' (2012) 31 New Genetics and Society 111.

Parliamentary Office of Science and Technology (POST), 'The 100,000 Genomes Project' (POSTnotes POST-PN-0504, 2015) <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-0504> accessed 04th Jan 2016.

Parthasarathy S, *Building Genetic Medicine: Breast Cancer, Technology, and the Comparative Politics of Health Care* (MIT Press 2007).

Paul Rincon, 'Science enters the $1000 genome era' (*BBC News*) <www.bbc.co.uk/news/science-environment-25751958> accessed 25 Jan 2014.

Peterson SE and others, 'Imaging in population science: cardiovascular magnetic resonance in 100, 000 participants of UK Biobank- rationale, challenges and approaches' (2013) 15 Journal of Cardiovascular Magnetic Resonance doi:10.1186/1532-429X-15-46.

Phillipson G, 'The Human Rights Act and Private Law' (2000) 116 LQR 48.

Plomer A, *Law and Ethics of Medical Research: International Bioethics & Human Rights* (Routledge 2005).

Poste G, 'Memorandum by Dr George Poste, Chief Science and Technology Officer, SmithKline Beecham' in Science and Technology Committee, *Second Report* (HL 1999-2000, HL 11).

Powledge TM, 'Revisiting Bermuda' (2003) 4 Genome Biology doi:10.1186/gb-spotlight-20030311-01.

Prainsack B and Buyx A, 'Solidarity in Contemporary Bioethics – Towards A New Approach' (2012) 26 Bioethics 346.

Presidential Commission for the Study of Bioethical Issues, *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts* (Presidential Commission for the Study of Bioethical Issues 2013) <http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf> accessed 14th March 2015

Professor Sir Rory Collins, 'Big Data in the UK Biobank: Opportunities and Challenges' (Gresham College Lecture, London, November 2014) <www.gresham.ac.uk/lectures-and-events/big-data-in-the-uk-biobank-opportunities-and-challenges> accessed 6 June 2015.

Ravitsky V and Wilfond BS, 'Disclosing individual genetic results to research participants' (2006) 6 Am J Bioethics 8.

Richardson HS and Belsky L, 'The Ancillary-Care Responsibilities of Medical Researchers: An Ethical Framework for Thinking about the Clinical Care that Researchers Owe to their Subjects' (2004) 34 Hastings Centre Report 25.

Rose H, 'The Commodification of Bioinformation: The Icelandic Health Sector Database' (The Wellcome Trust 2001) <http://www.wellcome.ac.uk/About-us/Publications/Reports/Biomedical-ethics/WTD003280.htm> accessed 18 July 2014.

Rothstein M, 'Expanding the Ethical Analysis of Biobanks' (2005) 33 JLME 89.

Salter B and Jones M, 'Biobanks and bioethics: the politics of legitimation.' (2005) 12 Journal of European Public Policy 710.

Sampford C,'Law, Institutions and the Public/Private Divide' (1991) 20 Fed L Rev 185.

Santosuosso A, 'Should Privacy Be Abolished in Genetics and Biobanking?' in Pascuzzi G, Izzo U and Macilotti M (eds), *Comparative Issues in the Governance of Research Biobanks: Property, Privacy, Intellectual Property, and the Role of Technology* (Springer 2013).

Schroder C, Heidtke KR, Zacherl N, Zatloukal K and Taupitz J, 'Safeguarding donors' personal rights and biobank autonomy in biobank networks: the CRIP privacy regime' (2010) 12 Cell Tissue Bank 233.

Science and Technology Committee, *Human Genetic Databases: Challenges and Opportunities* (HL 2000-2001, 57)

Scott C, 'Accountability in the Regulatory State' (2000) 27 J Law and Society 38.

Scott C, 'Analysing Regulatory Space: fragmented resources and institutional design' [2001] PL 329.

Shaw DM, Elger BS and Colledge F, 'What is a biobank? Differing definitions among biobank stakeholders' (2014) 85 Clin Genet 223.

Sjafjell B, Johnston A, Anker-Sorensen L, and Millon D 'Shareholder primacy: the main barrier to sustainable companies' in Sjafjell B and Richardson BJ (eds), *Company Law and Sustainability: Legal Barriers and Opportunities* (CUP 2015).

SmithKline Beecham memorandum to House of Lords Select Committee on Science and Technology 4th Report: Committee on Science and Technology, Human Genetic Databases: Challenges and Opportunities (HL 2000-2001, 57).

Stapleton J, 'The Gist of Negligence: Part I: Minimum Actionable Damage' (1988) 104 LQR 213.

Steinsbekk KS, Myskja BK and Solberg B, 'Broad consent versus dynamic consent in biobank research: is passive participation an ethical problem?' (2013) 21 European Journal of Human Genetics 897.

Sutrop M, 'Trust' in Hayry M, Chadwick R, Arnason V, Arnason G, (eds) *The ethics and governance of human genetic databases* (Cambridge University Press 2007) 190.

Tait J, 'Risk governance of genetically modified crops: European and American perspectives' in Renn O and Walker KD (eds) *Global Risk Governance* (Springer 2008).

Taylor MJ and Grace J, 'Disclosure of Confidential Patient Information and the Duty to Consult: The Role of the Health and Social Care Information Centre' (2013) 21 Med Law Rev 415.

Taylor MJ and Taylor N, 'Health research access to personal confidential data in England and Wales: assessing any gap in public attitude between preferable and acceptable models of consent' (2014) 10 Life Sci Soc Policy doi:10.1186/ s40504-014-0015-6.

Taylor MJ and Townend D, 'Issues in protecting privacy in medical research using genetic information and biobanking: the PRIVILEGED project' (2010) 10 Med Law Int 253.

Taylor MJ, 'Health Research, Data Protection and the Public Interest in Notification' (2011) 19 Med Law Rev 267.

Taylor MJ, 'Legal bases for disclosing confidential patient information for public health: Distinguishing between health protection and health improvement' (2015) 23 Med Law Rev 348.

Taylor MJ, *Genetic Data and the Law: A Critical Perspective on Privacy* (Cambridge University Press 2015).

Taylor PN, 'Enlightened Shareholder Value and the Companies Act 2006' (PhD thesis, Birkbeck College, University of London 2010).

Titmuss R, *The Gift Relationship, From Human Blood to Social Policy* (George Allen and Unwin 1970).

Townend D, Taylor MJ, Wright J and Wickins-Drazilova D, 'Privacy and Access: Privacy Interests in Biobanking: A Preliminary View on a European Perspective,' in J Kaye and M Stranger (eds), *Principles and Practice in Biobank Governance* (Ashgate, 2009).

Tutton R 'Person, property and gift: exploring languages of tissue donation to biomedical research' in Tutton R and Corrigan O (eds), *Genetic Databases: Socio-ethical issues in the collection and use of DNA* (Routledge 2004).

Tutton R, Kaye J and Hoeyer K, 'Governing UK Biobank: the importance of ensuring public trust.' (2004) 22 Trends Biotechnol 284.

Twining W and Miers D, *How to Do Things With Rules* (5th edn, CUP 2010).

UK Biobank, 'UK Biobank Ethics and Governance Framework' (Version 3.0, UK Biobank 2007) <www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> accessed 24 Jan 2016.

UNESCO, *International Declaration on Human Genetic Data* (UNESCO, 2003)

Vaught J, Rogers J, Carolin T and Compton C, 'Biobankonomics: Developing a Sustainable Business Model Approach for the Formation of a Human Tissue Biobank' (2011) 42 J Natl Cancer Inst Monogr 24.

Vincent-Jones P, 'Citizen Redress in Public Contracting for Human Services' (2005) 68 Modern Law Review 887.

Wakeford T and Hale F, Generation Scotland: Towards Participatory Models of Consultation (University of Newcastle, Policy Ethics and Life Sciences Research Institute (PEALS) 2004) <www.generationscotland.org/images/stories/GS_-_towards_participatory_models_of_Consultation.pdf> accessed 06 Feb 2016.

Wallace H, *Bioscience for Life?—Appendix A; The history of UK Biobank, electronic medical records in the NHS, and the proposal for data-sharing without consent* (Genewatch UK 2009) <

www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/UK_Biobank_fin_2.pdf> accessed 31 Jan 2016.

Wallace H,'The development of U.K. Biobank: excluding scientific controversy from ethical debate' (2005) 15 Critical Public Health 323.

Wallace S and Kent A, 'Population Biobanks and Returning Individual Research Results - Mission Impossible or New Directions?' (2011) 140 Human Genetics Journal 395.

Wallace SE, Gourna EG, Laurie G, Shoush O and Wright J, 'Respecting Autonomy Over Time: Policy and Empirical Evidence on Re-Consent in Longitudinal Biomedical Reasearch' [2015] Bioethics DOI: 10.1111/bioe.12165.

Walport M and Brest P, 'Sharing research data to improve public health' (2011) 377 The Lancet 537.

Warburton J, 'Charities, Members, Accountability and Control' (1996) Conveyancer and Property Lawyer (July-Aug) 106.

Warburton J, 'Charity corporations: the framework for the future' [1990] Conveyancer and Property Lawyer (March-April) 95.

Warburton J, 'Charity members: duties and responsibilities' (2006) 70 Conveyancer and Property Lawyer 330.

Watson PH and others, 'A Framework for Biobank Sustainability' (2014) 12 Biopreservation and Biobanking 60.

Wedderburn KW, 'Shareholders' Rights and the Rule in Foss v. Harbottle' (1957) 15 Cambridge Law Journal 194.

Wellcome Trust memorandum to Committee on Science and Technology Fourth Report: 'Human Genetic Databases: Challenges and Opportunities' (HL 2000-2001, 57) para 24.

Williams A, 'A Fresh Perspective on Hybrid Public Authorities under the Human Rights Act: Private Contractors, Rights-Stripping and "Chameleonic" Horizontal Effect' (2011) 139 Public Law 51.

Williams A, 'The Scope of Section 6 HRA Revisited' UK Const. L. Blog (*UK Const Law Assoc Blog*, 28th October 2013) <https://ukconstitutionallaw.org/2013/10/28/alexander-williams-the-scope-of-section-6-hra-revisited/> accessed 06th Feb 2016.

Williams D, 'Administrative Law in England: The Emergence of a New Remedy' (1986) 27 Wm & Mary L Rev 715.

Williams H, Spencer K, Sanders C, Lund D, Whitley EA, Kaye J and Dixon WG, 'Dynamic consent: a possible solution to improve patient confidence and trust in how electronic patient records are used in medical research' (2015) 3 JMIR Med Inform e3.

Winickoff DE and Neumann L, 'Towards a Social Contract for Genomics: Property and the Public in the 'Biotrust' Model' (2005) 1 Genomics Society and Policy 8.

Winickoff DE and Winickoff RN, 'The Charitable Trust as a Model for Genomic Biobanks' (2003) 349 N Engl J Med 1180.

Winickoff DE, 'A Bold Experiment: Iceland's Genomic Venture' in Mascalzoni D (ed), *Ethics, Law and Governance of Biobanking* (Springer 2015) 187.

Winickoff DE, 'Genome and Nation: Iceland's Health Sector Database and its Legacy' (2006) 1 Innovations 80.

Winickoff DE, 'Governing population genomics: law bioethics, and biopolitics in three case studies' (2003) 43 Jurimetrics 187.

Winickoff DE, 'Partnership in U.K. Biobank: a third way for genomic property?' (2007) 35 JLME 440.

Wolf SM and others, 'Managing incidental findings and research results in genomic research involving biobanks and archived data sets' (2012) 14 Genet Med 361.

Wolf SM, 'The Past, Present, and Future of the Debate over the Return of Research Results and Incidental Findings' (2012) 14 Genetic Med 355.

Wolf SM, Paradise J and Caga-anan C 'The Law of Incidental Findings in Human Subjects Research: Establishing Researchers' Duties' (2008) 36 JLME 361.

Woolf H, 'Public Law- Private Law: Why the Divide?' [1986] Public Law 57.

World Health Organisation, Governance for Health in the 21st Century: a study conducted for the WHO Regional Office for Europe (WHO 2011) EUR/RC61/Inf.Doc./6.

World Medical Association, *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects* (WMA 1964, Helsinki, Latest revision Fortaleza, 2013).

Zawati MH and Rioux A, 'Biobanks and the Return of Research Results: Out with the Old and In with the New?' (2011) 39 JLME 614.