

Regulation of biobanks in Mexico: Ethical and legal issues

Liliana Soto Gómez

**Submitted in accordance with the requirements for the
degree of**

Doctor of Philosophy

The University of Leeds

School of Law

August 2016

The candidate confirms that the work submitted is her own and that appropriate credit has been given where reference has been made to the work of others.

This copy has been supplied on the understanding that it is copyright material and that no quotation from the thesis may be published without proper acknowledgement

© 2017 The University of Leeds and Liliana Soto Gómez

The right of Liliana Soto Gómez to be identified as Author of this work has been asserted by her in accordance with the Copyright, Designs and Patents Act 1988.

Acknowledgements

Foremost, I would like to express my sincere gratitude to my supervisors: Graham Dutfield, Emma Cave and Frederique Ponchel. Their guidance helped me in all the time of research and writing of this thesis. Without their constant feedback this PhD would not have been achievable.

My sincere thanks to Dr. Ponchel for the exciting three year work opportunity in BTCure. I greatly appreciate the support received through this collaboration, my first practical job experience as a legal adviser.

I gratefully acknowledge the full funding received towards my PhD from CONACYT, the Mexican National Council for Science and Technology.

I would like to thank my family, especially my husband Robert James, my mother Carmen Paulina and my aunt Lilia, for their support in all possible ways throughout this journey. Thank you to my brother Raul, for being with me on the day of my *viva voce* and to my father Hermelindo, for being there despite physical distance.

I dedicate this thesis to my son Jacob Alec, my everyday joy, to my daughter Juliet Anastasia, who will arrive to fulfil my life with happiness, and to my late grandmother Anastasia, whose memory inspires me to always stay strong.

Special mentions to my uncles Abel and Raul.

Abstract

This thesis investigates the governance of biobanks in Mexico, exploring elements of legislative reform for the improvement of current legal and ethical guidance. It argues that the great benefits to be obtained from research using biobanks (e.g. personalised or stratified medicine) are at risk of being undermined by the absence of clear legal pathways.

A number of legal and ethical issues have emerged from the different aspects of biobanks. Diverse theoretical approaches are reflected in academic literature and heterogeneous legislation of biobanks around the world. Specific binding rules have worked for some, whereas self-regulation has proven suitable for others. Social solidarity has played a key role in innovative biobanking law and decision making, in which traditional governance approaches have become more reflexive, involving not only law and policymakers, but also the public.

A detailed legal analysis revealed significant gaps within the complex Mexican laws governing biobanks; this has caused confusion. Areas of concern were identified in relation to the ethical management of research samples and the protection of donors' rights. This is concerning in Mexico where economic interests influence legal reform, giving way to opportunistic actions by the international pharmaceutical industry and leaving vulnerable populations unprotected. The greatest challenges for Mexican legislators are finding ways to respond to legal gaps with new laws and improving the effectiveness of existing rules.

Due to the scarcity of literature on the topic, interviews were conducted with representative actors in strategic areas. Participation in the European Union research network BTCure enabled the inclusion of a study investigating how European experiences can be valuable examples for Mexico to follow. The results of this research indicate ways forward for Mexican governance, which are expected to influence further legislative reforms of biobanks.

Table of contents

Abstract.....	4
I. INTRODUCTION AND METHODOLOGY	
1. Introduction.....	13
1.1 Conceptualising biobanks.....	14
1.1.1 The characteristics of biobanks.....	15
1.1.2 Historical background.....	16
1.1.3 Legal consequences of conceptualising biobanks.....	17
1.1.4 The concept of biobanks from the international perspective.....	18
1.2 Different types of biobanks.....	19
1.2.1 Categorisation.....	21
1.3. The importance of personalised medicine.....	25
1.3.1. Personalised/stratified medicine.....	26
1.4 The main challenges of biobanking.....	27
1.5 Towards a sound legal and ethical policy to enhance biomedical research in Mexico using biobanks: research questions.....	30
1.6 Synopsis of each chapter.....	32
1.7 Concluding remarks.....	35
2. Methodology.....	36
2.1 Research methodology.....	36
2.1.1 Research methodology insights.....	36
2.1.2 Research methods.....	36
2.1.3 Desk based research.....	37
2.1.4 Fieldwork.....	38
2.1.4.1 Fieldwork development.....	39
2.1.4.2 Fieldwork: main challenges.....	47
2.2 The Mexican situation.....	48
2.2.1 Main biobanking concerns in Mexico.....	48
2.2.1.1 Conceptualisation issues: what is a biobank in Mexico?.....	50
2.2.1.2 What does a biobank contain?.....	52

2.2.2 The particular commercial pressures.....	53
2.2.2.1 Ethical conduct of the pharmaceutical industry.....	56
2.2.2.2 The relevance of the specific populations inside the country's boundaries.....	59
2.2.2.3. Ethical dilemmas on biobanking.....	60
2.2.2.3.1 The 'unique' Mexican genome and the claims of genomic sovereignty.....	61

II. THE MEXICAN CONTEXT

3. Risks, harms and values	63
3.1 Introduction.....	63
3.1.1 Historical cases.....	64
3.2 The concept of risk.....	66
3.2.1 Potential risks.....	67
3.2.1.1 Non-specific governance and consequent risks.....	69
3.3 Ethical values which should underpin regulation.....	70
3.3.1 Human dignity.....	71
3.3.2 Informed consent.....	72
3.3.2.1 Consent Withdrawal.....	74
3.3.3 Data protection.....	77
3.3.3.1 Data protection mechanisms.....	78
3.4 Mexican risks.....	80
3.4.1 Historical background.....	81
3.5 Case studies.....	85
3.5.1 Background: available guidance.....	86
3.5.2 Identified problems.....	88
3.5.2.1 Inconsistent self-regulation.....	88
3.5.2.2 Accessibility of the results.....	91
3.5.2.3 Consent.....	92
3.5.2.4 Data protection.....	95
3.5.2.4.1 Data protection mechanisms.....	96
3.5.2.4.2 Re-contact.....	96
3.5.2.4.3 Lack of coordination.....	97
3.6 Human rights.....	98

3.6.1 The human rights perspective in Mexico.....	100
3.6.2 Obstacles for the application of human rights international treaties.....	102
3.7 Concluding remarks.....	104
4. Current Mexican Regulation.....	106
4.1 Introduction.....	106
4.2 Mexican Internal Law System.....	106
4.2.1 Basic familiarisation concepts.....	106
4.2.1.1 Sources of law.....	107
4.2.1.1.1 Formal sources of law.....	107
4.2.1.1.2 Informal sources of law: custom, practice and doctrine.....	107
4.2.2 Main legal instruments.....	110
4.2.2.1 The Federal Constitution.....	110
4.2.2.2 Codes.....	111
4.2.2.3 Administrative standards.....	113
4.2.3 The Mexican Federal System.....	113
4.2.3.1 Relevant Federal Legislation.....	114
4.2.3.1.1 The regulation of public health: Federal Statutes.....	115
4.2.3.1.2 Regulation of human tissue.....	116
4.2.3.1.3 Regulation of the human genome.....	117
4.2.3.1.3.1 The human genome enactment.....	125
4.2.3.1.3.2 Genomic sovereignty..	128
4.2.3.1.4 Protection for vulnerable participants within scientific research.....	131
4.2.3.1.4.1 Participation of persons with legal incapacity.....	133
4.2.3.1.5 Administrative regulation of biobanks.....	135
4.2.3.2 Relevant local legislation.....	136
4.3 International law.....	138
4.3.1 International treaties and conventions to which Mexico is a party.....	142
4.3.1.1 Statutory recognition of international sources.....	144

4.4 Concluding remarks.....	143
5. Legal holes and weaknesses: fieldwork analysis.....	146
5.1 Introduction.....	147
5.1.1 Statements on the effectiveness of Mexican biobanking governance.....	147
5.2 Tissue regulation.....	148
5.2.1 Post mortem tissue.....	152
5.3 Informed consent	152
5.3.1 Governance perceptions on informed consent.....	156
5.4 Federal legislation on data protection.....	158
5.4.1 Data protection perceptions applicable to biobanks.....	160
5.4.1.1 Data protection mechanisms.....	162
5.4.1.2 Data and sample sharing.....	163
5.4.1.3 The impact on governing data protection on the national economy.....	164
5.4.1.4 Data protection on health research.....	165
5.5 Current guidance and institutions on health research.....	167
5.5.1 Reforms.....	171
5.5.2 Involved key governing institutions.....	172
5.5.2.1 The National Council for Science and Technology (CONACYT).....	173
5.5.2.2 The National Institute of Genomic Medicine (INMEGEN).....	173
5.5.2.3 The Federal Commission for the Protection against Sanitary Risk (COFEPRIS).....	174
5.5.2.4 The UNAM (National Autonomous University of Mexico) and other academic institutions.....	175
5.5.2.5 The National Bioethics Commission (<i>Comisión Nacional de Bioética</i> CNB).....	175
5.5.2.6 Ethics Committees.....	176
5.5.3 Rules for private companies.....	179
5.5.3.1 Private companies.....	181
5.5.4 Federal Sanctions.....	182

5.6 Concluding remarks.....	184
5.7 Identified problems in the current Mexican regulation of databases and/or biobanks.....	189

III. IMPLEMENTING CHANGE

6. European examples: What can be gained from the European experience?.....	192
6.1 Introduction.....	192
6.1.2 Background on international cooperation.....	192
6.2 Why Europe?.....	196
6.2.1 Guidelines based on human rights.....	197
6.2.2 The European Union background on biobanks.....	198
6.2.3 Pioneering biobanking legislation in Europe.....	200
6.2.3.1 The role of population biobanks in European regulation.....	201
6.3 Specific regulation subjects.....	202
6.3.1 Informed consent models and their implications.....	202
6.3.1.1 Consent of vulnerable population.....	207
6.3.1.2 Withdrawal of consent.....	208
6.3.2 Tissue.....	209
6.3.2.1 Post mortem samples.....	211
6.3.3 The relevance of data protection and the European data protection directive.....	212
6.3.3.1 Data and sample sharing.....	212
6.3.3.2 Data protection in Mexico.....	213
6.3.3.3 Data protection mechanisms	214
6.3.3.4 The European data protection directive.....	216
6.3.3.5 Re-contact issues.....	217
6.4 Oversight.....	219
6.4.1 Sanctions.....	221
6.4.2 Ethics committees.....	223
6.4.3 Self-regulation and E-governance.....	225
6.5 Concluding remarks.....	227
7. Implementing change in Mexican biobanking.....	230

7.1 Introduction	230
7.1.1 The role of governance.....	230
7.1.2 The model of reflexive governance	231
7.1.3 The legitimacy of governance actors.....	231
7.1.4 Public awareness and engagement.....	232
7.1.4.1 Public forums, a way to materialise public engagement?.....	233
7.2 Priority areas.....	235
7.2.1 Data protection.....	235
7.2.2 Informed consent: the suitability of a specific model.....	237
7.3 Main institutional issues.....	240
7.3.1 Coordinating governance issues.....	241
7.3.1.1 Institutional coordination efforts.....	242
7.3.1.2 CNB: they key to govern biobanks?.....	244
7.3.2 Main issues within health institutional committees.....	246
7.3.2.1 Integration and diversity.....	247
7.3.2.2 Members' background.....	247
7.3.2.3 Lack of Bioethics expertise.....	248
7.4 Proposal.....	249
7.5 Ethical guidance or binding rules?.....	251
7.6 The need for oversight in biobanking.....	253
7.6.1 The need for governance biobanking mechanisms.....	256
7.7 The role of trust.....	258
7.7.1 The impact of public trust in Mexican biobanking.....	259
7.7.1.1 Realistic promises or 'genohype'	260
7.7.2 Natural trust: an element to enhance.....	262
7.8 Emergent measures.....	262
7.9 Concluding remarks.....	264
8. Social Solidarity and justice.....	267
8.1 Introduction.....	267
8.1.1 The importance of social attitudes.....	267
8.1.1.1 The role of cultural attitudes in biobanking.....	268
8.1.2 Public accountability and awareness.....	270

8.1.2.1 Public awareness attitudes towards biobanking practices.....	271
8.1.2.2 Informed consent, an example of cultural influence.....	273
8.2 The role of social solidarity.....	276
8.2.1 Criticisms for solidarity in the literature.....	277
8.2.2 Social solidarity and biobanking.....	278
8.2.2.1 Social solidarity and ownership.....	280
8.2.3 Solidarity as a means to help disparities.....	281
8.2.4 Is social solidarity the most appropriate?.....	284
8.2.4.1 Vulnerable populations, a separate subject.....	284
8.2.5 Given the great inequalities in Mexico, can we expect solidarity?.....	287
8.3.1 Knowledge translation and social values.....	288
8.3.2 Knowledge translation and its regional boundaries.....	289
8.3.3 The desired impact of knowledge translation.....	293
8.4 The international experience.....	294
8.5 Education as means to avoid inequalities.....	297
8.5.1 Educating the public.....	298
8.6 Concluding remarks.....	299
9. Conclusions.....	301
10. References.....	306
Annex.....	1
Table 1.....	4
Table 2.....	5
Table 3.....	4
Table 4.....	7
Table 5.....	9
Table 6.....	11
Table 7.....	12
Table 8.....	14
List of figures	
Biobanks' classification.....	22
Participants' profile.....	41
Chronology on human genome legislative proposals.....	122
Biobanks' content.....	249

Most commonly used abbreviations

CANIFARMA	Mexican National Chamber of the Pharmaceutical Industry
CETIFARMA	Mexican Council of Ethics and Transparency for the Pharmaceutical Industry
CIOMS	Council for International Organizations of Medical Sciences
CNB	National Bioethics Commission
COFEPRIS	The Federal Commission for the Protection against Sanitary Risk
CONACYT	National Council for Science and Technology
CPEUM	Political constitution of the Mexican United States
DOF	Official Journal of the Federation
Funsalud	Fundación Mexicana para la Salud
GWAS	Genome-Wide Association Study
ICESR	The International Covenant on Economic, Social and Cultural Rights
IFAI	Federal Institute for Access to Information and Data Protection
IIJ	Institute for Legal Research (UNAM)
INMEGEN	National Institute of Genomic Medicine
LFTPAIG	Federal Law of Transparency and Access to Governmental Public Data
LGS	The General Health Law
OECD	Organisation for Economic Co-operation and Development
SNPs	Single nucleotide polymorphisms
UNAM	National Autonomous University of Mexico
UNESCO	United Nations Educational, Scientific and Cultural Organisation
WHO	World Health Organisation

I. INTRODUCTION AND METHODOLOGY

1. Introduction

This thesis investigates the governance of biobanks in Mexico, focusing mainly on clinical and research biobanks. It will explore elements of legislative reform for the improvement of current legal and ethical guidance and protective frameworks for research subjects within different biobanking areas. This research will cover public and private tissue banks for research purposes. Other biomaterial storages, e.g. cord blood banks will therefore be excluded, as their implications would constitute a completely independent research object.

In Mexico, where the proliferation of biobanks is significant, the current laws and ethics cannot remain indifferent to potential cases of abuse. Vulnerable populations include minority groups, such as indigenous populations, and any other group with a higher susceptibility than average to be exploited are susceptible to abuse or having their rights undermined. As we will see, this is due to the potential predictive power of genetic data. Similar unfortunate situations may occur if the alleged absence of specific ethical and legal rules is unresolved.

At the present time, the collection and storage of human tissue for the use of molecular or genetic information from specific groups sharing particular characteristics has proven to be of great potential for medical science and population studies. This is due to the biological capability of cells to replicate unique molecular and genetic information, no matter which body part they come from. Genetic and molecular elements can be studied in isolation from each other. Collections of patient samples – biobanks– play a central role in this work by revealing genetic, molecular and environmental factors of importance for the development of disease,

as well as for personality or longevity traits.¹ This potential has become crucial for the development of new therapies and significant knowledge on genetic history of populations. “The successful application of large-scale biological analyses to determine total genome sequences inspires similar grand attempts to understand the function of the encoded molecules in health and disease.”² As a consequence, the unknown ancestry elements of populations can now be traced and therapies developed or improved, sometimes as a result of increased drug effectiveness in a specific genetic profile.

This chapter establishes a statement of the problem to be addressed by this research. Biobanking practices have been the object of bioethical debates, the outcome of which directly impact on governance. The first section of this chapter will consist of the conceptualisation of biobanks and its boundaries. This will also include a review of the main classification criteria, supported by academic literature.

1.1 Conceptualising biobanks

It is necessary to begin by discussing the implications of the term biobank and the degrees of variation it presents. The conceptual spectrum is very broad, for example, “many scientists believe that effective biobanking amounts to no more than a freezer and a fraction of technician’s time to fill the freezer,”³ while Watson and Barnes understand the concept of biobanking is formed by two elements: a collection of human research biological samples (tissues, blood, and body fluids and their derivatives) and the associated data for research purposes.⁴ Taking

¹ L Jonsson and U Landegreb, *Storing and using biobanks for research* (Report I from the Research Project The Use of Human Biobanks Ethical, Social, Economical and Legal Aspects, Uppsala University, 2003) 1

² Ibid

³ Directorate-General for Research and Innovation European Commission, *Biobanks for Europe, A challenge for governance* (2012) 328

⁴ PH Watson and RO Barnes, ‘A Proposed Schema for Classifying Human Research Biobanks’ (2011) 9 *Biopreservation and Biobanking* 327

rheumatology as an example, body fluid could be synovial fluid, synovial fluid cell pellets or urine. Solid tissue may consist of synovium, lymph node, bone marrow, cartilage or bone. A derived product could be DNA (from whole blood or swab) or RNA (from whole blood, peripheral blood mononuclear cell or primary cell culture). Blood and blood-derived products are an easy source of biomaterial to collect, whilst collection of body fluids and solid tissues require more invasive procedures. Genetic data may be obtained from body fluids, solid tissue and derived products.

Barnes explains that the perception of biobanks has also evolved from merely “comprised formal entities within hospitals and research institutions” to “a variety of different biobank types spanning a broad spectrum.” Hence, today individual biobanks can include very small collections aimed to support specific research (mono-user biobanks), collections associated with several research groups or clinical trials (oligo-user biobanks), or larger collection programmes, commonly known as repositories (poly-user biobanks from national efforts).⁵

1.1.1 The characteristics of biobanks

In the absence of consensus on the definition of a biobank, a set of characteristics can be used to identify a biobank. In the opinion of Kaye⁶, these are the most common characteristics:

- (a) *Biological materials are collected for research purposes with either medical or epidemiological data associated (e.g. environmental exposures, lifestyle, occupational information);*
- (b) *Biological materials and data are collected on a continuous or long-term basis;*
- (c) *Research projects using samples can either be defined or not specified (e.g. not planned at the time of biospecimen collection);*
- (d) *Data protection mechanisms are likely to be established in order to assure donor privacy; coding or anonymisation with or without the possibility to be identifiable.*
- (e) *Use minimal structures of control (ethics review committees and informed consent) in order to balance stakeholders' interests.*

⁵ Ibid 327

⁶ European Commission 13

1.1.2 Historical background

The definition of biobanks has been commonly associated with their history and purpose. Approximately two decades ago, early collections would be organised, used for independent research and known as biobanks, but they have expanded in the past 20 years.⁷ However, this has happened “in a rapid, uncoordinated and unregulated proliferation,”⁸ which has led to the hasty, sometimes uncontrolled, establishment of biobanking activities.⁹ Even nowadays the purpose of these collections is not always clear. The commonly attributed diagnostic purposes tend to be frequently overtaken by further research, “when residual material exists after diagnostic procedures have been completed.”¹⁰

So much of science today revolves around using human biological tissue of some kind.¹¹ Any small, short-term, or project-specific collection generally involves research; all biobank formats are interlinked and, to a certain degree, represent a continuum within the infrastructure supporting all gradual steps of the biomedical research “pipeline.”¹² Biobanks are thought to have emerged from clinical pathological tissue samples collected for medical purposes. The formal organisation of specimens allegedly started in the United States, when biological materials were collected during the Civil War for pathological research purposes. A characteristic of those old collections is that they were not planned but residual. Since then, the collection of specimens has evolved in response to the changing landscape.¹³ In contrast, a biological sample is any

⁷ Watson and Barnes 327

⁸ Ibid 328

⁹ PHJ Riegman and others, ‘Biobanking for better healthcare’ (2008) 2 *Molecular Oncology* 327-333

¹⁰ Watson and Barnes 327

¹¹ S Zielinski, ‘Henrietta Lacks’ ‘Immortal’ Cells’ SMITHSONIANCOM <<http://www.smithsonianmag.com/science-nature/henrietta-lacks-immortal-cells-6421299/>> accessed 20 January 2012

¹² European Commission 15

¹³ E Eiseman and SB Haga, *Handbook of Human Tissue Sources A National Resource of Human Tissue Samples* (RAND Monograph Report, 1999) iii

biological material, which originates from human tissues, susceptible to preservation and capable of containing genetic information,¹⁴ a characteristic that makes this material difficult to be seen as simply biological leftovers.

1.1.3 Legal consequences of conceptualising biobanks

For legal purposes, it is crucial to clarify the main conceptual understanding in the practical biobanking areas. However, this is not a simple task. The concept of biobanks is highly debated in the literature and has caused great differences in practice. A great variety of academic terminology has been used to describe sample and tissue collections. It is necessary to make distinctions between them in order to clarify the scope of the concept; particularly in respect to associated key issues. These involve access and consent, and apply to the different categories in practice. The differences between tissue banks, biobanks, biorepositories and other bio collections cannot always be easily, or precisely, indicated. The terms ‘research biorepository’ and ‘biobank’ may be used indiscriminately to refer to a collection of biological human samples with preservation, sharing and scientific research purposes.

The differences are related to whether bio specimen collections were created specifically for health and medical research purposes, or created for other purposes but secondarily used also for research. This is further complicated when a variety of regulations differ in both literature and practical situations. The adoption of a concept for legal purposes is key in legislation in order to ascertain the relevant legal consequences, such as authorisations to use tissue for research. Kaye has highlighted the current inconsistency to denote, “organised collections in medicine.”¹⁵ Although the terms *biobank* and *biorepository* have been used

¹⁴ Ley reguladora de la base de datos geneticos para el estado de Chihuahua (Rules for genetic databases for the state of Chihuahua) (Mex)

¹⁵ European Commission 13

interchangeably,¹⁶ others have defined the latter independently, as “an actual or virtual entity that may receive, process, store or distribute specimens in support of a study or multiple studies and their associated data as appropriate.”¹⁷ According to this definition, a specimen resource generally refers to the specimens collected for a particular study;¹⁸ human tissue repositories “collect, store, and distribute human tissue materials for research purposes.”¹⁹ Repository activities involve three components:

- (i) the collectors of tissue samples;*
- (ii) the repository storage and data management center; and*
- (iii) the recipient investigators”²⁰*

The dissention on what biobanks are has an effect on regulatory issues. Evidently, “diversity in legal requirements has an effect on the development of a common infrastructure for biobanks and the sharing of data and samples from biobanks across the borders for scientific purposes.”²¹

1.1.4 The concept of biobanks from the international perspective

In the absence of specific legislation for biobanks, international guidelines must be revised, and these could constitute immediate emergent instruments to set and define the boundaries of biobanks. For example, the United Nations Educational, Scientific and Cultural Organisation (UNESCO) has used the term ‘database’ to denote the physical samples as well as the derived information, a tendency followed by the World Health Organisation (WHO). The WHO, regarding both

¹⁶ G Marodin and others, ‘Biobanking for health research in Brazil: present challenges and future directions’ (2012) 31 Rev Panam Salud Publica 523

¹⁷ International Society for Biological and Environment Repositories (ISBER), ‘Best practices for repositories: collection, storage, retrieval and distribution of biological materials for research’ (2012) 10 Biopreservation and biobanking 1

¹⁸ Ibid 88

¹⁹ HHS.gov U.S. Department of Health & Human Services, ‘Issues to Consider in the Research Use of Stored Data or Tissues’ (1997)
<<http://www.hhs.gov/ohrp/policy/reposit.html>>

²⁰ Ibid

²¹ European Commission 77

samples and data, states “no regulatory framework for genetic databases has been developed to date that is global in scope yet developed with regional input, while being specific enough to provide practical guidance.”²²

The conceptual divergence “with regard to the infrastructure and practices regarding the collection of human biological material for research,” is a major challenge in countries where biobanking governance is to be or was recently implemented. Most Latin American countries are in this situation, such as Brazil, where international sources inspired the national legal framework. International instruments are helpful sources of reference for standard biobanking definitions.

*The Organization for Economic Cooperation and Development (OECD) uses the term “biological resource center” (BRC) to refer to, not only repositories, but also suppliers of health research services. The International Agency for Research on Cancer (IARC) uses the term “biological resource center” for collections of human cancer samples. In the United States of America, the National Cancer Institute defines the term “biorepository” as an “organization, place, room, or container where biospecimens are stored,” and the term “biospecimen resource” as the “. . . formal organization as well as informal collections of biological material stored in a freezer by an individual researcher.” Likewise, the term “biobank” has been used in this context by other U.S. and European institutions.*²³

1.2 Different types of biobanks

Biobanks can be defined as structures containing biomaterials, and by the type of research they carry out, e.g. a breast cancer tissue bank.²⁴ Surgical leftovers, biopsies and other donated samples have been classified and tidied up for studying and drawing conclusions about the role(s) of genes in the presentation of diseases. As Watson and Barnes have pointed out, “biospecimens are critical for discovery and clinical

²² World Health Organization, ‘Human genetic databases: towards a global ethical framework ’ (Experts' Consultation Meeting, Geneva, 8 and 9 May 2006)

²³ Marodin and others 523

²⁴ RC Elston RC, JM Olson and L Palmer, *Biostatistical Genetics and Genetic Epidemiology*. (John Wiley & Sons 2002) 17

research.”²⁵ Biobanks belong to several general classes, but within these, they have specialised aspects relating to the range of research questions these intend to support.²⁶

A central point is classification. It is important to determine whether guidelines’ enforceability and design should be affected by the particular characteristics of collections. Population biobanks, for instance, is a category which deserves special attention. The main research objective of this category is the study of the genetic characteristics of particular groups. Population studies consist of analysing particular biomarkers of population groups, and how the environment (lifestyle and other factors) influences these. The Council of Europe’s Recommendation on Research on Biological Materials of Human Origin in March 2006 stated that biological materials are defined and are distinguished from ‘collections of biological materials’, and has listed the main characteristics of a population biobank:²⁷

1. A population biobank is a collection of biological materials that has the following characteristics:
 - i. *The collection has a population basis;*
 - ii. *It is established, or has been converted, to supply biological materials or data derived therefrom or multiple future research projects;*
 - iii. *It contains biological materials and associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated;*
 - iv. *It receives and supplies materials in an organised manner*

Population studies also include genomic studies on ancestry. Population studies “are becoming increasingly common as a means of identifying genetic predispositions to complex diseases in a particular

²⁵ Watson and Barnes 327

²⁶ Ibid 329

²⁷ Recommendation of the Committee of Ministers to member states on research on biological materials of human origin Art 17

population, as a result from an interaction of environmental, lifestyle and genetic factors.”²⁸

*The main research objective of population-based biobanks is generally to discover biomarkers for disease susceptibility within a specific population through prospective molecular epidemiology research strategies. These types of biobanks typically recruit health donors who are representative of a region, country or specific ethnic group. One of the most commonly stored biospecimen is germ-line DNA isolated from venous blood. Associated data comprise not only medical history but also physical measures and epidemiological information (e.g. life habits, socioeconomic status). The specifics of population biobanks are compiled and analyzed by the Public Population Project in Genomics in its internet resources.*²⁹

This may create a conflict between individual and societal interests towards the research study. In terms of public health, clashes of interests can also be present. Population biobanks address key issues at the time of recruitment and result interpretation.

1.2.1 Categorisation

Watson and Barnes refer to classification as “the process whereby ideas and entities, in this case biobanks, are recognized, differentiated, and understood”³⁰ but they also highlight that “there currently exists no accepted classification system for human research biobanks.”³¹ Biobanking terminology is inconsistent, reinforced by the application of the “preferred generic label.”³² Criteria based on the size of a collection and other parameters have been common. Barnes and Watson³³ proposed a schema based on the type of research they intend to support, which consists of the following categories:

- *population study biobank*
- *basic research biobank*
- *translational study biobank*
- *clinical trial biobank and pathology archive biobank.*

²⁸ R Andorno, ‘Population bio-banks: a juridical analysis based on Icelandic and Estonian experience’ (2006) 25 Rev Derecho Genoma Hum 55

²⁹ The Public Population Project in Genomics P3G, ‘P3G’ <<http://www.p3gobservatory.org/>> accessed 16 March 2011

³⁰ Watson and Barnes 329

³¹ Ibid 328

³² S Gibbons, ‘Regulating biobanks: A twelve point typological tool’ (2009) 17 MLR 6

³³ Watson and Barnes 331

Biobanking categorisation can be standardised according to the purpose of their creation. The classification scheme suggested by Watson and Barnes is based on four functional biobank “elements” donor/participant, design, biospecimens and brand.”³⁴ It is still debatable if factors such as the size of a collection could determine whether a collection should be regarded as a biobank and therefore subject to legal consequences. “The absence of a classification system may also soon impact research users by hampering the ability to interpret and reproduce research results.”³⁵ A Mexican academic biobanking classification³⁶ includes:

Usage	The classic biobanks and databases in a minor scale for clinic and	Academic research.
	Forensic biobanks integrated by samples and genetic data in order to solve legal cases.	Medical research.

Financial gain purposes	Pharmaceutical
	Biotechnological industry

Operation level	Local	Biobanks for research
	National	Population biobanks
		Genetic databased biobanks with forensic ends
	Transnational	Genetic assessment
Genetic advice		

General purposes	Clinic
	Academic

Trading purposes	Sample commercialisation	Through catalogues
	Data commercialisation	

³⁴ Ibid 328

³⁵ Ibid 329

³⁶ Ingrid Brena, ‘Biobanks, a subject pending upon legislation’ (2010) 129 Boletín Mexicano de Derecho Comparado 1055

However, Gibbons suggests that categorising biobanks based on their initial location or ownership is a trap to be avoided, due to potential future changes in terms of purposes, uses, and users, location and ownership.³⁷ According to Gibbons, regulatory exhaustiveness should never be attempted.³⁸ Biobanking definitions should not aim to be exhaustive. Rather general and inclusive rules would be more favourable. “In the end, trying to draw sharp or hard-and-fast dividing lines between different kinds of biobanks based on size may prove to be impossibly problematic, unworkable, and arbitrary.”³⁹ A more flexible, discretionary framework (with clearly stated assessment criteria and provision for reviews or appeals) may be preferable.⁴⁰ Gibbons⁴¹ has provided guidance for conceptual matters and criteria helpful to identify current biobanking issues. In her opinion, the field of biobanking is so heterogeneous that exhaustively listing all distinguishing characteristics of biobanks is difficult. However, simple criteria can be used for this purpose:

- a) *Size*
- b) *Research design*
- c) *Disease/research focus.*

<i>The extent of biobanks</i>	<i>a) The recruitment of donors</i>
	<i>b) The consent procedures</i>
	<i>c) The scale of informatics support needed</i>
	<i>d) The governance structures</i>
	<i>e) The potential for commercial exploitation.</i>

- *Age*
- *Timing*
- *Duration*
- *Nature of Participants*
- *Uses and users*
- *Other stakeholders*

³⁷ Gibbons 323

³⁸ Ibid 316

³⁹ Ibid 318

⁴⁰ Ibid 317

⁴¹ Ibid 314

Biobanks	Research purpose	Scientific	Public/governmental
		Academic	Private
		Clinic	Altruistic
	Private pharmaceutical		
	Stem cells		
	Public forensic		
	Population (analysis of the interaction genes/environment)		

According to the conceptual views by Gibbons, it would not be necessary to regulate separately every type of biomaterial (blood, serum and plasma), but to include all types in a single regulation which also takes into account key exceptions, such as forensic biobanks (an area under criminal law).

For an accurate biobank categorisation, terminology may not be so important. Shickle⁴² has expressed a concern that general information on terminological grounds is only a standard. Evidently, some terminological variations do not necessarily reflect substantive distinctions; excessively technical or descriptive definitions may work for specific areas, such as sample management, but a suitable definition for the resolution of ethical and legal dilemmas in practice should follow criteria able to deal with the diversity of terms used in practice. The following has worked for works done within the European Commission:

“Sample size is a characteristic that can be used to distinguish different kinds of biobanking activities. Biobanks comprise comparatively small collections of up to several thousand samples. Within the context of medical research there are multiple biobank formats which can be differentiated based on their design and scientific target.”⁴³

- *Disease-oriented*
- *Case-control*
- *Tissue banks*
- *Biobanking with the context of clinical trials*
- *Other specific biobanking formats: Guthrie cards, cord blood, stem cells.*

⁴² D Shickle, M Griffin and K El-Arifi, ‘Inter- and Intra-Biobank Networks: Classification of Biobanks’ 77 *Pathobiology* 181

⁴³ European Commission 14, 15

This is particularly relevant for recently generated genomic technologies, since acquisition involves significant costs in taxes covered by research budgets. In addition, other challenges arise in relation to equipment and chemical substances imported from other countries. The excess of rules and long procedures harm equipment and cause delays in the course of research projects.

Biobank classifications cannot aspire to incorporate the totality of diverse biobanking functions, this is an exhaustive, not to say impossible task to conduct. Some work is required to place particular importance on certain aspects of clarity, balance, inclusiveness, fitness for purpose, non-exhaustiveness and protection.

The choice is “whether differentiation, leniency, or even parallel governance frameworks may be justified”⁴⁴ or whether the general concept of biobanks should cover any biological collection and categorisation. The latter choice would imply that all biobanks would be covered by a single framework, scrutinised at the same level. Each choice would have a different impact on the governance of biobanks.

Therefore, a brief categorisation is necessary to fulfil legal gaps and avoid ambiguity. It will eventually be necessary to classify current Mexican biobanks (for regulatory purposes) while avoiding the pitfalls associated with attempts at exhaustive descriptions. General parameters can be very helpful, and generic categorisation, such as access and types of use can work as an emergent means for standardisation.

1.3 The importance of personalised medicine

Biobanking operates to improve the knowledge of health and illness processes, the identification of the causes of disease, the development of diagnoses and the application of preventive methods and

⁴⁴ Ibid

therapies. Human research biobanks are critical to the current drive for personalised medicine as they provide the necessary biospecimens to fuel the majority of research platforms. The Genome-Wide Association Study (GWAS), for example, attempts to establish associations between diseases and particular genomic variants, which is a significant area of great analysis potential.⁴⁵ A comparison is generally made between the mapped common genomic variants i.e. single nucleotide polymorphisms (SNPs) and unaffected controls.

Diagnostic purposes are one of the main priorities. In fact, many governments are seeking to improve the translation of medical research innovation by developing mechanisms to aid the flow of information between the laboratory and the clinic.⁴⁶ Another type of research is also associated with the use of genomic techniques; in this case, both array-based genotyping and whole-exomes, which are cost-effective alternatives to whole-genome sequencing. The exome represents a very small fraction of the human genome, but represents 85% of known disease-causing variants. Therefore, encoding protein regions can be used (instead of the whole sequence) to investigate how particular parts of the human genome are related to the occurrence of specific diseases.⁴⁷ This type of genomic study needs samples and clinical data, not only from the patient, but also from his relatives.⁴⁸

1.3.1 Personalised/stratified medicine

To paraphrase Gotweis and Lauss, personalised medicine, one of the promises of the so-called genomic revolution, would require different types of data associated with lifestyle information that could be used for

⁴⁵ J Kaye and others, *Governing Biobanks, Understanding the Interplay between Law and Practice* (Hart Publishing 2012) 283

⁴⁶ J Kaye, 'Embedding biobanks as tools for personalised medicine' (2012) 21 *Norsk Epidemiologi* 169

⁴⁷ S Banerji and others, 'Sequence analysis of mutations and translocations across breast cancer subtypes' (2012) 486 *Nature* 409

⁴⁸ Kaye and others 284

biomedical research purposes.⁴⁹ The potential of personalised medicine involves the ability to predict the risk of certain diseases based on ‘personal genome’ information in combination with lifestyle data, age, sex, occupation, etc.; and ‘preventativeness’, that is based on individualized risk prediction. This requires an active ‘participation’ of the individual concerned in proactively maintaining their health.⁵⁰

Some types of patient matching to a medicine include therapies in which a marker is available, indicating that a patient is likely to show a response to the therapy. Although this type of matching could be applied to an individual patient in principle, this is mostly prescribed in selected groups. A population group can be compared to a cohort that has previously shown a specific therapeutic response through genetic characteristics (biomarkers). Hence some have considered the term ‘stratified’ more suitable rather than ‘personalised’ for this area of biomedicine. “Stratified medicine involves therapies matched with specific patient population characteristics using clinical biomarkers.”⁵¹ And once population-identified genetic information can be easily accessed, even through online databases, the treatment of genetic categories becomes a matter of social responsibility.⁵²

1.4 The main challenges of biobanking

Biobanking has the potential to impact on countries’ economic development, offering them valuable opportunities; “with the rise of biomedical technosciences and the completion of the Human Genome

⁴⁹ H Gotweis and G Lauss, ‘Biobank governance: heterogeneous modes of ordering and democratization’ (2012) 3 *J Community Genet* 61

⁵⁰ European Commission 17

⁵¹ MR Trusheim, ER Berndt and FL Douglas, ‘Stratified medicine: strategic and economic implications of combining drugs and clinical biomarkers’ (2007) 6 *Nature Reviews Drug Discovery* 1

⁵² J Kahn, ‘Human Genes and Human Rights’ (2006) 96 *American Journal of Public Health* 1967

Project, tissue collections worldwide have become increasingly important to scientific and economic interests.”⁵³

For example, in 2004 the Federal government of Mexico officially unveiled a public health programme to analyse and utilise DNA information obtained from the Mexican population. Initial efforts led to the modification of existing regulations to enable the creation of the National Institute of Genomic Medicine (INMEGEN). This government agency on public genomics, created through parliamentary action, led the Mexican HapMap project. It aimed to “develop a national platform in genomic medicine that is focused on national health problems, based on the genomic structure of Mexican populations.”⁵⁴ The government initially invested US\$120 million from public funds. The purpose of the programme was to provide medication which would react optimally to the DNA profile of Mexican citizens.⁵⁵ The institutions responsible for these activities are the National Ministry of Health (*Secretaría de Salud*), the National Autonomous University of Mexico (*Universidad Nacional Autónoma de México*) (UNAM), the National Council for Science and Technology (*Consejo Nacional de Ciencia y Tecnología*) (CONACYT) and The Mexican Health Foundation (*Fundación Mexicana para la Salud*) (*Funsalud*). These institutions intend to enhance genomics training and research, and develop public education in the subject, and scientific divulgation. However, these efforts have expanded in a way that has allowed profound legal gaps in relevant regulatory aspects. More detail and further discussions on Mexican legal gaps will be forthcoming in chapter 5.

⁵³ M Bister, ‘Discovering informed consent: a case study on the practices of informed consent to tissue donation in Austria’ in C Lenk and others (eds), *Human tissue research, a European perspective on the ethical and legal challenges* (Oxford University Press 2011) 169

⁵⁴ B Séguin and others, ‘Genomic medicine and developing countries: creating a room of their own’ (2008) 9 *Nat Rev Genet*

⁵⁵ G Jimenez-Sanchez, ‘Developing a Platform for Genomic Medicine in Mexico’ (2003) 300 *Science* 295-6.

Nevertheless, biobanking presents significant governance challenges, which tend to be more specific to developing countries.⁵⁶ This is especially evident in Mexico, where the legal framework has not kept up with considerable biobanking expansion.⁵⁷ Mexico is in the process of developing genomics initiatives focused on challenges and opportunities of genomic medicine, which should gradually lead to a stronger regulation of biobanks. Some have commented that “as genomic medicine develops in Mexico, the need for modern legislation related to its ethical and social implications will also increase.”⁵⁸ However, the complex background of Mexican legal and socioeconomic problems has obstructed the government’s aims to produce effective biomedical public health research through the use of biobanks.⁵⁹

At the beginning of this research, the following relevant pronouncements by Mexican academics were identified: Alberto Arellano, researcher at INMEGEN, considered in 2005 in a study on genetic data protection that the Mexican legal guarantees regarding genetic privacy did exist but were insufficient.⁶⁰ Similarly, in 2008, medical law researcher, Ingrid Brena, expressed an interest in unifying Mexican biobank legislation. She organised a conference ‘*Coloquio Internacional Muestras Biológicas y Biobancos para Investigación Biomédica*’ *Estado actual y retos de futuro* (International Colloquium on Biological Samples and Biobanks for Biomedical Investigation, current status and future

⁵⁶ B Hardy and others (eds), *The Next Steps for Genomic Medicine: Challenges and Opportunities for the Developing World*, vol 9 (Nature Reviews Genetics 2012) S25

⁵⁷ Notimex, ‘Promueven entre empresarios aplicar la genómica a economía’ *SDP Noticias* (Mexico City, 17 August 2011) <<http://www.sdpnoticias.com/notas/2011/08/17/promueven-entre-empresarios-aplicar-la-genomica-a-economia>> accessed 12 March 2013

⁵⁸ G Jimenez-Sanchez and others, ‘Genomic medicine in Mexico: Initial steps and the road ahead’ (2008) 18 *Genome Research* 1196

⁵⁹ Séguin and others 486

⁶⁰ A Arellano-Mendez, ‘La regulacion juridica de la informacion genetica (the legal regulation of genetic information)’ *Derecho comparado de la informacion* <<http://www.juridicas.unam.mx/publica/rev/decoin/cont/6/art/art2.htm>> accessed 12 February 2013

challenges)⁶¹ with other scientists and researchers to discuss how this might be achieved. During the course of the conference, Brena became increasingly aware of the inadequacy and inconsistency of Mexican legislation regarding biobanks. Brena highlighted three main areas for improvement:

- i) *The consolidation of public rights.*
- ii) *Increasing public participation.*
- iii) *The establishment of a legal framework among stakeholders, i.e. the public, biobanks and researchers.*

At the conference called by Dr. Brena, the medical researcher Clara Godorezky⁶² agreed with Dr. Brena's recommendations. Moreover, she highlighted that over the previous fifteen years no progress had been made in personalised medicine⁶³ in Mexico. She attributed this to the poor standard of biobanking legislation. These initial pronouncements constituted enough reason for scepticism on the adequacy of Mexican biobanking rules.

1.5 Towards a Sound Legal and Ethical Policy to Enhance Biomedical Research in Mexico Using Biobanks: Research Questions

The following research questions cover the current main ethical and legal concerns within Mexican biobanking, the main one being: What are the best ways forward to alleviate legal weaknesses in Mexican biobanking governance? The spectrum of responses to this question can

⁶¹ I Brena, 'Biobanks in Mexico, legal aspects (Biobancos en Mexico, Aspectos Juridicos)' Coloquio Internacional Muestras Biologicas y Biobancos para la Investigacion Biomedica (International Colloquium Biological Samples and Biobanks for Biomedical Research), Mexico City, 4 July 2008

<<http://juridicas.unam.mx/vjv/activ.htm?e=122&t=14&m=884&p=384&mx=1>>

⁶² C Gorodesky, 'Biobanks and Umbilical Cord Banks: Common and Specific Aspects Related to Research. Social, Ethical and Legal Implications. Biobancos y bancos de celulas de cordon umbilical: aspectos comunes y especificos relativos a la investigacion en las implicaciones sociales, eticas y de regulacion.' (International Colloquium Biological Samples and Biobanks for Biomedical Research Current State and Future Challenges (Coloquio Internacional Muestras Biologicas y Biobancos para Investigacion Biomedica Estado actual y retos de futuro), Mexico City, 4 July 2008)

⁶³ A Nyika, 'Ethical and practical challenges surrounding genetic and genomic research in developing countries' (2009) 112 *Acta Tropica* s21

lead to numerous options. Hence, it is necessary to subdivide this question into the following research sub-questions:

- Are biobanks effectively regulated in Mexico?

This question leads to the investigation of the applicable legal biobanking frameworks which have been enforced. The legal assessment resulting from this question should provide criteria to recommend the form and classification which the guidelines ought to take.

- What risks, harms and values are involved?

After the legal analysis, the second sub-question looks at the ethical side of the thesis, aiming to investigate what risks and harms would be present if biobanking was not properly regulated. This question also investigates the criteria for a sound ethical policy, in other words, what guidelines would be effective at protecting participants' rights.

- What can we learn from the international experience?

In addition to questions on legal and ethical issues, this question aims to investigate how past experiences can help future implementation, using problems encountered by other countries and emphasising the importance of taking into account other countries' experiences within different contexts.

- What changes need to be implemented in Mexico?

Following the legal analysis, possible changes in governance need to be discussed, searching for suitable implementation measures and determining legal action to improve effectiveness on legislation for public and private biobanking. The role of self-regulation should also be discussed. It should be decided whether ethics needs to be split from law, e.g. through codes of ethics, or whether ethics should be part of the biobanking binding legislation in Mexico. The latter question aims to find

answers on elements of soft law, including international instruments that would best ensure effectiveness and transparency.

- What are the main challenges when implementing change in Mexico?

In terms of legal structure, it needs to be decided what options are the most viable for suitable proposals of reform, whether new legal frameworks or amendments are necessary, and whether biobanking rules should be compressed into a single framework or distributed across the various related laws.

- What is the role of social involvement in Mexican biobanking regulation?

Finally, proposing ways to improve the regulation of biobanking implies analysis beyond legal perspectives. In order to support the recommended criteria to be followed as a regulatory basis for biobanks, the last question leads to the investigation of the role of social justice within the regulation of biobanking. For this reason, the role of public engagement, and how it impacts the law, will also be discussed.

1.6 Synopsis of each chapter

As a brief synopsis of this thesis, each chapter is described here, including the main points to be covered.

In chapter one, the current legal and ethical position is considered through relevant literature based on the main concepts of biobanks. This primary examination of the situation highlights some of the background issues within the proposed research topic, such as the absence of biobanking definitions in Mexico.

Chapter two explains the methodology selected for this thesis. It describes how the theory was initially approached and how the scarcity

of research caused significant changes. These resulted in the incorporation of fieldwork, which impacted on the information considered, from theoretical expertise to analysis of fieldwork and primary evidence. Finally, it defines the questions addressed by this research project.

Chapter three investigates risks, harms and values of Mexican biobanks. It analyses potential harms from an ethical perspective, including a brief historical background. This chapter is supported by the analysis of two relevant case studies in order to illustrate how the potential identified harms have affected the development of biobanking projects. The Cohort Profile Study, population specific project and the Mexican HapMap have been selected as they clearly showed promissory benefits and uncertain dilemmas associated with biological material. Progress on human rights' protection has favoured suitable biobanking backgrounds. For this reason, the Mexican situation on human rights is also evaluated, since future biobanking governance could significantly depend on this factor.

Chapter four covers an extensive legal review in order to determine the competence of enacted regulations on the Mexican legal treatment of biobanks. It provides the legal rationale of the Mexican legal system and detects specific legal instruments affecting biobanking. Hence, health, administration, management, genomics, data protection and even some international perspectives are evaluated. The development of this chapter identifies formally enforced biobanking rules, allowing their analysis.

Chapter five aims to identify gaps in the regulation of biobanking in Mexico, recognising the absence of specific legal frameworks. Biobanking management rules, if they involve partial legal controls, are led in accordance to various parameters concerning issues such as sample preservation. It is apparent that a great number of Mexican governmental institutions follow self-defined guidelines; other institutions are based on

international standards through Internet governance tools.⁶⁴ This chapter also focuses on ethics research guidelines which may be indirectly applicable to biobanks. It demonstrates the existence of significant legal gaps and inconsistencies and identifies a set of guidelines for ethical biobanking based on 'soft law'.

Chapter six was inspired by my involvement in the **Error! eference source not found.** (an EU funded research network, whose details are provided in the introductory section of the chapter). It develops an illustrative legal study through European examples. European national biobanking frameworks vary significantly, depending on each country's situation. However, this chapter argues that the common European legal instruments on data protection and data sharing can be relevant examples to follow, especially where biobanking international collaborations take place. For this reason, a range of European frameworks is considered, in order to assess which are best suited to tackle issues prevalent in Mexican biobanking.

Chapter seven evaluates implementing change in Mexico. This chapter demonstrates how the governance of biobanks is still a relatively unexplored area in Mexico. Each implementation area requiring attention has been analysed independently, contrasting the different perceptions of involved actors. This chapter also reviews the governance principles under which implementation should be supported. Major issues in current practices, such as institutional project monitoring and oversight, are also included.

Chapter eight investigates the impact of public attitudes towards biobanking through the evaluation of social solidarity. The biobanking problem in Mexico is associated not only with governance issues but also with social attitudes, which influence the governance of biobanks

⁶⁴ P3G

internationally. The lack of public trust towards Mexican governance institutions is partly due to the poor communication of realistic biobanking promises to Mexican society and could be alleviated if they were strengthened. The grounds for legal regulation of standard bioethical guidelines could be determined, rather than being imposed, using particular social and cultural norms.

The construction of recommended criteria for biobanking in Mexico will be provided in a concluding section after chapter seven. This section presents possible solutions for the Mexican biobanking issues raised, and more specifically, a brief statement of what legal challenges Mexico should implement.

This section also includes a reflection on the value and relevancy of fieldwork, and the difference it makes to the research. Specific findings of each chapter are independently presented, followed by a brief explanation on the originality of the research and how it is expected to be helpful in practice.

1.7 Concluding remarks

The basis of any type of implementation for new policies should consist of inclusive concepts. It would also be relevant to include stakeholders, note the particular exceptions, and ascertain what should be the treatment of existing collections. This introductory panorama has helped to gain an insight into the current state and justification of the research by presenting the existing nature of ethical facts, which will support further views on Mexican biobanking regulation.

2. Methodology

2.1 Research methodology

This section describes the methods that were followed through the development of this research, how both desk-based research and fieldwork methods were combined, the reasons for their selection and their role within the research process. The research questions are included.

2.1.1 Research methodology insights

This research project was motivated by indicators of concern regarding the biobanks in Mexico. The verification of such indicators were based (in principle) on articles by INMEGEN; these reported the recent targeted governmental efforts, covering technical aspects, highlighting perceived population benefits and the economic potential of personalised medicine. The previous insights were obtained from academic literature up to September 2010, when this research project commenced. By that year, most research issues for Mexican biobanking were undocumented in published academic literature.

2.1.2 Research methods

The scarce academic literature identified supported the hypothesis that biobanking legislation was problematic. However, the topic presented some difficulties, such as the absence of written legal reports or opinions on the biobanking situation in Mexico. On the one hand, this proved insufficient to investigate the current position; on the other hand, this significant challenge contributed to the originality of this research, (leading to the design of empirical work). The determination of the following research questions is based on the biobanking concerns and will be complemented by those of biobanking actors in subsequent

chapters; e.g. Chapter 3 evaluates stakeholders' perceptions on biobanks and their regulation.

2.1.3 Desk based research

The ethical and the legal perspectives were combined using theoretical and practical approaches. The literature review began by searching for biobanking concepts and associated issues, the analysis of the critics, and up-to-date legislation. The initial search for biobanking literature was filtered by conceptual issues, regulatory issues and case studies, focused on Mexican and legal sources such as journals, reports, institutional reports and recent news from serious-minded newspapers. Emerging academic research and fresh government activity in this field were obtained and filed. Additionally, international sources were used, such as online broadcasting from news sources with international recognition; i.e. the BBC web page. This required constant review and updating. The state of documental Mexican and international literature has been under consultation and review for the length of this stage of the project.

Mexican academic articles on biobanks, from a legal perspective, were scarce and the methodology changed from desk-based research to include fieldwork on the topic. Progress up to chapter three demonstrated that no consistent legal study proposals had been presented for the regulation of biobanks in Mexico. Apart from being inconsistent, past studies were characterised by being purely based on theory. This motivated the organisation of a serious and detailed fieldwork plan, which finally made a substantial difference in the analysis of biobanking, by confirming ways forward and considering feasibility.

Further progress allowed the identification of potential representative actors, associated to governance, policy making, governmental ethical advice and academia. Their accounts were valuable for a full understanding of the issues so far identified. At least one actor

of each area was to be identified among accessible public institutions. This contributed to the originality of the research, as no previous integral studies were detected combining theoretical with practical works. Consequently, it also increased the reliability of the proposal.

The evaluation of the legal status of Mexican biobanking made it necessary to identify existing binding and soft law national guidelines, supported by the literature review. The criteria for the legal and governance analyses primarily focus on binding regulatory frameworks and their competence and secondly, on alternatives to improve effectiveness.

There seems to be valuable lessons to learn from countries that have already achieved a fit for purpose framework for biobanking. Hence, the analysis of relevant examples has been included. For this purpose the case of Europe was selected. It allowed the identification of viable sources of expertise that may be applicable to the Mexican framework.

This research also involved the investigation of sociologically focused resources. These were mainly obtained from recent innovative documental sources analysing issues on biobanks from a sociological perspective. Introduction and familiarisation of new concepts such as that of 'social justice' were necessary for this purpose. This approach was analysed in order to produce the development of the last stage of the thesis.

2.1.4 Fieldwork

Initially, the main research focus was intended to be desk based, with documented and reliable sources providing the main pillar of research. The National Institute of Legal Research of the National Autonomous University of Mexico was one of the first to report concerns from the legal academic perspective through conferences, whose results

were published in 2011 (one year after this research commenced). Nevertheless, the legal basis of biobanks was only starting to emerge, as shown in the initial related publications by Alberto Arellano (INMEGEN) based on genomic privacy and more specifically Ingrid Brena (National Institute for Legal Research). By 2011, the book “LatinBanks: study on the legal and social implications of creating banks of biological material for biomedical research,”⁶⁵ was published as a result of an academic collaboration of various countries. The book consisted of purely descriptive reports on the situation of biobanks in Germany, Portugal, France, Colombia, and Mexico, by the Institute for Legal Research as a result of the previously mentioned 2008 International Colloquium. The topic had also been observed from the anthropological point of view by Ernesto Schwartz⁶⁶ (INMEGEN-University of Exeter).

The variations in approach (biological, medical, economical and ethical) from a legal perspective caused significant challenges. As biobanking is a very wide topic, the initial research seemed exhaustive, in which any subtopic could justify an independent work. In principle, the determination of the research topic was meant to establish what constituted a biobank in the absence of a Mexican legal concept. These theoretical challenges were helped by a standard delimitation of legal and ethical analysis. The initial research approach was expanded to include governance, and international and sociological analyses.

2.1.4.1 Fieldwork development

Fieldwork was directed to participants who were selected from an online search for representative biobanking related institutions. Those who verbally agreed to be interviewed were given a chance to ask

⁶⁵ CM Romeo Casabona and JW Simons (eds), *Latin banks, study on the legal and social implications of creating banks of biological material for biomedical research*, vol 3 (Bruylant 2011) 277

⁶⁶ Ernesto Schwartz, ‘Genomic Sovereignty and the “Mexican Genome” an ethnography of postcolonial biopolitics’ (DPhil thesis, University of Exeter 2011)

questions beforehand, and then signed the consent form on the day of the interview if they were still happy to continue.

The questions were focused on biobanking research in Mexico. These were phrased in layman's terms with some technical language familiar to the respondents. This essential part of the research sought diverse opinions regarding biobanks through a semi structured plan. Participants were given freedom to talk about central points of each question, opinions, examples and experiences. I listened to them and often asked for clarification or further explanation. In some cases, the initial question led to relevant sub-questions during the course of the interview. If time allowed, up to 3 questions were added in relation to very particular activities associated with the role of each participant.

Interviews were recorded using a recording memory stick, which automatically created WAV files. Fifteen WAV files were stored on a hard drive. Interviews lasted no more than an hour and some notes were taken. Translations from Spanish to English are complete, data recorded, notes, transcriptions and translations are available for potential University audits at any point. Translations and notes are still available for participants if this were to be requested by them.

The representatives' opinions were collected in the participants' original language. After transcribing the interviews in the Spanish language, the information was selected, summarised and translated. Qualitative analyses have been necessary to fully examine the responses. To a lesser extent, quantitative analysis was also used. This was done with questions such as, "how many stakeholders considered that biobanking regulations were not effective?" in order to provide some comparative statistics.

The following table shows the profile of each participant, their identities are not disclosed for ethical reasons:

Participants	Area of expertise
A	Research manager INMEGEN
B	Researcher in medical science INMEGEN
C	Legal researcher in bioethics and human rights IIJ
D	Manager at the social, legal and ethics department INMEGEN
E	Researcher at the social, legal and ethics department INMEGEN
F	Legal researcher and manager in bioethics and medical law IIJ
G	Manager at the legal department INMEGEN
H	Ethics advisor at the CNB
I	Manager at the Ethics and law department of the Human Genome CNB
J	Legal researcher in data protection IIJ
K	Manager legislator in science and technology, Mexico City Assembly
L	Ethics advisor on informed consent at the CNB
M	Researcher at the Ethics and law department of the Human Genome CNB
N	Legal advisor at a health ethics committee
O	Philosophy and Law professor at UNAM

Fieldwork stages

Stage 1: Planning the fieldwork

Interviews with different stakeholders were planned shortly after completing chapter 4 of this thesis. Key Mexican biobanking stakeholders were interviewed to enable a fuller understanding of the issues involved. The main purpose was to evidence “the insufficient biobanking regulatory frameworks in Mexico⁶⁷” in practice. The initial fieldwork plan aimed to include direct views from those affected by the state of the biobanking regulations, i.e. stakeholders from the different biobanking areas. This focus would make a substantial difference. It would provide an examination of practical challenges and recent theoretical frameworks, with an empirical basis as a firm rationale of evidence. Consequently, interviews were planned with several biobanking stakeholders, mainly

⁶⁷ Arellano-Mendez 29

representatives of each area involved and those engaged in practical disciplines.

Stage 2: Ethical approval of fieldwork

The fieldwork plan necessitated careful consideration of ethical issues and required the ethical approval from the University of Leeds. The main points covered by the ethics application included responsibility to explain to participants as fully as possible what the research was about, the purpose of the interview, what was involved,⁶⁸ what was done with the information obtained and the forms in which interviewees have been protected, e.g. consent and confidentiality. The corresponding assessment was completed before the interviews (November 2012). Participants were informed that no economic benefit would be obtained from their participation.

Stage 3: Fieldwork to reveal further issues and problems

A series of semi-structured interviews were planned in order to measure any discrepancies shown by some stakeholders' opinions, how these differed from legal requirements, to the deepest disagreements and their attitudes towards the oversight law of formal regulations. Hence, the sample of participants aimed to be representative and balanced.

Interviews: The following questions were asked:

- a) For academics and law-makers involved in the design of biobanking guidance design. This set of questions focused on indirect biobanking treatment, e.g. it focuses on policy/law making, oversight and academic involvement.

1. What is a biobank in your own words?

⁶⁸ Bell J, *Doing your research project. A guide for first time researchers in education, health and social science* (Open University Press 2009) 156

2. What is the content of a biobank?(samples and/or data)
 3. Does Mexico require a specific biobanking legal act?
 4. Regarding the improvement of current frameworks, what would be more suitable: clear ethical guidance or stringent enforced rules?
 5. How are biobanks regulated in Mexico?
 6. How could the current framework be improved in legal/policy terms?
 7. What is the main legal basis of biobanking procedures in Mexico?
 8. What should an ethical informed consent form contain?
 9. Is sensible information from biobanks suitably protected in Mexico?
 10. Do genetic rules apply to any other types of biobanking?
- b) For researchers and stakeholders involved directly in biobanking practices. The objective was to obtain opinions from biobanking operators about their work in practice, the effectiveness of the current guidance, and governance on biobanking. These answers were used to compare points of view and identify priority areas of debate.
1. In your opinion, is biobanking governed effectively?
 2. Does Mexico require a specific biobanking legal act?
 3. What is the main authority for biobanking procedures in Mexico?
 4. What are the processes followed to conduct a clinical trial in Mexico?
 5. What are the most serious sanctions for a researcher responsible for unethical actions within a clinical trial relating to the mistreatment of samples?
 6. Have the recent changes in Mexican legislation been effective? (within your area)

7. Regarding the improvement of current frameworks, what would be more suitable: clear ethical guidance or stringent enforced rules?
8. Are there any restrictions for the processing of personal data from research samples?
9. Are you subject to periodical inspections?
10. If so, by whom?

For the purpose of the interviewer the two sets of questions were printed in cards.

Stage 4 Selection and recruitment of participants

- A governmental biobank
 - Legal department (1 participant)
 - Ethics department (1 participant)
 - Academic research department (1 participant)
 - Scientific department (2 participants)

 - Bioethics advisory governmental institution
 - Legal and ethical advice (2 participants)
 - Public policies (1 participant)
 - Social policies (1 participant)

 - Legal research institution at a public university
 - Law, health and bioethics section (2 participants)
 - Human rights (1 participant)
 - Data protection (1 participant)

 - Philosophy department at a public law school
 - Bioethics analysis (1 participant)
- a) Negative responses to recruitment

Data protection authority (1 participant)

b) No response to recruitment

The Mexican Parliament, science and technology law making (1 participant)

Biobanking national authority (2 participants)

c) Impossibility to arrange an appointment

Biomedical research at a public university (1 participant)

Ethical approval was acquired from the Faculty Research Ethics Committee of the University of Leeds.⁶⁹

Fieldwork principles

The following principles constituted the ethical basis of the fieldwork plan and development:

a) Informed consent

The autonomy of participants was the main principle to be protected for this type of research study. It was protected by providing the full information before formal consent was obtained. This involved the use of two documents; an information sheet and the actual informed consent form. Initially, participants were invited to participate by e-mail with the Information Sheet attached. Once they accepted this initial invitation, the documents were explained and signed in person. An appointment was organised in Mexico at their place of work. Information sheets and informed consent forms were provided in Spanish.

b) Withdrawal

It was agreed that information would be sent beforehand so that respondents had an opportunity to query the meaning and implications of any statements, and to withdraw at that stage. It was established that

⁶⁹ Ethics application formally approved by the ESSL, Environment and LUBS (AREA) Faculty Research Ethics Committee (16 of July 2012)

participants could opt out of the project at the following times: after reading the information sheet, at any point during the interview or at the end of the interview. Participants knew that in the case of voluntary or involuntary termination of the interviewer/interviewee relationship, they could leave with full dignity. They had the choice to withdraw from the research at any point, up until the point in which data was impossible to be removed, e.g. once it has been published.

c) Data protection and confidentiality

Due to the sensitivity which criticism about Mexican Biobanking regulation might cause, anonymisation was used at all times. Identity and other individual characteristics were changed for this purpose. Once participants agreed to be interviewed, they had the opportunity to ask questions. At this point, I asked them to sign a consent form. The information that was kept about them – including taped interviews, transcripts, notes etc. – have been stored on a secure university hard drive. The minor limitations to confidentiality and disclosure of information were also identified. The issue of access to data was covered by informing participants that their answers would be shared only for academic purposes in relation to my work. This meant that any further use of data for non-academic purposes (e.g. publication) or any action involving data sharing would be a reason for re-consent. The same would happen if for some reason data was shared outside of Mexico or the UK. This would be possible only if that country had the same levels of protection.

d) Transparency

Accurate identification of qualifications, both verbally and in writing were covered before the interviews. In this case, my position as a research student at the University of Leeds was presented in the information sheet for participants. They knew my identity and were free to contact me or my supervisors at any point through our university e-mails.

e) Respect for Diversity

Questions were deliberately presented in an objective way. Awareness of the diverse opinions of individuals, when dealing with the issues of biobanking in Mexico, ensured that the interview and research was objective. It was essential to recognise the need to work co-operatively in a multi-disciplinary background respecting the unique contribution of each member. The selection criteria were based on targeted areas, preferably decision makers in public biobanking management and academic analysts involved in the storage of samples for population/specific studies, ethical advisers, legal advisers, policy/law makers, data protection analysts, academics and human rights advocates.

f) Contact

The first step in making contact was to investigate the roles and particular functions from five main representative institutions associated with the targeted areas. Initially, twenty participants were identified. Each selected participant was contacted individually, two to four weeks before visiting Mexico, through publicly disclosed institutional e-mail addresses. I enclosed an information sheet, explaining the purpose of the visit and asking for an interview, between the 5th of December 2012 and the 10th of January 2013, and informing them that they could agree to participate at any time up until the end of my visit. All interviewees chose office hours at their workplaces. The tone of the invitation was informal. Out of twenty participants, fifteen were interviewed. One negative response was received, three participants did not reply to the invitation e-mail and one more participant accepted but was not available on the proposed dates.

2.1.4.2 Fieldwork: main challenges

Some difficulties had to be faced in order to achieve a representative sample of biobanking opinions. The early development of self-funded fieldwork allowed contact with only a few stakeholders, who

replied briefly after receiving the e-mail. About 50% of the participants replied once the dates were close (on the days before the interviews) and the rest were contacted by telephone. It was agreed that detailed information would be sent to their e-mail. The most obvious restrictions were time limits to carry out the interviews and adjusting visiting schedules for each of the participants without clashes. Time was limited and government members of staff tend to be very busy people. I appreciated the fact that most of them accepted to take part in the interviews. The necessary trips to Mexico were funded from the CONACYT (National Council for Science and Technology) grant for this project.

2.2 The Mexican situation

The United States of Mexico, commonly referred to as Mexico, is a Latin-American country divided into 31 states. Mexican society is diverse, consisting of mixed racial and genetic profiles with large regional variation. The World Health Organisation (WHO) has stated “the importing of medicines and other drugs may not be as effective to Mexico's population.”⁷⁰ Mexico needs medicines that respond to the particular characteristics of Mexicans. The characterisation of the genetic variation of the Mexican people and determination of drug response is undoubtedly a significant aim, which could be achieved through personalised medicine.

2.2.1 Main biobanking concerns in Mexico

These concerns will be explained in more detail in chapter 2. Biobanks emerged in Mexico as a result of jointly funded efforts by the Federal government and private enterprise. The first Mexican biobank was created as a result of a collaboration between the National

⁷⁰ World Health Organization, ‘Global applications of genomics in healthcare: Mexico’ (*WHO Genomic resource centre*)
<<http://www.who.int/genomics/professionals/applications/mexico/en/>> accessed 30 November 2012

Autonomous University of Mexico and the public hospital ‘Highly Specialised South Central Hospital PEMEX’ (*Hospital Central del Sur de alta especialidad de PEMEX*) in 1994.⁷¹ This first biobank stored radio-sterilised amniotic membranes for patients who suffered from serious burns. By 2000, Mexico had 53 tissue banks.⁷² In addition, the amount of both public and private biobanks have significantly increased.⁷³

The first brain bank in Mexico was opened in September 2012 “with the objective of a better understanding of neuro-degenerative diseases.”⁷⁴ Jose Luna Muñoz, neurology researcher, emphasised the open access that researchers will have to the new biobank centre, so that “all interested researchers can request the biological material and this will be facilitated under due ethical requirements.”⁷⁵ However, no further clarification has been provided in terms of preservation periods and secondary uses of biological samples within biobanks. It is also unclear whether the initial consent covers the specific research project on which the sample collection is based, or whether it can be extended to additional research projects. Researchers at INMEGEN (Mexican National Institute of Genomic Medicine) are not sure whether the destruction of valuable ‘leftover’ samples, after the collection purpose has been met, is the most ethical thing to do. In the experience of participant A, in some circumstances there is not enough information to make a suitable decision in the management and administration of the samples. There is nothing that can provide parameters, guidelines or policies in this respect.⁷⁶

⁷¹ M Montes Guadarrama and others, ‘Bancos de tumores (tumour banks)’ (2011) 49 *Patologia* 251

⁷² Daniel Luna-Zaragoza and Ma. Lourdes Reyes-Frías, ‘Donation transplants and tissue banking in Mexico’ (2001) 2 *Kluwer Academic Publishers* 255

⁷³ Gorodesky

⁷⁴ ‘Crean Banco Nacional de Cerebros’ *El Universal* (Mexico City, 21 September 2012) <<http://www.eluniversal.com.mx/articulos/73647.html>> accessed 20 October 2012

⁷⁵ *Ibid*

⁷⁶ Responsible-for-the-research-department-at-a-public-biobank-Participant:A, *PhD thesis fieldwork* (2012)

The most common samples taken in Mexico are blood, followed by tissue, (brain tissue, heart tissue, skin cells, plasma, cerebrospinal fluid, DNA, RNA, immortal lymphocytes, cellular lines and bone marrow fluid).⁷⁷

2.2.1.1 Conceptualisation issues: what is a biobank in Mexico?

This section will introduce the main problems when dealing with biobanks and the conceptualisation issues in Mexico. In the absence of a Mexican definition of biobanking, different measures have been taken. On the experience of INMEGEN's researchers,⁷⁸ everything is based on informed consent. This is based on the rules of the General Health Law on health research. It is explained to the research subject what will be done with his samples, where it will be kept, by whom and how the data will be protected. Research subjects are always told that the sample will be kept in a repository, not a proper biobank, just the storage freezer.

Legal challenges on biobanks in Mexico are related to conceptualisation and classification, sample-age, uses and users, duration of the study, types of participants, stakeholders and governance oversight and enforcement. The term "biobank" is now the over-arching term that is most commonly used. For governance purposes, at least in Mexico, the use of term "biobank" should be preferred due to the inclusiveness of the term and since it is widely used in practice.

The understanding of what a biobank means varies significantly in Mexico. Participant M believes that "biobanks are both the samples and the data contained in them."⁷⁹ However, in participant A's opinion,

⁷⁷ Casabona and Simons 277

⁷⁸ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE, *PhD thesis fieldwork* (2012)

⁷⁹ Responsible-of-the-Human-Genome-Department-at-a-public-ethics-advisory-institution-Participant:M, *PhD Thesis fieldwork* (2012)

“biobanks, as such, do not exist yet, just bio-libraries;”⁸⁰ For this participant, proper biobanks are like those in Nordic countries.

*“Those are immense, have great amounts of data and are super regulated, something Mexico is far from. Those in Europe are different in many aspects, in their laws, how they work and their health systems. They have centralised databases on health data from thousands of samples. We cannot compare them both. We have envisaged having a structured biobank in the future, not just a sample repository.”*⁸¹

Participant A expressed that a biobank is really a structured and particular collection.

*“We have collections from somebody who is doing a research project; we aim for a biobank, that each institution has rules allowing access to those collections and database, justified by a good research project. The collection preserved by INMEGEN could potentially encourage the creation of a national biobank, a resourceful database to support Mexican and overseas researchers. The project exists but has not been yet approved. We are working on that.”*⁸²

Participant A’s opinion resembles the description by Kaye; “the key factor that distinguishes a biobank from a research collection is that a biobank has established governance mechanisms in place to allow access to the resource in a systematic way to outsiders.”⁸³ However, this might involve a causality circular dilemma, at least if it was applied to Mexico. A great number of research collections in Mexico have no established governance mechanisms. Under Kaye’s approach, therefore, they could not be considered biobanks. If biobanks do not exist, a biobanking regulation for Mexico would not be so necessary. Participant A explained that she does not know whether the pathological collection at the National Institute of Cancerology, is a biobank; “there is a type of biobank of pathology samples.”⁸⁴

⁸⁰ Responsible-for-the-research-department-at-a-public-biobank-Participant:A

⁸¹ Interview with participant A

⁸² Interview with participant A

⁸³ European Commission 14

⁸⁴ Interview with participant A

2.2.1.2 What does a biobank contain?

Participant C believes that “a biobank is formed by biological samples and the information derived from them. A biobank may contain even bones, it is very broad. One of the problems is precisely that the content of biobanks can include tissues, organs, for different uses. Yet there is no suitable classification based on biobank types.”⁸⁵ For participant F, a biobank is a collection of samples. “There are different types of biobanks. Some are for research purposes, others preserve gametes, cord blood. Biobanking is the preservation of samples and organs with different purposes.”⁸⁶ It is difficult to provide a definition on the utility of the biobank and the material they contain as the latter varies significantly. It is the storage of biological material but differs from a simple storage because it is classified and organised, otherwise it would just be a repository. It is possible to exchange samples with other biobanks of the same type.⁸⁷

Participant C agreed on the fact that first, “we need a law defining what a biobank is, what the extent of a biobank is, who will control them, how will the data be regulated, the purpose, the content and each possibility. There might be biobanks in universities and we don’t even know they exist. They may be working with pathological samples and operating with no controls.”⁸⁸ In effect, defining what a biobank is would be a very good beginning.

Self-guidance is common where no biobanking definitions have been adopted. In the words of Participant B, a Mexican scientist, “a reference point would be good, it would seem arbitrary to me to determine a threshold, a limit in the quantity to define a biobank; I am not very

⁸⁵ Interview with participant C Legal researcher at a Public research institution. (Mexico City, December 2012)

⁸⁶ Interview with participant F

⁸⁷ Interview with participant F

⁸⁸ Interview with participant C

familiar with international law and I do not know if there are instruments that give these criteria.”⁸⁹ Participant B said that quantitative biobanking criteria was not a concern, “I do not think there are criteria to determine how many samples constitute a biobank. We could start by that.”⁹⁰ Large-scale biobanks are generally used for prospective and longitudinal molecular epidemiology research projects, while smaller scale biobanks are established for specific research projects, such as case-control studies. The latter “have been more the norm...while large scale biobanks are relatively recent.”⁹¹ These smaller scale projects represent an indispensable scientific resource complementary to large-scale biobanks. However, that still leaves the “remainder of the biobank spectrum that encompasses increasing levels of operational complexity and associated cost.”⁹²

2.2.2 The particular commercial pressures

Medina-Arellano observed that “lately, Mexico has seen increasing interest from private foreign companies in nurturing this area of research, creating international transnational alliances between countries and research institutes.”⁹³ Examples of such strategic alliances are those at INMEGEN, where they have been developed. 85% of them were formed in the first 3 years of the Institute. 12 state universities, including the main national university UNAM, and research institutes: the Mexican national institute for health NIH, and public health provider ISSSTE. Participating institutions abroad are: Vanderbilt University, the University of Toronto, Translational Genomics Research Institute (TGen), the New York State Centre of Excellence in Bioinformatics and Life Sciences and Nestlé.

⁸⁹ Interview with participant B

⁹⁰ Interview with participant B Researcher at a public biobank. (Mexico City, December 2012)

⁹¹ European Commission 14

⁹² Watson and Barnes 328

⁹³ MJ Medina-Arellano, ‘Stem cell regulation in Mexico: current debates and future challenges’ (2011) 5 *Studies in Ethics, Law, and Technology* 1941

Another area of interest is the activity of the pharmaceutical industry; it involves more focused clinical research by laboratories aiming to develop diagnostic and predictive tests from specific areas of the human genome. Increasing pharmaceutical activities have caused Mexico to attract the attention of industrial activity in this area. Additionally, the low cost of research and density of diverse population⁹⁴ has created interest in terms of patient recruitment for clinical trials.

Other reasons why Mexico has also become a popular location for clinical trials are the free trading facilities with the USA and Canada, which make the country an attractive place for the development of clinical trials. 30% of the total cost of the trials can be saved in comparison with the cost of trials performed in the USA. Besides, Mexico has been targeted by the pharmaceutical industry because of the diverse ethnicity among the population and the availability of “virgin patients” (those who have never participated in a clinical trial). Fernando Santiago considers current guidelines are rather general, weaker compared to current industry standard practices; and somehow inadequate to tackle challenges resulting from an expanding market.⁹⁵

A factor that makes Mexico a place of interest for the development of new drugs is the prevalence of diseases associated with genetic components, e.g., diabetes. In Mexico, the mortality caused by diabetes mellitus is 64% and has increased 5.2% in women between 1999 and 2009.⁹⁶ For example, the Slim Initiative for Genomic Medicine is a project funded by the *Carlos Slim Health Institute*. The foundation aims to

⁹⁴ KP Virk, ‘Trials in Mexico: Addressing the challenges. Clinical trials outsourcing Mexico’ (2009) 21 *Biotech and pharmaceutical research language connections* 21

⁹⁵ F Santiago-Rodriguez, *Facing the Trial of Internationalizing Clinical Trials to Developing Countries: With Some Evidence from Mexico* (UNU-MERIT, Maastricht, The Netherlands, 2008) 16

⁹⁶ Mexican Population National Council CONAPO, ‘Consejo Nacional de Poblacion CONAPO’ (*SEGOB (Mexican Ministry of Governance)*, 2009)
<<http://www.conapo.gob.mx/>> accessed 28 May 2011

develop steps in genetic knowledge leading towards the cure of diabetes type 2 and many types of cancer which have a significant public health impact in Mexico. Hence, it has sponsored studies such as “the sequence analysis of mutations and translocations across breast cancer subtypes,”⁹⁷ (a collaboration of the Broad Institute in Cambridge, USA, in which the INMEGEN also participated). The results of the study have been surprising in terms of the genetic alterations that had not formerly been associated with breast cancer. Genes unexpectedly participating in the breast cancer process have been discovered. The study represented a preliminary opportunity to evaluate the genetic first step toward breast cancer research in Mexico.

In Mexico, these types of studies are becoming more common. The Mexican government has centred on strategies to use evidence-based population studies to inform public health decision-making and target health interventions accordingly.⁹⁸ The intention is that medical advances would bring social and economic benefit to the population and encourage pharmaceutical research.

The import and export of human tissue is commonly used in research activities in Mexico. The UNAM study revealed that nine biobanks do not import or export, whereas four biobanks have import and export agreements with academic institutions (mainly in the USA and the UK). One biobank imports samples from a North American Company. “Samples are often sent to countries counting on a more solid structure in order to join efforts and accelerate research.”⁹⁹ International schemes for sharing samples will be analysed in chapter 6.

⁹⁷ Banerji and others 405-409

⁹⁸ Séguin and others 487

⁹⁹ Ibid 487

2.2.2.1 Ethical conduct of the pharmaceutical industry

Biobanks also involve the participation of the private sector, which, far from being limitless, should be controlled. There is an important gap between the development of the first clinical trials, in 1983 and the establishment of official minimum regulatory controls in 2008. COFEPRIS the Federal Commission for the Protection against Sanitary Risk (*Comisión Federal para la Protección de Riesgos Sanitarios*) has recognised that the authorisation protocols started when the Commission became an authority for the approval of clinical trials. COFEPRIS began to conduct elaborate statistical studies in relation to clinical trials in 2011. The latter creates great concern on the numerous past and present ethical issues. Biological samples can be preserved for years. The longer they are preserved, the greater the ethical risks become. The present situation of Mexican biobanking is problematic and it is possible that old biological collections are still being used. It is not determined whether retrospective actions should apply for those cases. Participant K, a policy maker, said he was not aware of any regulation of benefits obtained by industry from biobanking in the country.¹⁰⁰

According to an investigation made by the Mexican magazine “*Contralínea*,”¹⁰¹ 5025 clinical trials involving human beings have taken place from 1983 to 2011 with national and international participation. More than 3476 have been performed by national public health institutions and international health institutes. The National Institutes of Health (NIH) from the USA have also developed self-sponsored and collaborative biomedical research; at least 20 transnational firms have collaborated in half of the total research performed by Mexican health

¹⁰⁰ Member-of-The-Mexican-Parliament-at-The Science-and-Technology-Commission-Participant:K, *PhD Thesis Fieldwork* (2012)

¹⁰¹ M Sánchez, ‘En México, más de 5000 experimentos con seres humanos (more than 5000 experiments with human beings in Mexico)’ *Contralínea* (Mexico City, 19 February 2012) <<http://contralinea.info/archivo-revista/index.php/2012/02/19/en-mexico-mas-de-5-mil-experimentos-clinicos-con-humanos/>> accessed 21 March 2012

institutes.¹⁰² The investigation highlights the fact that the international private pharmaceutical industry has sponsored most of the clinical trials in the country (46%) through 20 laboratories established in Mexico.¹⁰³

Regarding international participation, the US NIH has developed 1549 clinical trials, 929 (60%) in collaboration with transnational pharmaceutical companies. Out of those 1549, 1472 (95%) have been invasive. More than 14187 people have participated. COFEPRIS has reported that most of the research protocols which have applied for approval were national and international private institutions, some of them were collaboration studies between national and international private institutions,¹⁰⁴ e.g. a private health centre from Mexico City and an international pharmaceutical company.

The main identified problem is the insufficient supervision by the Mexican authority to verify the compliance with minimum ethical requirements. According to information provided by COFEPRIS, between 2003 and 2011, 690 committees were authorised by the Commission (169 research committees, 516 ethics committees and 5 biosafety committees). From January to April 2012, 33 applications have been approved (15 research committees, 14 ethics committees and 4 biosafety committees).¹⁰⁵ However, these numbers are not proportional with those disclosed by the Contralinea investigation on the number of research trials developed in the country. In addition, biobanking evaluation should theoretically be done by a bio-safety committee and

¹⁰² Mayela Sánchez, 'En México, más de 5000 experimentos con seres humanos' *Contralinea* (Mexico City, 19 February 2012) <<http://contralinea.info/archivo-revista/index.php/2012/02/19/en-mexico-mas-de-5-mil-experimentos-clinicos-con-humanos/>> accessed 21 March 2012

¹⁰³ Ibid

¹⁰⁴ Ibid

¹⁰⁵ Comisión Federal para la Protección contra Riesgos Sanitarios (Federal commission for the protection against health risks) COFEPRIS, 'Registro de comités (Committees' registration)' (*COFEPRIS*, 4 December 2013) <<http://www.cofepris.gob.mx/AS/Paginas/Servicios%20de%20Salud/Comit%C3%A9-de-%C3%A9tica.aspx>> accessed 15 August 2012

only a small number of bio-safety committees have been approved. This means that biobanking is being evaluated by non-specialised ethics committees, a situation which could be advantageous for the pharmaceutical industry but not for research participants. Currently, 90% of experimental trials, which are related to biobanking, are advanced (phase 3)¹⁰⁶ and they need evaluation by people who are research or biobanking experts on ethics topics.

Problems associated with research protocols have also been detected. Research protocols of international pharmaceutical companies tend to follow their own formats, but these do not always comply with the specific regulations of each country and if the national authority has weak controls, transnational companies avoid updating their standards.¹⁰⁷

The CNB has provided a list of elements for the Mexican government to consider in order to increase the controls on the activities by the pharmaceutical industry. The institution has detected unethical conduct; laboratories have offered money to health staff instead of recruiting “virgin” patients.¹⁰⁸ This is a serious problem which could have numerous implications. One of them is the high probability that such recruitment also include the collection of biological samples.

¹⁰⁶ Ruy Perez Tamayo, ‘La investigación Médica en seres humanos (Medical research in human beings)’ (2008) 19 *Medicina Universitaria* 262

¹⁰⁷ Comisión Nacional de Bioética (The National Commission of Bioethics), *Reporte para el proyecto “Sistemas de regulación ética de la investigación biomédica en América Latina y Europa: Análisis comparativo de su pertinencia y aplicación para la protección de los sujetos de investigación - EULABOR” (Report for the Project EULABOR Latin American and European Ethical Regulation Systems of Biomedical Research: Comparative Analysis of their Pertinence and Application for Human Subjects Protection (CNB, 2006) 76*

¹⁰⁸ *Ibid* 75

2.2.2.2 The relevance of the specific populations inside the country's boundaries

The practice of personalised medicine involves not only a biological challenge but also one with significant cultural and social implications. In the opinion of Cavalli-Sforza and Feldman,¹⁰⁹ cultural influences in human behaviour are greater than those of biology. However, the authors support the idea that still “some release from genetic determinism” must not be underestimated. Following this idea, the particular cultural characteristics of indigenous populations in Mexico, including religious convictions and established legal or political claims, can be challenged by genetic studies at collective and individual levels.

Approximately 90% of the Mexican population is racially mixed. The remaining 10% corresponds to 56 indigenous groups, whose integration into modern Mexican society has been a long process related to national identity and recognition. This process is still taking place after centuries of discrimination, domination, exploitation and cultural submission. In contrast, great efforts are being undertaken to preserve this cultural, social and linguistic legacy.¹¹⁰ Participant D believes that in the case of indigenous groups, “no time has been dedicated to reflect whether indigenous populations need different protection, I believe that it is important to request their informed consent in their own language.”¹¹¹

It is well known within Mexican society that indigenous peoples are considered vulnerable for many reasons, including historical discrimination against indigenous ethnic groups, which is still within people's living memory. Indigenous groups are associated with ignorance and poverty by many. The word “*indio*,” i.e. Indian, a term associated with

¹⁰⁹ LL Cavalli Sforza and MW Feldman, *Cultural Transmission and Evolution: A Quantitative Approach*. (Princeton University Press 1981) 216

¹¹⁰ M González, ‘Ethnic minorities in Mexico, United States and Canada: a comparative study of coexistence ’ (2002) 5 *Diálogos Latinoamericanos*

¹¹¹ Responsible-of-the-ethics-department-at-a-public-biobank-Participant:D, *PhD Thesis fieldwork* (2012) 17

indigenous ancestry before Mexico was a Spanish colony, may be used in a pejorative sense. This could signify high risks of stigmatisation, since population studies also involve “reification of race, a mostly social construct as a highly meaningful biological construct.”¹¹²

There are good reasons for the emergence of different types of biobanking in Mexico. One of them is undoubtedly the diversity among the Mexican population. “Mexico serves as an important focal point for medical genetic analyses, because it harbours one of the largest sources of pre-Columbian diversity and has a long history of complex civilizations with varying contributions to the present-day population.”¹¹³ Genomic diversity studies represent the initial reasons for the creation of INMEGEN; the analyses of genomic variation in, and between, particular populations for various purposes. Such examples include ‘investigations on the Mexican human genome for population study purposes’ and ‘the consequent further development of genomic benefits.’¹¹⁴ The studies conducted by INMEGEN involve sample collection and, therefore, potential research ethical concerns. The genotyping results achieved in the HapMap study (the Map of the Mexicans’ Genome on national genomics identity) are planned to be used in future epidemiological research.¹¹⁵

2.2.2.3. Ethical dilemmas on biobanking

To encourage the participation of vulnerable groups requires funded projects with integral views, not simply disclosing scientific

¹¹² International HapMap-Project, ‘The International HapMap Project: Ethical, Social, and Cultural Issues’ (*International HapMap Project*)

<hapmap.ncbi.nlm.nih.gov/downloads/presentations/HapMapELSI.en.ppt>

¹¹³ A Moreno-Estrada and others, ‘The genetics of Mexico recapitulates Native American substructure and affects biomedical traits’ (2014) 344 *Science* 1280

¹¹⁴ L Pessini, P Barchifontaine and F Lolas Stepke (eds), *Ibero-American Bioethics: History and Perspectives*, vol 106 (J Bulcock tr, Springer 2011) 172

¹¹⁵ E Schwartz-Marín and I Silva-Zolezzi, ‘The Map of the Mexican’s Genome: overlapping national identity, and population genomics’ (2010) 3 *Identity in the Information Society* 498

research results, but demonstrating their utility towards the communities' welfare. Therefore, the topic of indigenous communities participating involves more than issues relating to data protection or a later return of scientists to disclose meaningless research results for the real needs of these communities. In practice, the ethics committee is the one responsible for looking at the needs and best interests of vulnerable people participating in research protocols.¹¹⁶ The CNB does not provide special training for the cases of vulnerable populations, a CNB representative admitted that "it has not happened."¹¹⁷

Hence, recruitment procedures, informed consent and confidentiality protections must include protective measures. The General Health Rules on Research anticipates protection for vulnerable people through specific chapters on research on underage persons, pregnant women or incapable persons. Protection for communities, students and workers is also anticipated.¹¹⁸

2.2.2.3.1 The 'unique' Mexican genome and the claims of genomic sovereignty

Population genetics is closely related to biobanking. Regulation has been introduced governing the research on human beings in relation to genomic studies. Genome resources that use samples from identified populations raise scientific, social and ethical issues that are, in many ways, inextricably linked.¹¹⁹ Eugene Thacker¹²⁰ has explained how the concept of genomic sovereignty has been understood from two different

¹¹⁶ Responsible-of-the-Genetics-department-at-a-public-ethical-advisory-institution-Participant:I, *PhD Thesis fieldwork* (2012)

¹¹⁷ Responsible-of-the-Human-Genome-Department-at-a-public-ethics-advisory-institution-Participant:M

¹¹⁸ Reglamento de la Ley general de Salud en Materia de Investigacion para la Salud (The Ministry of Health Rules of the General Health Law on Health Research) Title II Chapter II-V

¹¹⁹ The-International-HapMap-Consortium, 'Integrating ethics and science in the international HapMap Project ' (2004) 5 *Nature Genetics* 467

¹²⁰ E Thacker, *The global genome: biotechnology, politics and culture* (Cambridge MIT Press 2005) 163-164

views. The first is a progressive one from genetic identification and differentiation, in which individuals and populations can be analysed according to their unique characteristics. When the Spanish *conquistador* Cortés married his indigenous translator ‘*La Malinche*’, their union and many others like them depicted how two divergent genomes merged.¹²¹ This has led to the sometimes exaggerated measures to defend this allegedly unique genome. The second from bio-politics, combines the potential of population genomics with the risk of neo-colonialist practices, caused by potentially unfair appropriation of biological material from groups with specific genetic profiles (e.g. from transnational pharmaceutical companies). In Mexico this latter view has been the motive for protecting the allegedly ‘Mexican unique heritage’. The increasing popularity of this new concept contributed to the proposal of unusable legislative measures; in order to protect, not precisely Mexican indigenous groups, but the economic value of their samples. Additionally, group stigmatisation is inherent in any study of samples from identified individuals or populations, especially indigenous groups. This also constitutes a risk for the general population, who potentially can be affected on the grounds of genetic variation. This topic will be further discussed on chapter 4, as it involves a brief legal analysis of the current related Mexican rules.

¹²¹ L Wade, ‘Initiative Aims to Minister to Mexico's Unique Genetic Heritage’ (2013) 342 Science 788

II. THE MEXICAN CONTEXT

3. Risks, harms and values

3.1 Introduction

This chapter argues that the present guidelines do not favour the ethical treatment of biological samples in Mexican biobanks by researchers. The allegedly inconsistent legal framework, with ambiguous oversight and procedures, does not cover all biobanking practical areas. This involves a negative impact on the development of valuable research which, in many cases, is done at the risk of participants being exploited. Hence, this chapter aims to investigate the current risks and harms potentially posed by the current state of Mexican biobanking, covering their history. Troubling historical cases have often precipitated significant changes regular to reform all over the world. A few relevant examples are presented.

The first section briefly reviews traditional bioethical principles based on academic literature. The understanding of ethical values is elemental to understand the main legal weaknesses within biobanking. Hansson states that many ethical concerns ‘...test our traditional legal concepts, governance provisions and bioethical principles.’¹²² A number of risks and harms tend to emerge without a firm ethical consideration within legislation.

The second part of this chapter analyses the main Mexican research ethics guidelines for biobanking, as far as they exist; this includes inconsistent and weak guidelines, ethics committees, institutions and operational factors. Areas requiring more attention will be identified. A case study analysis on obstacles related to the effectiveness of research ethics will follow. A comparison will be done between two cases,

¹²² SMC Gibbons and J Kaye, ‘Governing genetic databases: collection, storage and use’ (2007) 18 Kings Law J 204

illustrating the main practical biobanking dilemmas in Mexico. The chapter will finish with a brief proposal on ways to improve the current framework for research ethics in Mexican biobanking.

The protection of human rights has also been a key element in alleviating potential risks and harms. Hence, the final section of this chapter will evaluate whether this could be the case in Mexico. How the state of human rights impacts on identified potential risks and harms will be analysed. Knowledge on the strengths and weaknesses of the Mexican human rights' system may be fundamental for suitable Mexican biobanking legislation.

3.1.1 Historical cases

The undetermined uses of biobanks have led to cases of alleged abuse through the history of biobanking. Lawsuits related to the inappropriate use of specimens and the absence of consent have been exposed by the U.S. press¹²³ The majority of these cases did not involve technical misuse but touched on ethical issues.

This was the case of Henrietta Lacks (1920–1951), whose cells were the first immortal human cells ever grown in culture. (Her cells, due to induced mutation, kept undergoing division through prolonged growing in vitro). During radiation treatments for a tumour, two samples of Henrietta's cervix were removed by the Johns Hopkins Hospital in the USA - a healthy part and a cancerous part - without her permission.¹²⁴ These were essential to developing the polio vaccine in 1954. Many

¹²³ A Harmon, 'Havasupai Case Highlights Risks in DNA Research' *The New York Times* (New York, 21 April 2010)

<http://www.nytimes.com/2010/04/22/us/22dnaside.html?_r=0> accessed 21 April 2010

A Harmon, 'Indian Tribe Wins Fight to Limit Research of Its DNA' *New York Times* (New York, 21 April 2010)

<http://www.nytimes.com/2010/04/22/us/22dna.html?pagewanted=all&_r=0> Eiseman and Haga

¹²⁴ R Skloot, *The Immortal Life of Henrietta Lacks* (Broadway Books 2011) 33

scientific landmarks since then have used her cells, including cloning, gene mapping and in vitro fertilization. Twenty years after Henrietta's death, scientists using her cells also began using her husband and children in research without informed consent. And though research using her cells had launched a multimillion-dollar industry that sells human biological materials, her family never saw any of the profits.¹²⁵ In the 90s, a cell line donor claimed the legal property of his sample used in unauthorized research (the Moore case in California)¹²⁶, leading to an intense ethical debate centred around the concept that "inadequate unclear laws generate distrust and anger."¹²⁷ For scientists, this has reinforced the lesson that there are human beings behind every biological sample used in the laboratory.¹²⁸

Post mortem tissue has been an object of controversy linked to gaps in legislation at national levels, such as that which led to national bioethics scandals in the UK, which would later be known internationally. What became one of the most controversial points was the absence of authorisation to use such sensitive biological materials for the development of potentially valuable medical research. Alder Hey Children's hospital scandal was centred on the retention of hearts and organs from hundreds of children, who died at the hospital between 1988 and 1996, without the parents' consent.¹²⁹ Decades after, and even when legislation was set in place, controversial cases keep emerging. Recently, in 2012, relatives of British soldiers killed in Afghanistan received a public

¹²⁵ D Keiger, 'Immortal Cells, Enduring Issues' Johns Hopkins Magazine <<http://archive.magazine.jhu.edu/2010/06/immortal-cells-enduring-issues/>> accessed 2 June 2012 1

¹²⁶ *Moore v. Regents of the University of California* John Moore, Plaintiff and Appellant, v The Regents of the University of California et al, Defendants and Respondents (Supreme Court of California)

¹²⁷ JB Prowda, 'Moore v. The Regents of the University of California: An Ethical Debate on Informed Consent and Property Rights in a Patient's Cells' (1995) 77 JPat & Trademark Off Soc 611

¹²⁸ Zielinski 2

¹²⁹ BBC News, *Organ scandal background* (BBC 2001)

apology over the revelation that body parts had been stored without permission. Approximately six organs and more than 50 tissue samples were reportedly discovered in Oxford,¹³⁰ raising suspicion that the biological material was being used for research. This and other international experiences highlight the importance of contemporary research ethics and the diverse perspectives of its regulation.

As previously reviewed, historical experiences have highlighted the significance of informed consent, as most cases of abuse are a result of its absence. The legal coverage of informed consent in Mexican regulation is controversial; even when it exists no single law covers its wide scope related to biobanking. No specific consent type has been determined; or what should be best, an open or generic informed consent.¹³¹ The latter would expand informed consent by allowing sample use in unforeseen future studies, whereas a consent type referring to a particular research “study,” would restrict any further studies.¹³²

3.2 The concept of risk

Risk has been traditionally approached by policy makers before situations of uncertainty arise, in the best ways they can. Sunstein has made a connection between society types, legal systems, and societies’ common methods tackling certain risks. Under the European Precautionary Principle, a margin of safety is meant to be taken into account in all decision making.¹³³ In Britain, it was not so much science, as expert judgement that formed the basis for assertions of safety; and in

¹³⁰ A McSmith, ‘Relatives of soldiers killed in Afghanistan receive public apology over body parts stored without permission’ *The Independent* (9 August 2012) <<http://www.independent.co.uk/news/uk/home-news/relatives-of-soldiers-killed-in-afghanistan-receive-public-apology-over-body-parts-stored-without-permission-8026974.html>>

¹³¹ MG Hansson and others, ‘Should donors be allowed to give broad consent to future biobank research?’ [2006] 7 *Lancet Oncol* 268

¹³² *Ibid*

¹³³ CR Sunstein, *Laws of fear, beyond the precautionary principle* (Cambridge University Press 2005) 19

Germany, to begin with, bureaucratic procedures and public consultation were the instruments of choice for allaying the fears of a nervous citizenry.¹³⁴

Sunstein has proposed that the best attitude before precaution is that reflected by the public, and not precisely a fearful but an informed one. Following this proposal, policy makers are still responsible for the best implementation of precautionary laws. However, this responsibility would be shared with a participative public and the values justified by them. Instances of actual discrimination, based on a participant's involvement in a biobank genetic research studies, are extremely rare, whereas population studies involve a higher risk of discrimination or stigmatisation, not only at the individual level but particularly the collective level. The change in focus from investigating risk factors with relatively large effects exploring networks of risk factors with weak effects requires a radically different approach. Thus, careful thought needs to be given to the level of evidence that justifies clinical use of genomic profiling,¹³⁵ taking into account the strength of the observational data, the clinical benefit and the potential to harm.¹³⁶ Risks are present with the introduction of a sole promissory discourse with ambiguous expectations.

3.2.1 Potential risks

There are numerous examples of medical advances that have relied upon human research biospecimens. Undoubtedly, even when discoveries are extremely important for national and international health science, ethical aspects must not be disregarded through the processes used to achieve such discoveries. There has been very strong public support for breakthroughs promising better medical diagnosis and

¹³⁴ S Jasanoff, *Designs on nature. Science and democracy in Europe and the United States* (Princeton University Press 2005) 117

¹³⁵ Frederique Ponchel and others, 'Gene expression analysis in RA: Towards personalised medicine' [2014] *The Pharmacogenomics Journal* 102

¹³⁶ SB Haga, MJ Khoury and W Burke, 'Genomic profiling to promote a healthy lifestyle: not ready for prime time' (2003) 34 *Nat Genet* 347–50

treatments but there are anxieties about “increased loss of privacy and the potential for genetic discrimination, as well as the capacity to regulate genetic science in the public interest.”¹³⁷

Biobanking risks are not the same for each type of research. For example, statistical analysis of samples within biomedical research has proven to be very low risk in comparison with genetic studies, which can be highly risky in the case of population studies where vulnerable populations take part. Genomic research should have a lower public health priority, because a population approach to prevention will achieve a greater public health benefit than interventions targeted at high-risk groups on the basis of genotypes.¹³⁸ There must be a balance between taking the necessary measures to reduce potential risks, where found, and avoiding biobanking policies because of social fears. In this case, the precautionary principle can be applied; better safe than sorry, “even though they face a statistical risk, they might well be seeking to avoid the anxiety that comes from an understanding of the inevitability of risk.”¹³⁹ Ulrich Beck portrayed risk as a systematic way of dealing with hazards and insecurities induced and introduced by modernisation itself.¹⁴⁰ As such, it would be capable of reshaping social relations throughout the industrial world. He suggested that people everywhere were at risk from their own creative powers, materially transformed into hazardous technologies, and the risks could strike one down regardless of one’s social or economic standing.¹⁴¹

¹³⁷ *Essentially Yours: The Protection of Human Genetic Information in Australia* (ALRC Report 96, 2003) 33

¹³⁸ B Lumbreras, M Porta and I Hernández Aguado, ‘Assessing the social meaning, value and implications of research in genomics’ (2007) 61 *Research in Genomics* 756

¹³⁹ CR Sunstein 53

¹⁴⁰ U Beck, *Risk society: towards a new modernity* (SAGE Publications 2004) 21

¹⁴¹ Jasanoff 97

3.2.1.1 Non-specific governance and consequent risks

The necessity for effective decision making, because of the struggle to find uniform and consistent guidance, has resulted in self-regulation for the protection of those who participate actively in biobanking activities. However, protection of vulnerable populations against high stigmatisation risks should not be solely governed by general guidance and the goodwill of population projects organisers, even if “only” biological samples are involved. If scientists are unable to follow existing rules in a simplified way, research subjects will not be fully aware of their rights.

Ruth Macklin, regarding the legal situation in the United States of America, describes how risky the absence of legal guidelines at a national level can be. “The researchers might be faulted for not waiting until such guidelines were established. On the other hand, they surely could not fail to conform to national guidelines when such guidelines do not exist.”¹⁴² In the USA there have been cases in which ethics committees are so vague in their wording that the researchers cannot be condemned for violation of unofficial, unclear ethical research guidelines; e.g. on preembryos. This was reported by the American Fertility Society (AFS). Something similar would happen in Mexico, where it is illegal to impose any penalty on the basis of interpretation, analogy or even by majority opinion. The sanction needs to be explicitly and accurately enforced to be applicable.¹⁴³

The fragmentation of legal rules can impact negatively on the practice of ethics in biobanking. Guidance can be accessed from international sources. In the opinion of Manson and O’Neill, when basic consent requirements are given in a purely ethical way (not legal), they

¹⁴² R Macklin, ‘Splitting Embryos on the slippery slope: Ethics and public policy’ (1994) 4 Kennedy Institute of Ethics Journal 213

¹⁴³ The Mexican Constitution (Mex) Article 14

become at risk of being considered optional. Hence, other more basic legal standards are necessary to make it compulsory.¹⁴⁴

3.3 Ethical values which should underpin regulation

Mayrhofer and Prainsack suggested that “the creation of ethical standards, as well as adherence to them (in the context of networks of biobanks) is neither imposed on the scientific communities, nor is it separable from the very core of scientific research; instead, ethics and science are literally co-produced.”¹⁴⁵ Governance tends to be based on the notion of a participatory arrangement relying on traditional ethical practices that impact on the reliability of scientific research and potential social benefit; such as autonomy, respect and privacy rights.

Ethical principles should provide the foundation for human research governance. Beauchamp and Childress¹⁴⁶ established four fundamental principles applicable to biomedicine: 1) autonomy or respect to persons, their opinions and decisions based on personal values and beliefs; 2) non-maleficence, which avoids harm to other persons; 3) beneficence, which forces the prevention or elimination of damage and to promote righteousness; and 4) justice in the equal treatment of persons unless there is a relevant difference between them.

Biobanking has been the subject of international concerns emerging from the need to protect universally recognised values and fundamental rights, such as: autonomy, liberty, equality, security, and self-determination of participants and donors of samples. It presents a number of significant legal challenges, the most important of which is the

¹⁴⁴ NC Manson and O O’Neill, *Rethink informed consent bioethics* (Cambridge University Press 2007) 78

¹⁴⁵ MT Mayrhofer and B Prainsack, ‘Being a member of the club: the transnational (self-) governance of networks of biobanks ’ (2009) 12 *International Journal of risk assessment and management* 64

¹⁴⁶ TL Beauchamp and JF Childress, *Principles of Biomedical Ethics* (Seventh edn, Oxford University Press 2012) 12

incorporation of universally recognised ethical principles. Morality and public order principles are being surpassed by the legal interpretation of positive contemporary systems. Such an interpretation is subject to the common rules of each positive legal system, which may contain ethical barriers.¹⁴⁷ According to Alexy, there is always a component of morality within legal issues; individual legal norms and decisions as well as whole legal systems necessarily make a claim to correctness. The ideal dimension of law connects it with a procedural, universalistic morality.¹⁴⁸ Ultimately, “the governance of biobanks demands complex analyses of both the legal and ethical framework.”¹⁴⁹ Legal incorporation should also be based on legitimising principles of fairness and justice; more specifically, the statutory ‘five principles of good regulation’: transparency, proportionality, accountability, consistency and targeting.¹⁵⁰

3.3.1 Human dignity

Kantian literature regards dignity as an absolute inner value of human beings.¹⁵¹ The view that human body parts (as samples could be regarded) cannot be considered commodities or property objects was discussed extensively by Kant.¹⁵² He rejected the prevalence of economic interests over priceless values such as human dignity. The ethical aspects of research are relevant not only in relation to property issues of the samples, but also recruitment, future use, privacy, benefit sharing and the

¹⁴⁷ RS Crespi, ‘Biotechnology patents and morality’ (1997) 15 Trends in Biotechnology 123

¹⁴⁸ R Alexy, ‘On Necessary Relations Between Law and Morality’ (2007) 2 Ratio Juris 170

¹⁴⁹ E Rial-Sebbag and A Cambon-Thomsen, ‘The Emergence of Biobanks in the Legal Landscape: Towards a New Model of Governance’ (2012) 39 Journal of Law and Society 119

¹⁵⁰ BRTF, *Principles of good regulation* (Better Regulation Task Force 2003) 1

¹⁵¹ D Beyleveld, D Townsend and J Wright (eds), *Research Ethics Committees, Data Protection and Medical Research in European Countries* (Aldershot Ashgate 2005) 412

¹⁵² I Kant, *Groundwork of the Metaphysics of Morals* (M Gregor and J Timmermann eds, M Gregor tr, Cambridge University Press 2012) 27

subject's consenting matters. A selection of ethical values will be described in the following section.

3.3.2 Informed consent

General concerns from the public take the form of “making an active and informed initial decision about biobank participation but that they have concerns about the need for and potential adverse impact on future-use consent mechanisms such as categorical and study-specific consent.”¹⁵³ Gibbons has emphasised the absence of certainty when collections “may simply happen to be held together, perhaps for reasons of convenience or necessity.”¹⁵⁴ It may be the case that the initial purpose of some collections change over time, or that the purpose was not clear or inexistent since the outset. “The material taken originally for diagnostic purposes may well have been kept simply as a matter of routine or professional culture or retained ‘on spec.’”¹⁵⁵

Typical informed consent means that clear information is provided through simple terminology, and must include a description of any research/medical related procedures and the use of technical terms. Consent is divided into two parts: information rights and election freedom. Election freedom, or expressive freedom, means every citizen's ability to make choices in an uncoerced manner. Several types of consent definitions have been proposed by the literature. Hansson¹⁵⁶ has proposed the following types of consent:

- *Blanket or broad consent is open and generic, expands informed consent by allowing sample use in unforeseen future studies*

¹⁵³ CM Simon and others, ‘Active choice but not too active: public perspectives on biobank consent models.’ (2011) 13 Genet Med 15

¹⁵⁴ Gibbons 7

¹⁵⁵ Ibid

¹⁵⁶ Hansson and others 268

- *Consent to biomedical research allows samples to be used for multiple purposes (even unspecified future purposes) in future biobank-based research*
- *Consent to a specific type of research is referred to a “type” of research, as precisely specified as possible, and conducted in the centre holding the sample. This ensures the consent is valid and the sample preserved beyond a particular study so that further similar studies on the same topic are possible later*
- *Multi-layered consent requires several options to be explained to the research subject in a detailed form*
- *Waived consent condition. If it is not possible to re-contact participants for re-consent, some guidelines allow for waived consent for the use of biological material, if certain conditions are met.¹⁵⁷ However, these conditions are not harmonized among international guidelines*

Broad consent models are becoming increasingly popular in recent literature by “the bioethics developed for epidemiological research aimed for social benefit.”¹⁵⁸ The unexpected changes which tend to appear from time to time constitute a reason to prefer flexible rules in order to ease required modifications. “Decisions will be needed about whether or not [one is] seeking fresh consent, or employing some alternative safeguard.”¹⁵⁹ A consent model sensitive towards public needs would consist of an agreement that includes even re-consent possibilities. Consent models have been designed to appropriately regulate tissue based research. It has been characterised by a maze of laws, policies

¹⁵⁷ E Vayena, A Ganguli-Mitra and N Biller Andorno, ‘Guidelines on biobanks: emerging consensus and unresolved controversies’ in B Elger and others (eds), *Ethical Issues in Governing Biobanks* (Ashgate 2013) 91

¹⁵⁸ T Caulfield and J Kaye, ‘Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas’ (2009) 10 *Medical Law International* 89

¹⁵⁹ Gibbons 321

and ethical recommendations that range from strict (specific informed consent) to unrestricted use (broad consent).¹⁶⁰

In the case of broad consent, “participants are asked to consent to the use of samples and data within a biobank at the time of collection rather than to a specific project or type of research.”¹⁶¹ This choice has been heavily criticised from various perspectives, to the point of being considered not meaningful enough to be informed consent. “A blanket approach to consent requirements, that seeks to standardise procedures for consent for all treatment or all research, shows a lack of understanding of the reasons why consent matters.”¹⁶²

3.3.2.1 Consent Withdrawal

The most widely acceptable trend is that “participants should be able to exercise their right to have their sample withdrawn at all times.”¹⁶³ However, other views suggest that withdrawal of consent is unrealistic or limits practical implementation.¹⁶⁴ It has also been proposed that tissue donors may determine “how far they will be informed and that (when it is technically possible) they remain free to rescind their initial choice.”¹⁶⁵ It is preferable to have all the necessary arrangements for withdrawal choices set out in advance in order to avoid working retrospectively. Some biobank models offer the following set of graded options for withdrawal of samples and data, which may vary according to different situations: irreversible anonymization, in which no code key and no re-identification are possible; reversible anonymization, in which a link exists, but the

¹⁶⁰ A Boggio and others, *Comparing guidelines on biobanks: emerging consensus and unresolved controversies* (The Réseau universitaire international de Genève—Geneva International Academic Network (RUIG-GIAN) Human Genetic Databases: Towards a Global Ethical Framework, 2005) 3

¹⁶¹ European Commission 51

¹⁶² Manson and O’Neill 82

¹⁶³ G Helgesson and L Johnsson, ‘The right to withdraw consent to research on biobank samples’ (2005) 8 *Medicine, Health Care and Philosophy* 315-321

¹⁶⁴ A Cambon-Thomsen, E Rial-Sebbag and BM Knoppers, ‘Trends in ethical and legal frameworks for the use of human biobanks’ (2007) 30 *Eur Respir J* 373–382

¹⁶⁵ O’Neill, ‘Some limits of informed consent’ (2003) 29 *J Med Ethics* 6

researcher does not have access; and coding, in which the researcher has access to the code through a code key.¹⁶⁶

For instance, a UK-based, self-regulated public biobank, offers the following withdrawal choices:

Option 1 – Withdraw

Samples and identifiable data would be destroyed. Any links to medical records would be broken.

Option 2 - Discontinue participation

*No more information would be collected. Any links between the participant and samples or data, including the link with the health record, would be destroyed. This would allow the samples and data already contained in the UK Biobank to be used, but no further contact with the participant would be made.*¹⁶⁷

The preference of a specific model rather than a broad one favours the inclusion of withdrawal choices. “Efforts to consent individuals are needed to satisfy public and other stakeholder expectations for being informed and given the opportunity to refrain from research participation.”¹⁶⁸ A specific consent model would be committed to explain the cases in which withdrawal, at a point, would be impossible. However, in Mexico, discarding existing samples could stop future research projects which involve collaboration among the main national health institutions. Sample destruction, when consent was not obtained for further specific purposes, is an ethical measure to protect participants’ autonomy. It does not mean that this is the only way forward, but possibly that new contact with patient/donor needs to be established in order to ask for re-consent.

¹⁶⁶ BS Elger and AL Caplan, ‘Consent and anonymization in research involving biobanks: Differing terms and norms present serious barriers to an international framework’ (2006) 7 EMBO Rep 663

¹⁶⁷ Opinion Leader Research Consultation, *Summary of the UK Biobank Consultation on the Ethics & Governance Framework* (UK Biobank Ethics & Governance Framework, 2003) 26

¹⁶⁸ Simon and others 821

Normally, it requires an ethics committee to decide on the fate of those samples. This would be ethically controversial if it is weighed against the concerns involving privacy and data protection of participants who are still alive. From the position of the International Ethical Guidelines for Biomedical Research Involving Human Subjects (WHO AND CIOMS¹⁶⁹ 2003), “access will always require prior approval of the project by a properly constituted ethics committee, and verification that the proposed research is within the scope of the initial consent.”¹⁷⁰

The participant’s autonomy and privacy could be put at stake on the grounds of respecting the initial granted consent. Currently, there are no means of controlling potentially unethical biobanking behaviours that are not overt. The donor’s informed consent is required since it is prohibited to commercialise germ cells (reproductive cells). If samples are anonymised and no privacy risks are involved, the ethics committee could determine that no further re-consent is necessary.¹⁷¹ The most important ethical aspect is the maintenance of “a strong link between the use of biological samples and donor’s informed consent.”¹⁷² It could be interpreted that if samples are collected for the study of diabetes, more than one national institution can access the samples (as long as they do research related to diabetes). The meaning of the word “incompatible” is subjective; it could mean that compatibility involves further research purposes on the disease that motivated the collection or even other ‘compatible’ diseases. If that is the case, secondary purposes could be

¹⁶⁹ Council for International Organizations of Medical Sciences CIOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS, 2002)

¹⁷⁰ Margaret Otlowski, Dianne Nicol and Mark Stranger, ‘Biobanks Information Paper’ *Journal of Law, Information and Science* <<http://www.austlii.edu.au/au/journals/JILawInfoSci/2010/5.html>> accessed 5 May 2012 205

¹⁷¹ MK Schmidt, ‘Regulatory aspects of genetic research with residual human tissue: Effective and efficient data coding’ (2009) 45 *European journal of cancer* 2380

¹⁷² C Porteri and P Borry, ‘A proposal for a model of informed consent for the collection, storage and use of biological materials for research purposes’ (2008) 71 *Patient Education and Counseling* 141

carried out legally without asking the donors for authorisation or re-consent. Although legal, this would not be ethical.

3.3.3 Data protection

Research results involve potential medical results or findings of interest for research participants. The participant should be consulted on the uses of the samples as this could compromise privacy or confidentiality. In terms of privacy and confidentiality, questions of insurance, employment, discrimination and loss of privacy are negative developments to be guarded against. Margaret Otłowski has pointed out that “concerns about genetic screening are magnified once account is taken of future gene chip analysis and the potential for testing for a range of non-medical traits, such as aggression, alcoholism or criminality; traits that an employer would undoubtedly be keen to screen for.”¹⁷³ Mark Taylor has pointed out that “in circumstances where data does not relate to an identifiable individual, data protection law will not cover the processing of the data at all”¹⁷⁴ and in Van Veen’s opinion, “under certain conditions two-way coded data can be considered as anonymous data under the European data protection directive.”¹⁷⁵

Coding is sufficient to avoid an individual patient being traced back, unless many variables are included. Ensuring that a bio-collection entry is completely anonymous is technically impossible, particularly as DNA data will be linked with biographical data and medical records. Furthermore, biographical data will need to be more than a ‘one-off snapshot’ to be of real use. This means that follow-up checks will need to

¹⁷³ M Otłowski, *Implications of Genetic Testing for Australian Employment Law and Practice*, vol 2 (Centre for Law and Genetics, University of Tasmania ; Faculty of Law, University of Melbourne 2001) 9

¹⁷⁴ MJ Taylor, ‘Special Focus: Ethical and Regulatory Concerns Regarding Human Genomic Databases - Perspective’ (2007) 4 *Personalized Medicine* 472

¹⁷⁵ EB van Veen, ‘Obstacles to European research projects with data and tissue: Solutions and further challenges’ (2008) 44 *European Journal of Cancer* 1438

be undertaken with individuals and this will necessitate researchers knowing their identity.

3.3.3.1 Data protection mechanisms

There is a need to be precise in the use of concepts and to distinguish between data sets being anonymous, encoded or encrypted. The conceptual confusion here is such, that this may in itself form a topic for research and investigation. However, even if the social arrangements for protecting confidentiality are clear, given the nature of genetic information, it may prove impossible to ensure that biological samples can be truly anonymous.¹⁷⁶

Anonymisation has not proven to be the best choice for some areas of tissue bank research on specific diseases, such as rheumatology, due to its limited scientific value¹⁷⁷ and the impossibility to truly anonymise data. Penelope Manasco argues that “due to the increasing amounts of clinical and genomic data, the ability to truly anonymise data and samples is impossible.”¹⁷⁸ The best option for any research type should be decided on these grounds. Extrapolating this question to large-scale rheumatology studies involves the treatment of huge volumes of DNA sequence and expression data from large numbers of people.¹⁷⁹ Anonymity will be further jeopardised by the need to gain repeat consent for each new study. Therefore, the priority is the implementation of safeguards to prevent theft or error and the access of data for purposes that may have discriminatory consequences.¹⁸⁰

¹⁷⁶ The Wellcome Trust and Medical Research Council, *Public Perceptions of the Collection of Human Biological Samples* (Qualitative research to explore public perceptions of human biological samples, 2000) 100

¹⁷⁷ S Eriksson and G Helgesson, ‘Potential harms, anonymization, and the right to withdraw consent to biobank research’ (2005) 13 *Eur J Hum Genet* 1074

¹⁷⁸ PK Manasco, ‘Ethical and legal aspects of applied genomic technologies: practical solutions’ (2005) 5 *Current Molecular Medicine* 25

¹⁷⁹ MK Cho, ‘Understanding Incidental Findings in the Context of Genetics and Genomics’ (2008) 36 *J Law Med Ethics* 1

¹⁸⁰ GeneWatch UK, ‘Genetic discrimination by insurers and employers: still looming on the horizon An update on the use of genetic test results by employers and insurers’

Diverse data protection mechanisms are described in the literature.¹⁸¹ The main ones, with some overlap, are presented as follows:

- *Identified.* The information that allows identification (e.g. name) is associated directly with the tissue or data, (i.e. the participant's nametag is attached to the sample.)¹⁸²
- *Identifiable.* All information related to identification (such as patient name, D.O.B) is stored separately from the samples/data but available.¹⁸³
- *Unidentifiable.* Sample/Data which cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems."¹⁸⁴
- *Anonymous.* Association between samples/data and a particular individual is impossible; no code key and no re-identification possible. Samples are collected without identifiers.¹⁸⁵
- *Anonymised.* Sample/data has been de-identified in such a way as to remove the link between them and an identifiable individual.¹⁸⁶ In European documents, the term anonymised could mean either unlinked or linked anonymised.¹⁸⁷

Biological hazards have captured the public imagination and fostered a kind of 'genetic anxiety' in several countries, as remarked by Jasanoff.¹⁸⁸ The tensions generated by the promise of personalised medicine have worked as a test for the politics and policy capacity of

www.genewatch.org

<<http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/GeneticTestingUpdate2006.pdf>>

¹⁸¹ Elger and Caplan 663

¹⁸² Ibid

¹⁸³J Tansey and MM Burges, *The foundation, applications and ethical dimensions of biobanks* (Electronic Working Paper Series W Maurice Young Centre for Applied Ethics, University of British Columbia, 2004) 7

¹⁸⁴ HHS.gov U.S. Department of Health & Human Services, 'Guidance on Research Involving Coded Private Information or Biological Specimens' OHRP

<<http://www.hhs.gov/ohrp/policy/cdebiol.html> >

¹⁸⁵ Tansey and Burges 7

¹⁸⁶ Taylor 476

¹⁸⁷ Elger and Caplan 663

¹⁸⁸ Jasanoff 38

mature liberal democracies which have dealt with this differently. For example, in Britain “the regulatory and political upheavals of the early 1990s undermined the social role of the expert, forcing the creation of new advisory institutions that were both more diverse and more transparent.”¹⁸⁹ It was part of a process where traditional standards were challenged. The German example “is in many ways the most interesting, because here an experimental democratic settlement was revoked in favour of a return to a more technocratic approach.”¹⁹⁰

The idea of a universally acceptable process to create an open deliberative space for science and technology did not work for Germany, in the same way that facticity of science and the reliability of expertise had done in countries like Britain.¹⁹¹ The situation of Britain during the 1990s revealed new fault lines between those demanding empirical evidence of risk to justify more stringent regulation and those urging greater precaution, in the presence of the unknowns.¹⁹² Similarly, it needs to be determined what will best work for Mexico.

3.4 Mexican risks

Risk analysis is an area of interest, since it reflects the relationship between the laws of democratic societies and their most common fears, which can be very variable. Following Jasanoff, biotechnology politics and policies have been influential in generating cognitive and political views. This, in turn, has caused biotechnology to serve as a comparative instrument to measure technological development in capitalistic democracies.¹⁹³ Some of the current biobanking ethical guidelines are too broad. As a result, these general principles can be interpreted in more than one way leading to mistreatment and exploitation. An active

¹⁸⁹ Ibid 117

¹⁹⁰ Ibid

¹⁹¹ Ibid

¹⁹² Ibid

¹⁹³ Ibid 13

participation and a systematic clarification of guidelines are necessary to achieve this at the regional level.¹⁹⁴ In Mexico's case, this leads to reflection in terms of responsibility, for instance how the challenges posed by biobanking will be tackled.

3.4.1 Historical background

A historical analysis is useful and relevant to help understand the current ethical problems because of inoperable guidelines, which have proven weak when confronted with the issues and dilemmas posed by the practice of research. Mexican ethics frameworks have traditionally been understood as moral mandates; e.g. medical ethics had been linked to respect for moral values. Although governance is closely linked to ethics, both areas have been treated differently by Mexican governance and ethics has not been necessarily binding. This may be due to cultural reasons. In the past, it was not considered necessary to have stringent laws as there were few violations. In the opinion of Aluja and Birke, "violations of codes of ethics were not as common as in developed countries."¹⁹⁵ However, situations and circumstances have changed and become more complex due to historical factors. Tamayo¹⁹⁶, a Mexican biomedical researcher, has pointed out that historically, health research has been regarded in numerous laws and regulations rather than just one. However, the most basic questions on the regulation of health research, such as who is responsible and what for, have still not been answered.

¹⁹⁴ JC Vázquez-Elizarrarás, 'El Derecho Internacional ante los desafíos del genoma humano y la bioética, en el marco de la organización y las declaraciones internacionales. Su proyección al derecho mexicano ' (2008) 8 Anuario mexicano de derecho internacional 1

¹⁹⁵ M Aluja and A Birke (eds), *El papel de la Ética en la investigación científica y la educación superior. (The role of ethics in Scientific research ethics and high education)* (Fondo de Cultura Económica 2004) 61

¹⁹⁶ Tamayo 262

Biomedical research in Mexico started in the 1940s, when the role of professor-researcher was recognised.¹⁹⁷ This happened as part of the creation of merged labs in existing health care facilities. Other events which caused Mexican research to emerge were the creation of international foundations supporting research (Rockefeller, Kellogg and Carnegie, Kaiser and Pasteur institutes), the formal inclusion of new medicine subjects (such as biochemistry and molecular biology), the use of antibiotics, the microscope, the X-ray and other new diagnostic techniques.¹⁹⁸

No evidence of ethical guidelines for research was identified before 1966. The creation of the The Mexican Institute of Social Security (IMSS) (*Instituto Mexicano del Seguro Social*), led to the simultaneous establishment of healthcare units for research. However, health research was officially institutionalised when the activities of the department of scientific research within the National Medical Centre started in 1966.¹⁹⁹

The first health committees were created to protect the rights of research subjects'.²⁰⁰ Seven years later (1973), the Code for Sanitary Care²⁰¹ (*Código sanitario*) was enacted as the main federal health regulator. Thus, protective measures for the rights of Mexican research subjects were also implemented. These measures were the first to crossover between law and ethics on health research. This Code was the first regulation which specifically covered health law in Mexico, and the social right to physical and psychological health was implemented through it. Additionally, this regulation reflected the first ethical

¹⁹⁷ Secretaría de Salud (The-Mexican-Ministry-of-Health), *Programa de Acción: Investigación en Salud (The Ministry of Health, Action programme on health research)* (The Mexican Ministry of Health, 2001) 21

¹⁹⁸ Ibid

¹⁹⁹ Ibid

²⁰⁰ J Garduño-Espinosa and others, 'Local research ethics committees of the Mexican Institute of Social Security: results of a national survey' (2004) 118 *Public Health* 329

²⁰¹ Código Sanitario de los Estados Unidos Mexicanos (The Health Code of Mexico)

considerations as a source for some criteria. However, this was left to the discretion of ethics committees.

Ethical guidelines have formally existed since 1982, but have changed in nature due to the evolution of Mexican research and have had differing levels of enforceability due to the diverse legal and institutional attempts to effectively regulate it. The Code for Sanitary Care was amended in 1982.²⁰² The amendments included the obligation to create research and ethics commissions (which would later become committees) wherever biomedical research was performed (one in each research institution, potentially including universities); these commissions were responsible for the evaluation and approval of research protocols. In 1984 the Sanitary Code was derogated and The General Health Law enacted,²⁰³ which covered health research in a more specific way. However, it took three more years for the requirements to be extended to cover the approval of research protocols within health research.²⁰⁴

In 1989 the General Health Council CSG (*Consejo de Salubridad General*), the second health authority after the General Health Law, founded a group for the study of bioethics, which three years later would be established as the National Commission of Bioethics (CNB). This was done in response to the need for a bioethics culture and also, the need for worldwide instruments. Not many of the public understood what bioethics meant when it emerged in 1970.²⁰⁵ Therefore, even when the remit of ethics committees was defined in 1982, it was necessary to

²⁰² Acuerdo mediante el cual se comunica que es obligación de los directores de los establecimientos en donde se efectúen investigaciones biomédicas construir una comisión de investigación (Agreement which communicates it is compulsory for managers, where biomedical research is carried out, to organise a research commission)

²⁰³ Ley General de Salud (The General Health Law) (Mex)

²⁰⁴ Reglamento de la Ley general de Salud en Materia de Investigacion para la Salud (The Ministry of Health Rules of the General Health Law on Health Research)

²⁰⁵ P Van Rensselaer, 'Bioethics, the Science of Survival ' (1970) 14 *Perspectives in Biology and Medicine* 127-53

encourage responsible attitudes towards the consequences of biomedical research. Moreover, the international bioethics boom caused the Mexican government to show an interest in developing guidelines concerning research, health and environment.²⁰⁶ In 1992, the CNB was founded for the promotion of hospital bioethics committees in private and public institutions as an advisory institution focused on human rights. By 2000, the CNB was officially declared a permanent institution by presidential agreement²⁰⁷ and its purpose was re-established as an institution for promoting ethical principles in health care and health research²⁰⁸. In 2004 the General Health Law was amended once more. This time article 41 *bis* recommended the creation of hospital ethics committees. Consequently, the IMSS established an institutional programme on ethics, promoting the creation of hospital ethics committees. In 2001, COFEPRIS, the national health authority, was created.

According to Ingrid Brena, “the expectations on biobanks overpass the scarce Latin American legislation.”²⁰⁹ This seems to be the case with Mexican biobanking, in which a too general framework is partially applicable to biobanks in the absence of specific legally enforced guidelines. For this reason, the following section will demonstrate that currently, the ethical frameworks are not fit for purpose. In order to guarantee effectiveness, the increasing number of research activities in the country demand guidance and an effective ethical regulation, culturally sensitive yet binding.

²⁰⁶ I Luengas, D Feinholz and G Soberón, ‘The National Bioethics Commission, understanding and remit (Comisión Nacional de Bioética. Su entender, su quéhacer) ’ (2007) 1 *Debate bioético* 27

²⁰⁷ *Acuerdo Presidencial por lo que se crea con carácter permanente la Comisión Nacional de Bioética (Presidential agreement, which creates with permanent character, the National Commission of Bioethics)*

²⁰⁸ Luengas, Feinholz and G Soberón 27

²⁰⁹ I Brena, ‘Biobanks, a subject pending upon legislation’ (2010) 129 *Boletín Mexicano de Derecho Comparado* 10

3.5 Case studies

This section will provide a legal insight across aspects of practical biobanking in Mexico under two case studies: The Mexico City Cohort Profile Study and The HapMap Study. The Mexico City Cohort Profile Study and The HapMap Study²¹⁰ have been selected as they clearly show the dual aspects of biobanking; “these studies will in turn facilitate research that will focus on relating genomic information, of the Mexican population to significant causes of morbidity and mortality in Mexico, such as macular degeneration, diabetes mellitus, hypertension and obesity, cancer, infectious diseases, and cardiovascular diseases;”²¹¹ in contraposition with the apparent; the absence of guidelines causing delays, inconsistencies and problems. Apparent conflicting areas will be identified and explored on a general basis. The similarities found between these two examples allow a detailed comparative case study. A summary of the central issues is presented in tabular form to aid comparison (See table 8 in annex p. 10). The issues will be elaborated upon in the following sections to demonstrate the inconsistencies and regulatory issues referred to in the present chapter.

The HapMap study followed a comparative methodology to analyse Mexican ancestry; “by including one Mexican Amerindian group and data from the HapMap: northern Europeans (CEU), Africans (YRI), and East Asians (EA), including Chinese (CHB) and Japanese (JPT)”. The first analysis of genomic diversity in Mexican populations from INMEGEN was published bearing in mind that most of the global burden from chronic diseases, and especially vascular diseases, at the time, was borne by low and middle-income countries, few large-scale epidemiological studies of chronic diseases in such countries had been performed.²¹²

²¹⁰ P Kuri-Morales and others, ‘The prevalence of chronic diseases and major disease risk factors at different ages among 150 000 men and women living in Mexico City: cross-sectional analyses of a prospective study’ (2009) 9 BMC Public Health 1-9

²¹¹ Jimenez-Sanchez and others 1191

²¹² I Silva-Zolezzi and others, ‘Analysis of genomic diversity in Mexican Mestizo populations to develop genomic medicine in Mexico’ (2009) 106 PNAS 1

The researchers aimed to explain the origin of genetic differences among Mexican *Mestizos* from different regions in Mexico. “Mexican *Mestizos*, as other Latino populations, are a recently admixed population composed of Amerindian, European, and, to a lesser extent, African ancestries. Although the diversity of Latino populations poses several challenges for genetic studies, it makes them a powerful resource for analysing the genetic bases of complex diseases.”²¹³

INMEGEN’s first step focused on generating the Mexican HapMap in order to facilitate the next phase of the research, which concentrated on examining genomic information of the Mexican population to identify significant causes of morbidity and mortality in Mexico. All data analyses were performed at INMEGEN in Mexico City.

The Mexico City Prospective Study,²¹⁴ a genetic association study or ‘Cohort Profile,’ investigated the relationship among chronic diseases and lifestyle among Mexican people. It was conducted by ‘The Mexican Ministry of Health’ (SSA) and the Clinical Trial Service Unit (CTSU), Oxford, England. This independent, joint project by the Ministry of Health and CTSU Oxford relied on support from the National Council of Science and Technology. Apparently the goals of incorporating genomics into economical methods of prevention, diagnosis, and treatment of disease have not been continued since. On the other hand, the intervention from an overseas institution causes unresolved issues in areas such as the acquisition of informed consent and sample exchange and management.

3.5.1 Background: available guidance

The main element to be discussed within the case studies is the control on this type of participation, which is tantamount to being optional. This can be translated into potential risks, which could be mitigated by

²¹³ Ibid

²¹⁴ Kuri-Morales and others 1-9

further guidance. Mexican population biobanks involve the participation of ethnic groups whose genetic data may need special protection. INMEGEN is affiliated to P³G,²¹⁵ 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 expertise.

P³G is an Internet repository of scientific information and tools to aid in developing, realising and harmonising research projects on health and social science, including biobanks. P³G works with researchers from around the world providing best practice guidelines. Margaret Otlowski from the Australian National Health and Medical Research Council (NHMRC) considers “these harmonisation initiatives cover a broad spectrum, from highly-technical scientific matters, through to governance and access principles and procedures.”²¹⁶ This situation can be problematic as Mexico may not be prepared, in terms of legal guidelines, for international exchange of biobanking data.

It includes a series of catalogues documenting large population based biobanks worldwide, and it allows a rapid overview of the similarities, differences and potential for harmonisation between participant biobanks. Moreover, the facility could be used for more than guidance in research. This type of electronic resource has been used in Mexico. A member of INMEGEN²¹⁷ stated that the P³G Observatory²¹⁸ worked as helpful guidance for the Mexican HapMap project. The member also pointed out that The International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002) were being followed by INMEGEN in the HapMap Study. However, this type of resources tend to be limited. Participant A claimed that the website was no longer being

²¹⁵ P³G

²¹⁶ Otlowski, Nicol and Stranger

²¹⁷ Responsible-for-the-research-department-at-a-public-biobank-Participant:A

²¹⁸ P³G

consulted by 2010 “because the subscription was no longer affordable.”²¹⁹

3.5.2 Identified problems

These projects were intended to contribute to emerging globalised scientific information, in which samples are a key issue. Both projects have in common an attempt to develop proper genomic and personalised medicine research projects. However, the particular conduct and regulation involved constitute reasons for criticism. This is an example of “the rapid advances of scientific research and the need for a suitable legal framework.”²²⁰ Both pieces of research present risks, though each of them followed different measures to prevent them.

3.5.2.1 Inconsistent self-regulation

In the absence of codified ethical standards, Mexico-based biobanks have resorted to self-regulation and internal decision-making. Self-regulation is most likely due to the inconsistent rules mentioned in various partially applicable regulations. This issue was identified within both studies; while the study conducted by the CTSU and Ministry of Health actually reports that it was self-authorized. The two case studies also illustrated the different forms of Mexican biobanking guidelines (general legal rules, self-regulation, and soft law) used by scientists and academics. Experience has demonstrated that self-regulation has not been effective in related topics. “Historically, physician self-regulation has not been particularly successful in controlling the behaviour of individual physicians.”²²¹

²¹⁹ Responsible-for-the-research-department-at-a-public-biobank-Participant:A

²²⁰ E Godoy, ‘El negocio de los genes. Ante la proliferación de biobancos, surge el interrogante de cómo se maneja la información de los donantes (The bussiness of genes. Towards biobanks' proliferation, the question of how donors' data is managed has emerged)’ *Poder 360° Electronic magazine* <<http://www.degerencia.com/>> accessed 30 March 2010

²²¹ PD Jacobson PD, ‘Regulating health care: from self regulation to self regulation?’ (2001) 26 J Health Polit Policy Law 1175

Recapitulating one of the case studies described above, INMEGEN led the participation of Mexico in the International HapMap project. The project was carefully organised to focus on ethical aspects associated with participants' protection, paying special attention to the participation of vulnerable populations. The project was approved by the committee of ethical, legal and social aspects of the International HapMap project, one of the main sources of ethical guidance for the project. The participant from INMEGEN mentioned the diverse resources for guidance followed by the project; a great number of which were international and were put into practice by the internal committee of the institution. The INMEGEN representative explained that the institution has created its own guidance, which is very strict.

In this case, self-regulation was prevalent within the HapMap study; the application of rules to deal with data from 3000 sample donors was internal. The consent process, in the presence of two witnesses, was decided following international standards, in the absence of specific national rules. Similarly, the Mexican HapMap was organised in independent collaboration with the International Genomics Consortium;²²² although no benefit sharing rules have been defined. INMEGEN seems to follow general self-regulatory guidelines. The HapMap study was nevertheless widely approved by the internal commissions of INMEGEN. Self-regulatory practices are not always something negative. As will be analysed in chapter 7, it has been a viable choice in other countries. However, this type of practice has not been suitable for Mexico, mostly due to cultural reasons, which will be discussed in chapter 8.

²²² The International Genomics Consortium IGC, 'The International Genomics Consortium' (IGC, 2009) <<http://www.intgen.org/>> accessed 19 December 2009

INMEGEN followed the guidelines encouraged by the international HapMap organisation²²³ as the main source for ethical guidance. The HapMap international standards are very detailed in specific topics for population studies, which provide sufficient ethical parameters on biobanking (even when they are not specifically directed at biobanking). Relevant standards consisted of specific criteria for participants of different ages, competence to provide informed consent, re-consent from living donors, non-inclusion of medical information, non-inclusion of small isolated populations, justification for targeting that part of the population, clarification that no intellectual property rights would result from the study, and clarification that there would be no immediate benefit for the population participating.²²⁴

The standards provided by the international HapMap project are general; it was not complicated for the INMEGEN to apply independent standards directly. The rest of the applicable standards were adapted into the national rules of the country. In this case, a national ethics committee had to provide a clear opinion on the ethical aspects of research and evaluate the research protocol in terms of risks, benefits and informed consent. Another standard provided by the HapMap organisation was non-inclusion of names or other identifying information; “anonymous blood samples from 300 nonrelated and self-defined Mestizos and 30 Amerindian Zapotecos were collected in 7 states in Mexico.”²²⁵ The interviewed members from INMEGEN confirmed that every collected sample from the Mexican HapMap study was anonymised. “All data was anonymised and it is only known whether the donor is a man or a woman and from what ethnic group.”²²⁶ It was also a recommendation to provide “opportunity for consideration of the specific ethical and cultural factors

²²³ National Human Genome Research Institute, ‘ International HapMap Project ’ (2012) <<https://www.genome.gov/>>

²²⁴ The-International-HapMap-Consortium 467

²²⁵ Silva-Zolezzi and others 8616

²²⁶ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

relevant to the decision how to identify each population.”²²⁷ INMEGEN complied with the recommendation, and several forums were organised as a means of communication with participating members to resolve any concerns raised by the Mexican HapMap project, including cultural questions.

INMEGEN has intended to show “a transparent and responsible performance that respects life and human dignity within human research and medical applications.”²²⁸ INMEGEN claims to be following CIOMS regulations in this respect, guidance which should become binding under minors’ best interest. Minimum requirements by CIOMS are still not covered by the Mexican civil rules. These include cases in which children will be accepted to participate (or deny to participate) in research trials.²²⁹ Another example can be taken from the UNAM study in which at least fourteen participants providing samples across two biobanks were under 18.

Exceptionally, it is possible that INMEGEN followed a strict self-regulation. However, this, being self-reported by the institute, cannot be totally proven. Self-regulatory efforts have been made to date to ensure capability, but lack of coordination and disparity on measures taken by different stakeholders are important signs that biobanks need specific attention.

3.5.2.2 Accessibility of the results

Due to the findings of the above analysed cases, both studies should be widely distributed among concerned bodies. The HapMap study provided “evidence of genetic differences between Mexican

²²⁷ Researcher-at-a-public-biobank-Participant:B, *PhD Thesis Fieldwork* (2012)

²²⁸The National Institute of Genomic Medicine INMEGEN, *Consortio Promotor del Instituto de Medicina Genómica, Un paso más hacia el establecimiento del INMEGEN (One more step towards the establishment of INMEGEN)* (INMEGEN Inform of activities, 2003-2004 2004) 64

²²⁹ CIOMS

subpopulations that should be considered in the design and analysis of association studies of complex diseases.”²³⁰ However, the findings from the CTSU study seem to be not easily accessible, e.g. they are not available in Spanish. It was stated that the researchers in charge would be open to questions.

The unavailability of results has several ethical implications at both individual and general levels. The subject whose sample will be used needs to decide whether to know or not to know²³¹ the purpose and findings of the research project. At the collective level, the nature of some research findings can be of extreme importance for public knowledge or a specific group, e.g. a scientific community may have a particular interest in data collection for research purposes.

In some instances, it can be clarified from the beginning that no results will be available, for example, when data becomes anonymised or it is established that it will be used for statistical purposes for data protection purposes.

3.5.2.3 Consent

HapMap

INMEGEN, in the absence of available clear guidelines, attempted to follow guidelines from different sources within the Legal Mexican framework including: the Mexican Constitution, the General Health Law, expertise from the National Bioethics Commission, the CIOMS guidelines and advice from the President of the World Human Genome Organisation. This intervention may operate to increase protection, thereby putting the vulnerable in a better position. Informed consent was obtained in the presence of two witnesses (members of the community). Participants

²³⁰ Silva-Zolezzi and others 8611

²³¹ R Andorno, ‘The right not to know: an autonomy based approach’ (2004) 30 J Med Ethics 435

would have access to the informed consent documents. 3,000 informed consent forms were printed for the *mestizo* population and 500 for indigenous populations, as well as 25,000 information leaflets. Comics were used to explain in an illustrative way what genomic medicine is. Some of the documents presented a finger print instead of a signature. Some samples were taken from family groups of three. There were open forums in the communities and the participants were formally approached three weeks before the study started in order to explain the purpose. Communities (including children) showed interest and participated. The informed consent form was translated from Spanish to the required language and translators came from the community itself. No compensation was offered to the participants and no withdrawal rules were established. Participant A expressed “the anonymised samples that were used for the HapMap study are still being kept,”²³² even when the purpose of the research was satisfied.

However, despite the use of meaningful sources such as laws, regulations, guidance materials, codes of practice, reports, regional and international instruments of various kinds, academic literature, policy documents, scientific papers, professional guidance and good practice materials were used to endorse elements as important as informed consent for the HapMap study, something else is required. In this instance, it was not established whether, once consent was provided, the donor could revoke it at any time with no consequences. “*La Jornada*” Newspaper investigated the forms for informed consent, within the INMEGEN HapMap Study. The forms stated that “it is not always possible to predict the research results. This involves unpredictable future risks.” The statement has been seen by the press as a way to evade risk responsibility.²³³

²³² Responsible-for-the-research-department-at-a-public-biobank-Participant:A

²³³ S Ribeiro, ‘Genómica, biopiratería y pueblos indígenas (Genomics, biopiracy and indigenous towns)’ *La Jornada* (Mexico City, 31 March 2007) Opinion

ICTSU

Consent acquisition of ICTSU followed a brief procedure. The CTSU study was affordable through maximisation of economic resources, in which sample taking and the corresponding recording of IC was performed using electronic methods. The possibility of “open consent” has been considered when either multiple research or total anonymisation takes place. However, in this case, it is risky to consider electronic consent as genuine informed consent.

It would be impractical to attempt to discuss only issues of informed consent deeply in this chapter, it is just relevant at this stage to point out that electronic informed consent was apparently not the best choice for the type of research conducted. Even disregarding the fears of discrimination, there are good reasons for rejecting electronic informed consent, such as the fact that it cannot be formally applied in legal terms. It can be argued that participants were significantly unprotected due to inconsistencies to determine the type of informed required; a consequence of insufficient, clear, legal and institutional guidelines. Participant B described the informed consent form within the HapMap project as presented as questions and answers. Participant B pointed out that:

“This made it easy for the participants to understand. However, there are people that design it as a long complicate narrative with little meaning for the participant, who may find it difficult to understand. It can be valid as well. I think a pre-established basic proforma would work; then, we could adapt it to our project. This should be more accessible for those who are interested in these areas.”²³⁴

The idea suggested by participant B is of a pre-established consent form that could become effective in terms of clarity, as long as general pre-established consent parameters could be orientated towards the specific nature of the project. The means to achieve effectiveness

<<http://www.jornada.unam.mx/2007/03/31/index.php?section=opinion&article=021a1pol>>

²³⁴ Researcher-at-a-public-biobank-Participant:B

involve ethical and legal perceptions within the national context. “We cannot understand informed consent, the standards that it must meet, or the limits to its use, without taking that background picture seriously.”²³⁵

3.5.2.4 Data protection

The topic of data protection within the INMEGEN was established by the ethics committee of the institute and they are responsible for establishing the best way to protect the privacy and confidentiality of genetic data contained in samples.²³⁶

The HapMap was an assessment of the potential benefit of generating a haplotype map to optimize the design and analysis of genetic association studies in Mexicans and to improve the identification of genes related to common diseases within the Mexican population. Access to samples and medical files was possible. The specific purposes were related to Mexican diversity. This was evaluated through “linkage disequilibrium patterns, and extent of haplotype sharing using genome wide data from Mexican *Mestizos*. They are from regions with different histories of admixture and particular population dynamics (300 nonrelated self-identified Mestizo individuals from 6 states located in geographically distant regions).”²³⁷ In participant A’s opinion, “the value of the samples is contextual. Security is needed as the value of the samples involves participants’ data independently of the samples’ conditions, location or context.”²³⁸

²³⁵ Manson and O’Neill 198

²³⁶ Responsible-of-the-legal-department-at-a-public-biobank-Participant:G, *PhD Thesis fieldwork* (2012)

²³⁷ Silva-Zolezzi and others 8611

²³⁸ Responsible-for-the-research-department-at-a-public-biobank-Participant:A

3.5.2.4.1 Data protection mechanisms

Following data protection mechanisms at INMEGEN, the samples are completely anonymised and unlinked²³⁹ and participants are told whether their data will be codified.”²⁴⁰ Hence, in the HapMap project, all the samples were anonymised and it is assumed they “belong” to INMEGEN. In this case, data protection mechanisms are being used partially. Regarding data sharing, participants D and E pointed out that because of the absence of rules, subjects are not informed of further potential sample sharing with other projects or the protection mechanisms that that would involve. They are simply told that their samples may be used for other projects.²⁴¹

3.5.2.4.2 Re-contact

Similarly, as with informed consent issues, only a few brief comments are presented regarding re-contact. Possibilities for re-contact are shown differently in each of the studies, although they deal with similar ethical issues such as the destination of the samples in the future. Due to the absence of specific re-contact rules, it is not clear whether the participating institutions should should not recontact participants, and if so, under what terms. Within the HapMap study, the samples were coded with no intentions of further re-contact. However, the possibility of a future exceptional re-contact, under special reasons, was not discarded. It is not clear what would be done in case the samples were required overseas. Probably INMEGEN would decide internally. The nature of the Oxford profile study, where samples have been made identifiable, may require future re-contact.

²³⁹ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

²⁴⁰ Researcher-at-a-public-biobank-Participant:E, *PhD Thesis Fieldwork* (2012)

²⁴¹ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

3.5.2.4.2 Lack of coordination

The overview of the current biobanking issues shows insufficient national communication between academics, scientists and policy makers. This has caused these stakeholders to follow different processes when dealing with biobanks. The ideal would be if public health institutes collaborated together in order to develop projects. In such cases, the research manager would be responsible for making decisions on collaboration, due to the specific guidelines establishing the terms under which collaborations should be done. Participants D and E pointed out that INMEGEN projects rarely have collaborations with other institutions and that researchers often store what they consider “their” samples.²⁴² The two analysed studies were carried out with no collaboration, even though they targeted common national problems such as genetic illness studies. Researchers, citizens and policy makers all have an important role to play.²⁴³

Ideally, “a dedicated, independent statutory authority could reduce this risk.”²⁴⁴ A great issue with biobanking is that fundamental human rights would be threatened by the further use of biological samples in relation to biobanking topics. The envisioning of future governance calls for accessible guidelines where ethical issues such as informed consent, data protection and data protection mechanisms will be given a clearer definition. In the case of Mexico, it would be unnecessary to concentrate on placating unrealistic fears which biobanking could create. On the contrary, the main discourse needs to be centred on the control of biological samples, associated genetic information and the cultural impact around them, especially when vulnerable populations have become involved in biobanking activities.

²⁴² Ibid

²⁴³ Responsible-of-the-ethics-department-at-a-public-biobank-Participant:D

²⁴⁴ Gibbons Ch. 4

3.6 Human rights

Every sample has a history going back to the original human donor. Blood samples have the potential to threaten fundamental human rights; stored collections of genetic samples in the form of blood or tissue can be linked to medical, genealogical or lifestyle information from a specific population.²⁴⁵

A great part of the current Mexican self-regulatory guidelines depends on adherence by national institutions to international documents. The implementation of international documents regarding human rights and fundamental freedom (e.g. autonomy, privacy, non-discrimination and non-stigmatisation) has been diverse. The regulation for the use and procurement of biological samples and data has appeared, both at the national and international levels, sometimes through specific legally binding instruments or by general regulatory texts.²⁴⁶ Consequently the topic is highly variable.

“In Europe the laws that have been applied to biobanks have largely been drawn from the legal traditions and jurisprudence that have been developing around the protection of human rights and the advancement of public health.”²⁴⁷ A number of biobanking human rights related instruments have been established as a result.

The initial discussions within the ‘Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine’ included principles and topics of interest for developing countries. The term ‘human rights’ was mentioned in the title of the declaration and the principles of social responsibility, health, shared benefits and international cooperation were included. The

²⁴⁵ MA Austin, SE Harding and CE McElroy, ‘Monitoring ethical, legal, and social issues in developing population genetic databases’ (2003) 5 *Genet Med* 451

²⁴⁶ Cambon-Thomsen, Rial-Sebbag and Knoppers 374

²⁴⁷ European Commission 35

latter implied the introduction of bioethics from a social perspective. The first draft of the declaration (2004) highlighted the reinforcement of cooperation, taking into account the needs of the least developed countries.²⁴⁸ The concept of health as an individual right has not been effective in terms of global international cooperation. Social bioethics is concerned with the right for citizens to obtain minimum health conditions, a concern shared by many Latin American countries. In the final draft, vulnerable populations were also recognised as possible benefactors of international cooperation.

The Universal Declaration on Bioethics and Human Rights (October 2005)²⁴⁹ was designed to encourage international cooperation to remove inequalities, caused by different development stages, among countries like those in Latin-America. Those most entitled to the benefits, according to the declaration, are those who take part in research activities. The Latin American perspective was crucial for the development of this inclusive instrument. There have been various attempts at international cooperation among countries with different development stages. The Declaration stated the need for bilateral agreements allowing developing countries to create the necessary basis for exchanging scientific and technical knowledge for benefit sharing, and involving the protection of those who participate. The resulting benefits from the use of this genetic data, proteomics or human samples for health or scientific research are to be shared with society and the international community:

1. *Article 15: Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:*
 - (a) *special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;*
 - (b) *access to quality health care;*
 - (c) *provision of new diagnostic and therapeutic modalities or*

²⁴⁸ The Universal Declaration on the Human Genome and Human Rights

²⁴⁹ Ibid

products stemming from research;
(d) support for health services;
(e) access to scientific and technological knowledge;
(f) capacity-building facilities for research purposes;
(g) other forms of benefit consistent with the principles set out in this Declaration.

2. *Benefits should not constitute improper inducements to participate in research.*²⁵⁰

3.6.1 The human rights perspective in Mexico

All human rights rules in Mexico will be interpreted under the constitution and international treaties in favour of a persons' protection. The rights of vulnerable groups will take priority over any other rights. In this case, the role of international law is complementary, never contradictory.²⁵¹ The latter, known as 'conformed interpretation', is also covered by article 1 of the Mexican constitution.

Fundamental reforms on human rights and incorporation of human rights international treaties took place in 2011. They have been enacted to alleviate "the profound deficiency in human rights protection"²⁵². The concept of human rights had not been previously recognised by the Mexican Constitution CPEUM (1917). The denomination was changed from "individual guarantees" (*garantías individuales*) to "human rights and their guarantees" (*derechos humanos y sus garantías*). The latter "is much more modern than that of individual guarantees and it is commonly used in international law."²⁵³ In the opinion of Miguel Carbonell,

²⁵⁰ The Universal Declaration on Bioethics and Human Rights

²⁵¹ E Ferrer Mac-Gregor, *Interpretación Jurisprudencial a la Jerarquía de los Tratados Internacionales en el Derecho Interno (Jurisprudential interpretation on the hierarchy of the international treaties in internal law)* (UNAM-IIIJ 1999) 70

²⁵² Comisión Mexicana de Defensa y Promoción de los Derechos Humanos, 'Estudio sobre la actual legislación en vigor (Study on the currently enforced legislation)' El Marco Legal Internacional de los Derechos Humanos y la Normatividad Interna, Mexico City, 2001 <<http://cmdpdh.org/publicaciones-pdf/cmdpdh-incorporacion-del-derecho-internacional-de-los-derechos-humanos-al-sistema-juridico-mexicano.pdf>> accessed 13 April 2014 63

²⁵³ M Carbonell, 'La reforma constitucional en materia de derechos humanos: principales novedades (The constitutional reform on the subject of human rights: main

constitutional law expert, it would have been more pertinent to use the denomination “fundamental rights” (*derechos fundamentales*), as a stronger denomination which could impact biobanking related rules; “scientific research, innovation, technological development and human genome applications are orientated to the protection of health, in which respect for human rights, freedom and dignity of the subject prevail. They are subject to the corresponding legal framework.”²⁵⁴

According to the last constitutional reform (2011), specifically article 1,²⁵⁵ the constitution does not grant rights, but recognises them. Since this reform the Constitution is believed to be more open to international law on human rights. The second paragraph is the inclusion of the interpretative principle ‘pro personae’. This principle consists of the legal duty to select, among all normative choices, that which favours a subject of human rights at all times. If two norms are applicable in a concrete case, the judge must select the most protective regarding human rights.

The third paragraph is the governmental duties; human rights must be protected, promoted and respected at all governmental levels. This includes human rights recognised by the constitution and international treaties. Government employees who do not accept the recommendations from the National Human Rights Commission (*Comisión Nacional de Derechos Humanos*) (CNDH) will have to publicly provide the reasons. The CNDH has the following attributions for the application of human rights duties derived from international law:²⁵⁶

- *Receive complaints (including those from citizens) on presumed human rights violations.*

novelties)³ miguelcarbonell.com

<<http://www.miguelcarbonell.com/articulos/novedades.shtml>>

²⁵⁴ LGS Article 105 bis 5

²⁵⁵ The Mexican Constitution (Mex) Chapter one

²⁵⁶ Ibid Article 102 B

- *Formulate non-binding public recommendations before authorities.*
- *Formulate actions to support compliance with adopted international human rights treaties, conventions and agreements; i.e. governmental coordination programmes.*
- *Proposing to the president the legal subscription of international agreements on the subject.*

The topic of human rights is also related to recommendations; both biobanks and human rights would need to be given more legal power.²⁵⁷

3.6.2 Obstacles for the application of human rights international treaties

Ariel Dulitzky has stated that “before thinking of new laws, it is necessary to think of ways to guarantee enforcement,” implying that well written laws, by themselves, will not be effective enough for the protection of human rights if the three governmental powers do not commit to such a goal and it is necessary for some of them to be adapted through secondary legislation.²⁵⁸

The Mexican non-jurisdictional human rights protection system is believed to be “one of the most complete”²⁵⁹. However, several inconsistencies have prevented the consolidation and implementation of international treaties regarding human rights. This is due to the “absence of systematic organisation in the constitutional framework;”²⁶⁰ i.e. only a

²⁵⁷ Science-and-Technology-Commission-Participant:K

²⁵⁸ A Dulitzky, ‘Aplicación de las Normas Internacionales en Derecho Interno (Application of the international norms in the internal law)’ (Memoria del Foro: El marco legal internacional de derechos humanos y la normatividad interna, Mexico City, August 2000) 20

²⁵⁹ Oficina del Alto Comisionado para las Naciones Unidas en México (UN High Commissioner Office), *Diagnóstico sobre la situación de derechos humanos en México (Diagnostic on the situation of human rights in Mexico)* (SRE (The Mexican Ministry of External Affairs), 2003) 7

²⁶⁰ JU Carmona Tinoco, *La aplicación Judicial de los Tratados Internacionales de Derechos Humanos (The judicial application of human rights international treaties)* (IIJ-UNAM, 2002) 185

few precepts expressly mention international instruments and there are no special rules to comply with the decisions from international human rights bodies. In the opinion of Carmona, a constitutional law researcher, the Mexican constitution is “neither detailed nor tidy regarding rules on international treaties.”²⁶¹

Another practical issue is the general belief by authorities that international rules do not apply if they are not integrated into federal legislation.²⁶² Judges may refuse to apply international treaties, partly because of a lack of knowledge and partly because they do not consider them a part of Mexican law: this is worthy of criticism, especially if law makers based on the same grounds do not enforce secondary legislation. If indeed transition is occurring now, following the reforms on human rights, it is likely that this situation will gradually improve. The knowledge of the limits of international rules needs to be improved by training and professionalism at local and federal levels.²⁶³ The content of treaties and CNDH recommendations must be followed by the government and disclosed to the public.

Another important obstacle is the absence of effective interaction between governmental and non-governmental organisations. The National Development Programme (2007-2012)²⁶⁴ (PNDH) has stated “it is necessary to encourage training for NGOs on international human rights standards;” since their role is relevant for the defence and promotion of human rights. The obstacles to Mexican adoption of human rights treaties can be summarised in three issues,

1. Absent or insufficient legislation, allowing the incorporation of international law;

²⁶¹ Ibid

²⁶² Ibid

²⁶³ Ibid

²⁶⁴ México Presidencia de la república (The Presidential Office), ‘Plan Nacional de desarrollo (2007-2012) National Plan for Development’ (2007)
<www.presidencia.gob.mx>

2. The absence of adherence to the hierarchy of international treaties;
3. Reservations or interpretative declarations of international treaties.

Awareness on prevailing limitations for human rights rules is determinant since biobanking is not an isolated topic. It is fundamental for Mexico to encourage a responsible regulatory body that can deal with the oversight challenges as soon as possible.

3.7 Concluding remarks

The acceptance of scientific principles can be extremely broad. Specific biobanking ethical rules legally implemented could be of great benefit for Mexican research. The legal inclusion of research ethics in Mexico is fragmented. It does not provide sufficient guidelines. When legal incorporation is nonexistent, incomplete or unsuitable, ethical principles become subject to disorganised interpretation. As pointed out by Kaye, “as with ‘governance’, so too with ethics: the development of these complicated and shifting forms of research collaboration and their associated biological samples and data is leading to the parallel emergence of ethical considerations not previously encountered in combination... It is important to pay attention to these features of biobanks, which have ethical as well as sociological significance.”²⁶⁵

Attention must be paid to the consequences of conducting high level research; ethics need to become more stringent to benefit both researchers and research subjects. Ethical management guidelines, mainly for researchers, could govern biobanks from their creation. Gibbons suggests that “this could prevent controllable issues from becoming complex.”²⁶⁶ Mexican biobanking practices are becoming more complex as a result of the irregular and too general legal coverage of different ethical aspects, e.g. biobanking for the analysis of genomic

²⁶⁵ Kaye and others 289

²⁶⁶ Gibbons 338

medicine, population studies, clinical trials and pharmaceutical studies. “Genetic research on Amerindians — who are much sought after for their distinctive genetic lineages — is even more sensitive.”²⁶⁷ These practices raise different ethical concerns. If there were violations to human subjects as part of biomedical research, it would be difficult to constitute a legal offence.

Public academic biobanking follows self-regulatory guidance resulting from minimum legal requirements and self-regulatory principles, such as respect for the participants’ human dignity, honesty, prevalence of the individual interest over the interest of science and society, and predominance of the potential benefits over the possible risks. The guidelines state that “research involving humans must follow scientific principles generally accepted, including a solid theoretical basis and a suitable methodology”²⁶⁸ and “it is considered unacceptable that a patient accepts to participate in a research study as the only choice to receive treatment.”²⁶⁹ These phrases are subjective and ambiguous on the direct application of general principles to biobanking.

A number of cases, from population genetics to academic biobanks, depend on urgent harmonisation of guidelines in practice. These should be motivated from a more humanistic and moral perspective, based on human rights protection. Institutional efforts adhere to alternative guidelines that generate self-regulation. Both cases studies were approached differently by stakeholders due to the inconsistency of current laws.

²⁶⁷ R Dalton, ‘Tribe blasts ‘exploitation’ of blood samples’ (2002) 420 Nature 1

²⁶⁸ Reglamento de la Ley general de Salud en Materia de Investigacion para la Salud (The Ministry of Health Rules of the General Health Law on Health Research)

²⁶⁹ UNAM, ‘Código Ético para el personal académico del Instituto de Investigaciones Biomédicas (Code of Ethics for the academic staff of the Institute of biomedical research)’ (2005)

<https://www.biomedicas.unam.mx/_administracion/reglamentos_formatos/archivos_pdf/CodigoIIBO.pdf>

4. Current Mexican Regulation

4.1 Introduction

This chapter reviews the Mexican legal system, providing familiarisation with basic concepts, such as the regulation of the human genome. According to Kaye, the main advances in this area signalled a change in research focus, an evolution starting with genetics.²⁷⁰ Therefore, this chapter also explores relevant frameworks that would apply directly to biobanks, including the human genome, an area partially regulated by Mexican Law, and population biobanks.

This chapter is the basis for further analysis of the current legislation to identify legal holes and weaknesses. Formally binding rules will be emphasised, which consist of primary laws (federal statutes) and secondary laws (local statutes). This thesis will recommend changes affecting the current regulation, and understanding the legal competence of the actors involved is essential for these purposes.

4.2 Mexican internal law system

4.2.1 Basic familiarisation concepts

Before analysing the legal situation of biobanks in Mexico, it will be necessary to understand how the law is formed. There are different legal categories of laws, guidelines and recommendations within the Mexican legal system applicable to biobanks. The established primary legislation in the following paragraphs cannot be ignored as it constitutes a basis for further extensive legal analysis. In the words of Jane Kaye,²⁷¹ the term 'law' can be understood in both a broad and a narrow sense. The first refers the national legal system, whereas the latter refers to the structure of systematic rules contained in a regulatory framework governing a specific area.

²⁷⁰ Kaye and others 3

²⁷¹ Ibid

4.2.1.1 Sources of law

The hierarchy of laws and other legislative instruments (acts, statutes and regulations) will depend, primarily, “on the legal source where they emerged from with formal governance bodies at three high-level players: legislators, judiciary and government.”²⁷² In the case of Mexico, formal governance emerges from parliamentary action. Law making generally belongs to the Mexican Congress, which is subject to a formal process, as described in the following paragraphs.

4.2.1.1.1 Formal sources of law

Any formal law in Mexico, to be given such a character, requires to go through a formal legislative process,²⁷³ which consists of the following stages:

A. Initiative

Deputies and senators of the Congress of the Union and the legislatures of the states have authority to initiate this process. The initiatives submitted will go follow the legal procedures established in the Ordinance of Debates (article 56 of the Constitution). The initiatives submitted by members of the chambers will go through the Commissions.

B. Discussion and approval or rejection

The initiatives could be submitted to either of the Chambers (Deputies or senators). The chamber where the proposal came from is called the ‘Chamber of Origin’ and the other is called ‘Chamber of Revision (or report)’. The members of one Chamber cannot present initiatives to the other Chamber. Hence, the initiatives from deputies shall be discussed in the Deputies’ Chamber. The discussion of legislative initiatives or proposals will remain in the chamber of origin for at least one month. If after one month it is reported or revised with no submission, the

²⁷² Ibid

²⁷³ The Mexican Constitution (Mex) Articles 71, 72 and 95

proposal will be transferred and discussed in the other Chamber (senators). Three situations may occur:

- a) The legislative proposal is approved by both the Chamber of Origin and the Chamber of Revision. In case of approval it will be sent to the Executive (the President of Mexico), if no observations are given, for immediate publishing.
- b) If the legislative project is rejected by the Chamber of Origin it cannot be sent again until the following session period (which takes place twice a year, from the 1st of September to the 15th of December and from the 1st of February to the 30th of April).
- c) If a legislative proposal is approved by the Chamber of Origin but partially rejected by the Chamber of Revision, the project will be returned to the Chamber of Origin with observations to be discussed. If it is approved by the majority of the present members, the proposal will be sent to the Chamber of Revision for a second review.

C. Sanction

Once a proposal has been approved by the Chambers, it will be sent to the National Presidency for sanction. However, the Presidency can exercise a veto right. If the Executive rejects a proposal, this will be sent back to the Chamber of Origin to be discussed again. If the observations from the Executive are rejected by two thirds of the Chamber of Origin, the project will be sent to the Chamber of Revision. If two thirds of this Chamber's members approve the proposal, the project will be sent to the Executive for publishing with no rejection possibilities. The discussions are made in plenary sessions.

D. Promulgation and publication

Once a law is approved and sanctioned, the Executive is obliged to order publication. The publication of the law is done in the Federal Official Diary (DOF). The president is exceptionally authorised to enact

legislation in some situations²⁷⁴ and it has been specified in which cases this will happen,²⁷⁵ for instance, “to issue regulations for the purpose of interpreting the language of legislative enactments.” It is also within presidential powers and duties to promulgate and execute the laws enacted by Congress.

4.2.1.1.2 Informal sources of law: custom, practice and doctrine

In addition to formal sources of law, custom and practice is also relevant in some circumstances. The custom in Mexico formed gradually by custom or habitual practice. These will be recognized as a source of law when an explicit provision of the applicable law formally allows such recognition. The general principles of law are also helpful when a legal rule is obscure. Jorge A. Vargas has stated that “a principle is a general proposition of law of some importance from which concrete rules derive.”²⁷⁶ A European Union framework decision has stated that these principles can be “unwritten and derived from the courts.”²⁷⁷ This is the case for Mexico. For example, within the legal system²⁷⁸ is a ruling dictating that the general principles of law are not applicable when there is an explicit legal text governing a specific legal situation. Following this precedent, the role of general principles of law is for guidance or clarification. The basis for these principles as a source of law is included in the Mexican Constitution, according to which legal academic opinion is a source of law formed by the written ideas, interpretations and comments from legal experts. These generally occur when the law is not clear, although these scholarly contributions are not legally binding.

²⁷⁴ Ibid Article 71

²⁷⁵ Ibid Article 89

²⁷⁶ JA Vargas, ‘Features - The Federal Civil Code of Mexico’ Law and technology resources for legal professions <<http://www.llrx.com/features/mexcc.htm>> accessed 27 February 2012

²⁷⁷ T Tridimas, *The General Principles of Law in the European Union Legal Order* (2 edn, Oxford European Union Law Library 2007) 1

²⁷⁸ Principios generales del derecho Su funcion en el ordenamiento juridico (TCC) 573

Regarding how informal sources of law can be applied to biobanks, their role should be seen as influential but not determinant. Normally, states adopt external regulation models through formal processes based on their own specific needs. For example, the complexity of biobanks implies the formal adoption of suitable safeguards, in which the international custom can be inspirational, but not sufficient. Participant F explained, “when we have these gaps in legislation, international law is very important. Many countries have adapted their national legislations from international instruments and the custom.”²⁷⁹

4.2.2 Main legal instruments

4.2.2.1 The Federal Constitution

Mexico has a written constitution. The constitution forms the written rules in which the Mexican legal system is founded. It contains fundamental basic legal principles. As Carroll states:

*“A constitution consists of the laws, rules (e.g. conventions) and other practices which identify and explain the institutions of government, the nature, extent and distribution of powers within those institutions, the forms and procedures through which such powers should be exercised, the relationship between the institutions of government and the individual citizen, often expressed in terms of a ‘Bill of rights’.”*²⁸⁰

The Mexican Constitution (*Constitución Política de los Estados Unidos Mexicanos*) (1917) (CPEUM) came with essential reforms, as a result of the Mexican Revolution’s achievements (1910), which embodied a move towards “the inclusion of social rights, for the first time in the history of constitutional law.”²⁸¹

²⁷⁹ Legal-researcher-at-a-public-research-institution-Participant:F, *PhD Thesis Fieldwork*

²⁸⁰ A Carroll, *Constitutional and Administrative law* (5 edn, Longman 2010) 3

²⁸¹ E Rabasa, *La dualidad en el derecho constitucional mexicano (The duality within the Mexican Constitutional Law)* (Instituto de Investigaciones Jurídicas UNAM 2012) 392

The Constitution incorporates basic guarantees which apply to all of its citizens.

According to Carroll;

*“Within the nation-state to which it applies, the constitution will usually be regarded as both the ultimate source of legitimacy and authority for the practice of government and as a framework for the application of that society’s political beliefs concerning how the process of government should be conducted and by whom.”*²⁸²

No secondary regulations can contradict the dispositions stated by the constitutional document, which is the main founding instrument of the legal system. Constitutionally, Mexican law is founded in several sources in accordance with this hierarchy: The Federal Constitution, international treaties and conventions (to which Mexico is a party), federal statutes, codes, doctrine, custom and the general principles of law.

4.2.2.2 Codes

In current Mexican law, a code is “the written formulation of a specific branch (i.e., civil, commercial, criminal, etc.) of positive law (i.e., the law which is in force today) presented and organized under a certain subject, plan, system and method.”²⁸³ The Mexican Constitution²⁸⁴ provides a list of the Congress’ faculties. The enactment (and change) of a “Federal Civil Code” is not the Congress’ attribution as it is not explicitly mentioned. Vargas has pointed out that “out of a lengthy list of areas where Congress is explicitly empowered to legislate, enunciated in great detail in thirty paragraphs, there is no reference whatsoever to civil law matters.”²⁸⁵

The Mexican codification originated from the European tradition. By definition, countries within the civil law tradition have codes, which

²⁸² Carroll 4

²⁸³ MR González, *Nuevo Diccionario Jurídico Mexicano (The new Mexican legal dictionary)* (IIJ, Porrúa-UNAM 2009) 584-586.

²⁸⁴ The Mexican Constitution (Mex) Article 73

²⁸⁵ Vargas

form an important part of their legal system and sustain it. Having codes as part of the definition of countries within a civil law tradition comes from ancient Roman law ‘for the people’ (family, property, offences etc.) “*corpus iuris civilis*.” After the fall of the Roman Empire, this obsolete law compilation was codified, later expanded and finally put into use by European countries, including Spain, in the 19th century. Codification in Europe started as “the work of a special commission, appointed by the federal or local executive, for the enactment of the corresponding codes.”²⁸⁶ In Jorge Vargas’ point of view, one of the main sources in the Mexican codification efforts was “the powerful influence exercised by leading European countries, in particular Spain and France, followed by Italy and Germany.”²⁸⁷ Mexico became independent from Spain in 1810, with the Spanish colonial law remaining in place. Most of the modern codes relate to a common and universal ancestor, the French Civil Code (1804) known as *Code Napoleon*, designed and formulated by Napoleon Bonaparte. It has been said that “this Code initiated the contemporary system of civil law as we know it today with codifications.”²⁸⁸ The first Mexican “codification efforts were initiated at the state level.”²⁸⁹ As a result, Mexico has the five basic codes in any civil law country; the Civil Code (1928), the Code of Civil Procedures (1943), the Penal Code (1931), the Code of Penal Procedure (1934) and the Code of Commerce (1889), originally dating back to 1822.

²⁸⁶ JA Vargas, ‘ Mexico and its Legal System ’ Law and Technology resources for legal professionals (llrxcom) <<http://www.llrx.com/mexicolegalsystem.htm>> accessed 18 January 2012

²⁸⁷ JA Vargas, ‘ An Introductory Lesson to Mexican Law: From Constitutions and Codes to Legal Culture and NAFTA ’ San Diego Law Review Association <<https://litigation-essentials.lexisnexis.com/webcd/app?action=DocumentDisplay&crawlid=1&srctype=s mi&srcid=3B15&doctype=cite&docid=41+San+Diego+L.+Rev.+1337&key=d6072d42f4e12efe3c30337714413506>> accessed 18 of January 2012 1

²⁸⁸ L Baudouin, ‘The influence of the Code Napoleon ’ (1958) 33 Tul L Rev 1

²⁸⁹ Vargas, ‘ An Introductory Lesson to Mexican Law: From Constitutions and Codes to Legal Culture and NAFTA ’ 1

4.2.2.3 Administrative standards

The administrative standards have been enacted in order to protect non-specialised consumers. These binding “Official recommendations” (*Normas Oficiales*), (also known as “NOMs”), help to secure quality requirements in activities, such as design and the production of goods and services. These technical standards are covered by the *Mexican Regulation of Metrology and Standardisation*. (*Ley Federal de Metrología y Normalización*) (1992). In most cases the NOMs include applicable requirements, generally on technical management, that must be complied with by both individuals and companies. For example, the Federal commission for protection hazard analysis in health products and services grants licenses for health control. The Official administrative recommendation NOM-087-ECOL-SSA1-2002 *Norma Oficial Mexicana NOM against sanitary risks 087-ECOL-SSA1-2002*) provides the classification and management of dangerous biological infectious residues, regarding how remaining samples from hospitals must be disposed. NOM Standard methodologies for collection, processing, storage, transport and preservation period need to be established across Mexico.

4.2.3 The Mexican Federal System

The Constitution establishes in article 50 that the legislative power, one of the Federal Government’s three powers, aside the executive and judiciary, will consist of a Federal Congress. The Federal Congress will be divided into the Chamber of Deputies (*Cámara de Diputados*) and the Chamber of Senators (*Cámara de Senadores*). Each chamber is divided into commissions: specialised workgroups for legislation among diverse areas, i.e. agriculture, science and technology, national defence, culture, human rights, health, public education and educational services, etc. Apart from the Federal Congress, the 32 autonomous entities that form Mexico count on the three powers at a local level. Therefore, each entity has the ability to legislate through 32 local legislatures.

The Federal Congress creates regulations, that is, laws and decrees (Art. 70). Federal regulations (statutes) are divided into two categories by relevance: a) Laws (Regulatory acts) and b) Ordinary laws. Laws or regulatory acts (*Leyes reglamentarias*) are those that detail the provisions of the Federal Constitution, establishing the legal bases for effective implementation. Ordinary laws (*Leyes ordinarias*) are the statutes enacted by the Federal Congress that do not derive from a specific constitutional provision. They legislate on a specific subject.

4.2.3.1 Relevant Federal legislation

This section describes relevant federal legislation. The binding level and competence of any biobanking instruments will depend on their status in the legal hierarchy (i.e. whether they are local or federal, administrative rules '*reglamento*,' or a statute '*ley*').

At the time of writing, there is no specific federal legislation dealing with biobanking. However, there is a range of federal laws which impact on it. Currently, The Parliamentary Science and Technology Commission, which is responsible for biobanking, "does not count with specialised experts in bioethics."²⁹⁰ According to participant K, "in science and technology we have someone in charge called the technical secretary." This participant, who has a scientific profile, pointed out that "if the commission legislated on bioethics, it would contact academia, institutes, labs and experts who could provide an opinion on the topic. We need to be coordinated. The budget cannot cover experts for each area, instead we organise opinion forums."²⁹¹ In principle, the lack of biobanking regulations could be due to this structural fact.

²⁹⁰ Science-and-Technology-Commission-Participant:K

²⁹¹ Ibid

4.2.3.1.1 The regulation of public health: federal statutes

The Mexican health care system is governed by the General Health Law (*Ley General de Salud*) (1984), which is a federal law. The right to health is provided by article 4 of CPEUM; “All persons have a right to the protection of their health. Laws will state the ways in which the federation, and the federative entities, will concur to provide health services.” Moreover, this article establishes that every person has the right to an environment for development and wellbeing. This further alludes to the human rights perspective.

It has been stated that “during the past few years, Mexico has proven to be one of the most important advocates with regards to the notion of the right to health.”²⁹² This has been achieved through legal reforms and the implementation of public programmes. By the year 2000, the WHO reported that Mexico had great issues with financial distribution of public funds in regards to healthcare. This affected people since their access to the health system had significantly reduced.²⁹³

The Ministry of Health is responsible for the direction of the national medical policy, medical legislation is meant to be covered at the federal level by the Ministry of Health regulations. The main regulation is the General Health Law (1984),²⁹⁴ which also deals with scientific research. However, it is not clear whether biobanks are adequately covered. The General Health Law establishes the guidelines and principles for scientific and technological regulation in relation to health. The secondary rules of this act (*ley*) aim to comply with the primary legislation in the public and private sectors. Secondary laws are: The Regulation on Sanitary Disposal

²⁹² H Jaff, ‘The Right to Health in Mexico: Seguro Popular’ (*World Poverty and Human Rights Online: Supporting the Right to Life, Liberty, and Development*, 2010) <<http://wphr.org/blog/2010/03/27/the-right-to-health-in-mexico-seguro-popular>> accessed 19 March 2012

²⁹³ Ibid

²⁹⁴ LGS

of Human Organs, Tissues and Cadavers (1985),²⁹⁵ the Regulation on Scientific Health Research (1987)²⁹⁶ and the regulations put forth by the National Institutes of Health Law (2000). The Regulation on Scientific Health Research in health research (*Reglamento de la Ley general de Salud en materia de Investigación para la Salud*) (1986) establishes specific allowances for research in specific matters e.g. infertility. All those integrate the regulation of health related law in Mexico.

4.2.3.1.2 Regulation of human tissue

The General Health Law covers human tissue, and the transport of human tissue (blood, blood components, hematopoietic stem cells and derivatives) that can be used as a source of genetic material for population studies. Genomic research, under these amendments, must be part of a research project. The only reference identified in terms of biobanking for genetic studies is the rule mandating that “genetic material obtained for population studies cannot be used for different or incompatible purposes from those that motivated the collection.”²⁹⁷ Although the legal amendment signified progress, little ethical guidance can be derived.

In 2008, The Mexican Senate unanimously approved the reforms to the General Health Law which was meant to make “the sampling of genetic material and its transport outside of Mexico without prior approval illegal,²⁹⁸” although this currently does not happen in practice due to poor enforcement. The amendment states that Mexican-derived human genome data is the property of the Mexican government. It prohibits the collection and utilization of human genome data without prior approval, and stipulates that the Ministry of Health will reserve the right to consult

²⁹⁵ 'Federal Regulations for the Control of Organs, Tissues and Cadavers of Human Beings' ('Reglamento Federal para la Disposición de Órganos, Tejidos y Cadáveres de Seres Humanos')

²⁹⁶ Rules of the General Health Law on Scientific Research (Reglamento de la Ley General de Salud en Investigación Científica)

²⁹⁷ LGS Article 317 *bis* 1

²⁹⁸ Séguin and others 487

INMEGEN for opinions pertaining to requests for the transporting of any human genetic material outside of Mexico.²⁹⁹

4.2.3.1.3 Regulation of the human genome

Peterson points out that strong criticism of the political-regulatory handling of genomics is not surprising. The high expectation is that "the science of genomics should materialize in the near future."³⁰⁰ In this context, the former Ministry of Health initiatives provided the grounds for further law making discussions. As a result, the human genome would be a matter of health. Many of the policy decisions, therefore, have to do with resource allocation and where to invest for maximum possible health gain.

Background

In 1990, The Human Genome Project started, funded by governments and charities under the leadership of James Watson. The project aimed to reveal the entire genetic code of our species, which would be crucial for the continuing progress of medicine and other health sciences,³⁰¹ and also to underlie "the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it would be the heritage of humanity."³⁰²

Mexico has not been indifferent towards the use of the human genome and the consequences. By the year 2000, genomic research was starting to develop, for example genomic mapping and searching on diabetes and arthrosclerosis were starting to be a reality in the country. However, the country lacked the capacity to participate in the Human Genome Project due to the poor human and material national

²⁹⁹ Ibid

³⁰⁰ Robin Bunton and Alan Peterson (eds), *Genetic governance: health, risk and ethics in the biotech era* (Routledge 2005) 203

³⁰¹ M Henderson, *50 genetics ideas you really need to know* (Quercus Publishing Plc 2008) 49

³⁰² The Universal Declaration on the Human Genome and Human Rights

infrastructure³⁰³ to develop genomic research. Such an absence had a negative effect on the development of high profile scientific research in academic areas and the means to interact with social demands.³⁰⁴ It was clear that for Mexico to catch up with cutting edge genomic advances, it would be necessary to prepare the national health system and physical infrastructure, create more research groups and update the legal framework. Otherwise, the social cost would be too high; the country would depend on the import of required genomic resources, which would be difficult to afford.

Despite no Mexican scientists officially participating in the Human Genome Project, the Mexican scientific community (and government) followed its progress. The National University of Mexico (UNAM), through the Centre for Studies in Health and Law (*Núcleo de Estudios Interdisciplinarios en Salud y Derecho*) was one of the first national academic institutions to evaluate the human genome from a legal perspective.³⁰⁵ As the Human Genome Project released findings, this produced new expectations and concerns within parts of the Mexican government. Hence, the Mexican State began concentrating on the bioethical debate with a view to developing new bioethical laws.³⁰⁶

Mexican National Bioethics Commission³⁰⁷ has adopted the following UNESCO³⁰⁸ documents: The Universal Declaration on

³⁰³ Vázquez-Elizarrarás 477

³⁰⁴ Hugo Aréchiga and others, 'El proyecto del genoma humano: perspectivas de la medicina genómica (The human genome project, perspectives from genomic medicine)' (2000) 43 Rev Fac Med UNAM 204

³⁰⁵ Vázquez-Elizarrarás 475

³⁰⁶ *Ibid* 477

³⁰⁷ The National Bioethics Commission (Comisión Nacional de Bioética CNB), *National guidelines for the integration and operation of the research ethics committees (Guía Nacional para la integración y el funcionamiento de los comités de ética en investigación)* (The Ministry of Health (Secretaría de Salud), 2010) 23

³⁰⁸ UNESCO, 'Social and Human Sciences' (*UNESCO*)

<<http://www.unesco.org/new/en/social-and-human-%20sciences/themes/bioethics>> accessed 11 October 2012

the Human Genome and Human Rights,³⁰⁹ The UNESCO International Declaration on Human Genetic Data and The Universal Declaration on Bioethics and Human Rights.³¹⁰ However the binding character of these sources of international law is relative. The merely declaratory focuses of these documents were taken on the need to protect data derived from the genome, which worked as a partial rationale for the former Mexican legislative project on the human genome.³¹¹

1990-2000

In 2001, legislators from the Democratic Revolution Party started to draw up the project for the “Law on investigation, encouragement, development, control and regulation of human genome.”³¹²

In addition, in 2000, an alliance of four key institutions (the Ministry of Health, the UNAM, CONACYT and the Mexican Foundation for Health (FUNSALUD) analysed genomic medicine opportunities. This alliance resulted in the foundation of the National Commission of the Human Genome (*Comisión Nacional del Genoma Humano*). The Human Genome Commission called for legislation on the regulation of research on the human genome for the first time. The main focus of this legislation attempt was to inclusively cover the regulation of human genomics, “the design and development of suitable governmental policies regarding research on human genetics which had become necessary.”³¹³

³⁰⁹ The Universal Declaration on the Human Genome and Human Rights

³¹⁰ The Universal Declaration on Bioethics and Human Rights

³¹¹ M Wistano, ‘Explanatory preamble for reforms to the General Health regarding the human genome (Exposición de motivos que reforma la ley general de salud, en materia de genoma humano)’ Partido Acción Nacional National Action Party PAN
<http://sil.gobernacion.gob.mx/Archivos/Documentos/2001/12/asun_1025_20011214_838707.pdf>

³¹² F Patiño Cardona, ‘Iniciativa de ley sobre la investigación, el fomento, el desarrollo, control y regulación del genoma humano (Law project on research, encouragement, development, control and regulation of the human genome)’
<http://www.diputados.gob.mx/sia/coord/OBRA_LEG_LIX/obraleg_lix/inic/htm/02dic03_3.htm>

³¹³ Wistano

The results of the analysis identified possible areas of benefit, including the contribution of a more individualised, predictive, preventive medical practice, the development of pharmacogenomics, and the development of an ethical and legal framework for genomic medicine in Mexico.

Biobanking was identified as a key area for the discovery and development of new drugs.³¹⁴ Illnesses could be identified and treated before the manifestation of symptoms. If genomic medicine is not developed in Mexico, this could prove to be expensive in the long term as preventative treatment might be delayed.³¹⁵ Hence, the development of genomic medicine would save public funds and the cost associated with treatments for common diseases would be significantly reduced.

2001

Two legislative initiatives on the human genome development were identified:

- 25th September 2001 Deputy Francisco Patiño Cardona, from the Democratic Revolution Party (PRD), announced a legislative proposal entitled “The human genome in terms of investigation encouragement, development, control and regulation.”³¹⁶ This was sent to the Congress, more specifically to the Commissions of Health, Science and Technology, for analysis and report.
- 14th December 2001 Deputy Manuel Wistano Orozco Garza, from National Action Party (PAN), announced a proposal in order to amend the General Health Law, including the addition of title XVIII: “The human genome.”³¹⁷ This was sent to the Commissions of Health, Science and Technology for analysis and report.

³¹⁴ RE Hewitt, ‘Biobanking: the foundation of personalized medicine ’ (2011) 23 *Current Opinion in Oncology* 115

³¹⁵ Jimenez-Sanchez and others 1191

³¹⁶ Francisco Patiño Cardona, *Iniciativa de ley sobre la investigación, el fomento, el desarrollo, control y regulación del genoma humano (Law project on research, encouragement, development, control and regulation of the human genome)* (2001)

³¹⁷ Wistano

Both proposals focussed on the prevention of the misuse of genetic data by private companies and governmental agencies. The potential diminishment of confidentiality when individual genetic data is exposed to third parties was also considered. Additions to the General Health Law ('Title XVIII: The human genome') were designed to establish a regulatory framework for the treatment of the knowledge on the human genome. This potential loss of confidentiality limits people's expectations and affects their personal decisions. One of the main purposes was to find the balance between the individual right of genetic privacy and the social duty of avoiding harm to third parties. The Congress saw in these proposals "an advantage to guarantee health rights and a better quality of life."³¹⁸ Illness diagnosis, therapeutic techniques and drug use could be more effective within medical practice and problems, such as the body's rejection of specific medicines and side effects, could be avoided.

Opinions from relevant groups, such as INMEGEN, researchers from health institutes, the UNAM and the Mexican Academy of Science were taken into account. The 2001 proposals for the General Health Law were later condensed into one³¹⁹ It was evident by 2001 that new primary legislation was necessary. Since the Congress had considered the human genome as a health topic, conceptualisation, research orientation, knowledge and applications for health protection, data protection and confidentiality, and prohibition of discrimination, were central to the proposal. It should be noted that the current controls for biobanking in Mexico resulted from these legislative efforts to regulate the human genome. The following table, obtained from the official website for

³¹⁸ Comisión Parlamentaria para la Salud (Parliamentary-Health-Commission) and Comisión Parlamentaria de Ciencia y Tecnología (Parliamentary-Science-and-Technology-Commission), *Dictamen con proyecto de decreto que adiciona la fracción ix bis al art. tercero, adiciona un título quinto bis y su capítulo único, y el artículo 421 bis, todo a la ley general de salud (Report on the Project for decree that reforms fraction IX bis to article third, title V bis and article 421 bis of the General Health Law)* (2003)

³¹⁹Cardona and Wistano

legislative information system, shows the details of the proposed addition of Title XVIII.³²⁰

DENOMINATION (TITLE)	<u>Proposal for decree in order to add Title XVIII to the General Health Law.</u>			
SUB-CATEGORY	Secondary Law			
CHAMBER OF ORIGIN	Deputy's chamber			
PRESENTATION DATE	14/12/2001			
PRESENTED BY	<u>Deputy Manuel Wistano Orozco Garza</u>			
POLITICAL PARTY	National Action Party PAN			
LEGISLATURE	LVIII			
TRANSFERRED TO	<u>1.- Deputies - Science and Technology For report</u>		<u>2.- Deputies -Health.- For report</u>	
STATUS		<u>Published in D.O.F. on 16- NOV-2011</u>		
TOPIC	1.- Education and Culture		2.-Health	

³²⁰ SEGOB (Ministry of Governance), 'Sistema de información legislativa SIL (System of legislative data SIL) '

<<http://sil.gobernacion.gob.mx/Numeralia/Iniciativas/resultadosNumeraliaIniciativas.php?SID=&Serial=a0202d11e1b71fd95dbc40d37ad3c2ae&Reg=19&Origen=IL>>

Source: Legislative data System³²¹

2002-2003

In 2002, another proposal was introduced by the Green Ecologist Party (*Partido Verde Ecologista de México* PVEM):

- 27th November 2002 The Congress' Commissions of Health, Science and Technology approved the human genome focused proposals; hence, the legislative process began.

This proposal intended to modify the Constitution as follows:

- Article 1 originally expressly prohibits discrimination. Examples of discrimination are defined by the constitution. "All discrimination motivated by ethnic or national origin, genetic characteristics, gender, age, different abilities, social condition, health condition, religion, opinions, preferences, civil status or is prohibited."

The Congress members of PVEM planned on adding "Genetic characteristics" as one of the reasons for discrimination, among others, "against human dignity, undermining the rights and freedoms of people."

- PVEM had planned on defining the human genome within article 4 (regulating the health system) and stating that "The law will protect the investigation, control and regulation of the human genome."
- Article 28 prohibits monopolies in Mexico, but exempts various activities. To counteract this exemption, PVEM suggested that an inclusion should be made; "Under no circumstances will the human genome be able to be patented in its natural state."
- Article 89 grants inventors or developers of particular industry areas exclusive privileges for a limited time. PVEM also proposed that these

³²¹ Ibid

privileges “will never be granted in terms of human genome in its natural state.”³²²

On 2 December 2003, a report made by the Congress’ Commissions of Health, Science and Technology, was presented to the Congress in a plenary session. It was approved and remitted to the Senate.³²³

On 4 December 2003, the Mexican Senate received the report from the Congress in a plenary session. The proposal for a decree included: the addition of section *fracción IX bis* to article 3; title V *bis* and its unique chapter; and article 421 *bis* of the General Health Law. It was exposed for analysis and report to the Senate Commissions of Health, Social Security and Legislative Studies. An extension was requested to the Health and Science Commission of the Congress and the extension was accepted.³²⁴

2008-2011

In 2008 regulation was introduced governing research in human beings, apparently targeting genomic studies.³²⁵

- On 3 April 2008, the report by the Senate’s Commissions was approved. On the 8 of April 2008, the report was sent back to the Congress’ Commissions, which officially encouraged the amendments, following the requirements of Article 72 of the Mexican

³²² *Proyecto de Decreto que reforma los artículos 1, 4, 28 y 89 de la CPEUM (Proposal for decree to amend the articles 1.4. 28 and 89 of the Mexican Constitution)* (2002)

³²³ SCJN, ‘Suprema Corte de Justicia de la Nación (The Mexican Supreme Court of Justice)’ <<https://www.scjn.gob.mx/Paginas/Inicio.aspx> > accessed 20 May 2011

³²⁴ *Ibid*

³²⁵ A Becerril, ‘Aprueba el Senado sanciones a quienes trasladen tejido humano fuera de México’ *La Jornada* <<http://www.jornada.unam.mx/2008/03/28/index.php?section=sociedad&article=046n1soc>> accessed 28 March 2008

Constitution. The report was finally presented to the Congress' Commissions.³²⁶

4.2.3.1.3.1 The human genome enactment

In 2011, ten years after the first attempt at human genome regulation, the proposal was finally approved. The decree was enacted with the main intention to avoid undermining fundamental rights by bio-scientific research. As a general health policy, public interest, ethical research and development began to be preserved, but the policy only covered the human genome. Individual registration by authorities was required, establishing the object and specific applications of research projects.³²⁷ In the new decree³²⁸ added to the General Health Law, key issues are covered, such as the recognition of the human genome as a world heritage, recognition of the human genome as belonging to the individual, confidentiality on genetic data, prohibition of discrimination based on genetic characteristics and the establishment of penalties for breaching these rules. Even when the new amendments established that the human genome would belong to each individual, it was not made clear what implications this could have. Under the recently modified General Health Law,³²⁹ the request for expressed consent is compulsory: "every study in this area (human genome) must count on the expressed acceptance of the subject." This is the only rule in terms of informed consent. This reform was meant to be "the foundation for scientific research, innovation, technological development and medical applications in terms of human genome; and to have an impact on the regulation of genetic screening, biobanks and gene therapy."³³⁰

³²⁶ SCJN

³²⁷ LGS

³²⁸ *Ibid* Title V *bis*

³²⁹ *Decreto por el que se adiciona la fracción IX Bis al artículo 3o.; se adiciona un Título Quinto Bis y su Capítulo Unico; y el artículo 421 Ter de la Ley General de Salud. (DECREE which adds section IX Bis to article 3, the title "V bis" and its unique chapter and article "421 Ter" of the General Health Law)* (2011)

³³⁰ Tsuru Morales Isla Abogados SC, 'Publicación de la Reforma a la Ley General de Salud en materia de Medicina Genómica' Tsuru Morales Isla Abogados SC,

Legislative delay was attributed not only to a lack of resources and infrastructure to achieve scientific progress, but societal, political and historical elements have also influenced the late emergence and development of genetic research in the country.³³¹ Additionally, the complexity of the topic made the legislative examining commissions amend the proposal several times, for example, it was reported that “it did not have the necessary elements for protection.”³³²

When the preliminary report on the proposal³³³ was ready, Congress members, who were deputies from the National Action Party (PAN), conditionally approved the proposal on the basis that “any type of cloning activities” were rejected by Congress. José Galán attributes this to the pressure made by civil and religious groups when they were consulted by the legislators.³³⁴ Silvia Alvarez Bruneliere and María Eugenia Galván Antillón, PAN deputies responsible for the Commission of Science and Technology, and the Commission of Health, denied approval for the report of the decree proposal because “enforcement would cost nearly 250 million dollars” although this is somewhat contradictory since it was initially believed that not developing guidelines for the human genome would be more expensive in the long term.³³⁵

The above chronology highlights the overall steps, within the former law making process, towards the approval of a regulated human

<<http://www.tmtlaw.com.mx/reformas-medicina-genomica.php>> accessed 19 January 2012

³³¹ A Barahona and FJ Ayala, ‘The emergence and development of genetics in Mexico’ (2005) 6 *Perspective Nature Reviews Genetics* 864

³³² *Decreto que incluye el artículo 41 bis y reforma el artículo 98 de la Ley General de Salud (Decree which includes article 41 bis and amends article 98 of the General health law)* (2011)

³³³ Cardona

³³⁴ J Galán, ‘Condiciona PAN su respaldo a legislación sobre el genoma humano (PAN political party conditions support to human genome legislation)’ *La Jornada* (Mexico City, 18 May 2002)

<<http://www.jornada.unam.mx/2002/05/18/041n2soc.php?origen=soc-jus.html>>

³³⁵ *Ibid*

genome project. This successful legislative attempt, passed into law in 2011, could provide the rationale for future biobanking governance. In general, normative and practical frameworks have evolved logically through the derivation and adaptation of existing biomedical regulatory frameworks applicable to research on humans.³³⁶ Before these 2011 regulations, human tissue was regulated with the exception of the human genome. The regulation of the human genome is now included, however it will be necessary to clarify the most effective mechanisms for the enforcement of the reforms, e.g. granting authorisation. Some statements are similar or the same as those in previous legislative proposals, such as considering “the only reasonable way of dealing with the human genome sequence is to say that it belongs to us all -it is the common heritage of humankind.”³³⁷

Similarly, as with other areas of biobanking, different interpretations may be applied within population biobanking. Juan Carlos Elizarrarás, academic researcher in law and bioethics, recognised that some rules within the Mexican legal system indirectly protect aspects such as informed consent, right to health and right to privacy. This can seriously affect human rights. Hence, “immediate action must be procured to avoid Mexico converting into a ‘genetic and bioethical paradise.’”³³⁸ Participant O’s critical opinion of the human genome regulation expressed that “laws such as the human genome rules become “dead documents” (laws that are enforced but not applied).”³³⁹ The enforcement and clarification of the laws implemented in 2011 is a key issue for Mexico to avoid being a country where controls cannot be effectively applied to biobanking activities.

³³⁶ Rial-Sebbag and Cambon-Thomsen 114

³³⁷ Henderson 48

³³⁸ Vázquez-Elizarrarás 483

³³⁹ Expert-on-Bioethics-Philosophy-and-Law-at-a-Public-university-Participant:O, *PhD Thesis Fieldwork* (2012)

The improvement of medical practice, through more effective methods of the diagnosis, therapeutic techniques and drug use was included amendments to article 103 *Bis* of the general Health Law.³⁴⁰ Despite the current regulation for genomic studies it does not cover the ethical aspects of biobanking satisfactorily. Some aspects of the human genome remain unregulated and the associated bioethics confusing, for example, only human tissue that could be a source of genetic material is covered. This was enacted “in order to protect the national sovereignty on the genomic data of Mexican citizens.”³⁴¹

4.2.3.1.3.2 Genomic sovereignty

The concept of genomic sovereignty has been at the centre of an intensifying debate in Mexico, which led to amendments to General Health laws. These aim to protect the national genomic sovereignty of Mexican citizens. With respect to the transfer of tissue to foreign countries, the Mexican General Health Law³⁴² establishes that organs, tissues and cells may not be taken outside national territory without authorization. Requirements to obtain an authorisation to transfer genetic information are confusing. Human research is only allowed at medical facilities under the supervision of competent health authorities and with the approval of the INMEGEN (National Institute of Genomic Medicine). It would be desirable to clarify which government agencies are authorized to grant approval. The abovementioned approval of the INMEGEN reportedly does not happen in practice.

The proposals provoked high criticism from members of the Mexican scientific community, who considered the proposals as too

³⁴⁰ , *Decreto que incluye el artículo 41 bis y reforma el artículo 98 de la Ley General de Salud (Decree which includes article 41 bis and amends article 98 of the General health law)*

³⁴¹ Becerril

³⁴² LGS Article 317

extreme. Extracting ‘a little tube of DNA’³⁴³ could mean imprisonment or a fine. It was also claimed that the final objective was the creation of a governmental monopoly on genomic research. The only institution legally entitled to perform research on population genomics would be the INMEGEN, whose greatest achievement (the genomic map of the Mexican population) generated economic interest in the “uniqueness of the Mexican genomic profile.”³⁴⁴ Schwartz has pointed out that the reforms of 2008 were “initiated in response to reports of ‘safari research’, in which foreign researchers attempted to obtain blood samples from Mexican subjects, including indigenous groups, without the approval of the Ministry of Health and local ethics committees.”³⁴⁵

The requirements set forth in Article 317 for transferring tissue outside national territory are still unclear; e.g. cases requiring urgency are mentioned but not defined. Regulations enacted to protect Mexico’s genomic sovereignty, an attempt to control international tissue transfers, have been criticized for being ineffective rules, where the bioethical approach is incipient.³⁴⁶ Progress was achieved, although with the amendments on genomic sovereignty, greater improvement had been expected. According to Schwartz, the amendment is an incipient bioethical framework.³⁴⁷ Similarly, participant E has stated that “the production of the Mexican HapMap was too relevant to health issues to end up with a simple modification to the General Health Law,” and “the term genomic sovereignty is not helpful.”³⁴⁸ It has been made to sound like a discourse, i.e. the “key to understanding the socio-legal design of population genomics and the political framing of this new technology in

³⁴³ Responsible-of-the-Genetics-department-at-a-public-ethical-advisory-institution-Participant:I

³⁴⁴ Schwartz-Marín and Silva-Zolezzi 495

³⁴⁵ E Schwartz, ‘Filosofía para la nueva genética (Philosophy for the new genetics)’ (Simposios Filosofía para la Nueva Genética, Mexico City, 25 January 2010)

³⁴⁶ Ibid

³⁴⁷ Ibid

³⁴⁸ Researcher-at-a-public-biobank-Participant:E

the public sphere.”³⁴⁹ However it consists of something simple: samples will not leave the country if they do not have approval in order to protect the Mexican DNA. If samples have approval, they will leave the country, but in words of participant J, this is “just a rule,” not genomic sovereignty. The participant wonders, “whose genomic sovereignty? What does it mean?”

The provision contained in article 317 *bis* 1 is not clear in ethical terms. The opinions of Mexican indigenous populations have never been taken into account and, in the end, the debate resulted in “an inoperable regulation which was somehow forced under assumptions far from the practice of population genomics.”³⁵⁰ Hence, the attempt to protect national sovereignty³⁵¹ caused a confusing regulation. The only human tissue covered for research is DNA, which left other type of tissues unprotected. Similarly, the only other point covered regarding DNA was in terms of genomic sovereignty; all other aspects remain unregulated.

In principle, economic interests have clearly prevailed over humanistic and ethical ones. In the opinion of Ruha Benjamin, “protection should be provided against foreign companies producing therapeutics, targeting the population without the population’s involvement.”³⁵² The emerging proposals, being purely based on nationalistic populism, signified the total exclusion of the Mexican population from international genomic projects. The concept of genomic sovereignty should signify the ethical treatment of samples containing Mexican genetic data and the translation of principles into policies. If it happened, the so called neo-colonialist action or safari research would become a legal offence.

³⁴⁹ Schwartz 1

³⁵⁰ Carlos López Beltrán (ed), *Genes (&) Mestizos: Genómica y Raza en la biomedicina Mexicana* (Ficticia Editorial / UNAM 2011) 181

³⁵¹ Becerril

³⁵² B Ruha, ‘A Lab of Their Own: Genomic sovereignty as postcolonial science policy’ 28 *Policy and Society* 351

4.2.3.1.4 Protection for vulnerable participants within scientific research

The General Health Rules on Research anticipate protection for vulnerable people through specific chapters on underage persons, pregnant women or incapable persons. Protection for communities, students and workers is also anticipated.³⁵³ Relevant articles are as follows:

Research in communities

Article 28 Research referring to human health in communities will be admissible when the expected benefit is reasonably assured.

Article 29 Within research in communities, the main researcher must obtain approval from health authorities and other civil authorities of the community under study and the letter of informed consent of individuals included in the study.

Article 30 When the individuals from a community have no capacity to understand the implications of participating in research, the ethics commission (that which the main researcher belongs to) will authorise that the informed consent of the research subjects be obtained through a reliable person, with moral authority over the community. If the authorisation is denied, the research cannot be done. Individuals must participate under a free decision and each of them can withdraw from the study at any moment of the study.

Article 31 Experimental research in communities can be done only by establishments that count with the previous authorisation of the Ministry. These must comply with toxicity tests.

Article 32 In all communities' research, the experimental design must offer practical measures for individuals and assurance that valid results will be obtained, making participation minimal and representative. In any community research, ethical considerations for individuals must be extrapolated to the communal context in pertinent aspects.

Regarding research of minors or incapable people:

Article 36 For research of minors or incapable people, informed consent must be obtained, at anytime, from the parents or legal guardian. Any of the parents can consent if it is impossible to obtain both parents' consent or in the case that the life or health of the minor is at imminent risk.

Article 37 If mental capacity and psychological state of the minor allow it, his/her acceptance must be obtained to be a research subject, after an explanation of what will happen. The ethics commission is authorised to allow justified exemptions.

Article 38 Research classified as risky, and with direct probabilities of benefit for the minor or incapable person, will be acceptable when:

- I. Risk is justified for the importance of the health benefit.
- II. The benefit is equal or greater than current diagnostic and treatment options.

³⁵³ Reglamento de la Ley general de Salud en Materia de Investigacion para la Salud (The Ministry of Health Rules of the General Health Law on Health Research) Title II Chapter II-V

No specific rules for the protection of samples have been identified. As emphasised by Participant D, “The rules on health research are too scarce regarding vulnerable people.”³⁵⁴ “Ciencia y desarrollo” (Science and development) magazine,³⁵⁵ concerning sample uses, reported that at least one of the investigated biobanks obtained samples from specific targeted communities, e.g. Chiapas and Oaxaca. The article also reflected that the sample collection was promoted through a national campaign, in which most participants were *mestizo* students.

Regarding article 28, it is not explained what ‘benefit is reasonably assured’ means. Participant F has posed some of the problems that this type of research implies in practice:

*“In genomic population studies it is not clear how the community is benefited, how the individual and the group are protected. Sometimes the individual is protected through anonymisation. However, the group remains unprotected. I have heard someone saying ‘here it is, the DNA from the tepehuanes,’ an indigenous people. That is unacceptable because the group can be discriminated against.”*³⁵⁶

In this case, no data protection measures are mentioned for the group. In participant E’s opinion:

*“The feedback from results is somewhat peculiar because it is uncertain whether the publication of research results will benefit participants. Researchers do not come back to the sample source to inform them of the publication. If they received that information, it would also be necessary to explain to them what the publication is about. I do not know anyone who has done that. The ethical commitment becomes interesting as well as deciding if such a commitment should be more stringent. It is difficult since the information of research publications tends to be very technical, rather than individually beneficial.”*³⁵⁷

Regarding withdrawal, the conditions under which it can happen is not specified and what would happen if the samples were already

³⁵⁴ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

³⁵⁵ A Hidalgo and others, ‘Proyecto Mapa Genómico de los Mexicanos (Project Genomic Map of the Mexicans)’ *Ciencia y Desarrollo (Science and Development)* (Mexico, January, 2006) 46

³⁵⁶ Legal-researcher-at-a-public-research-institution-Participant:F

³⁵⁷ Researcher-at-a-public-biobank-Participant:E

collected. In general, withdrawal from a research study would imply the automatic destruction of the samples collected however research withdrawal can happen at different stages. Sometimes, withdrawal is no longer possible at a particular research stage; the participant can withdraw from the research project but his data may still be used.

4.2.3.1.4.1 Participation of persons with legal incapacity

Participant D remarked that “there are no guidelines on biobanking to protect children or other members of the vulnerable population.”³⁵⁸ There have been cases in which under 18s and vulnerable people have participated in genomic research studies, such as the Mexican HapMap project. Another case showed the following:

The Faculty of Medicine at UNAM follows a specific consent model for those under the age of 16.³⁵⁹ The consent letter covers a significant number of aspects, such as consent withdrawal, economic aspects of participation, confidentiality protection, clarification that refusing participation will not lead to negative consequences and compensation in case of harmful consequences. The presence of two witnesses has been made compulsory for the institution. No consent documents within UNAM mention biological samples from minors.

The provision by the General Health Law prevents under 18s from being (living or dead) organ donors. This provision is not extended to biobanking, and ethics committees allow the participation of children through the use of written consent and forms signed by parents, relatives or guardians “for all severely ill patients whose decision making difficulties

³⁵⁸ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

³⁵⁹ UNAM Facultad de Medicina, ‘Carta de consentimiento informado para menores de edad e incapaces (Informed consent model for underage persons and those incapable)’ <<http://investigacionfacmed.com.mx/wp-content/uploads/2015/03/cartaDeConsentimientoParaMenoresDeEdadEIncapaces.pdf>>

are compromised by their illness and for all research involving children up to 18 years old.”³⁶⁰ Although the General Health Law has not determined whether it is lawful to obtain samples from children, the Rules of the General Health Law on Health Research establish that “when the minor’s mental capacity and psychological state allow it, acceptance must be obtained to become a research subject, after explaining to him what is intended.”³⁶¹ Children commonly participate and according to participant L:

*“Children are normally asked for their acceptance as well but the parents have the final decision. I know that the parents are responsible until their children are 18. In medical practice, mature children are asked for acceptance if their parents agree.”*³⁶²

CIOMS guidelines are unofficially followed by Mexican research institutes like INMEGEN. However, Mexican regulations do not guarantee, for example, psychological assistance for the child and his family if it were necessary as the result of participation in research, as recommended by CIOMS guidelines. CIOMS guidelines recognise the decision of a 9 year old child refusing participation in research trials, which could consist of sample donations from children, though this parameter remains unresolved under the current Mexican regulations. Regulations for sample donations to biobanks by persons with legal incapacity depends on the decisions of ethics committees.

The legal implications of samples are different to those covered by the General Health Law Rules on Health Research. Therefore, biobanking institutions are presumably bound by legal regulations, supplemented with additional, non-legal regulations, namely: integration

³⁶⁰ Reglamento de la Ley general de Salud en Materia de Investigacion para la Salud (The Ministry of Health Rules of the General Health Law on Health Research) Chapter III

³⁶¹ Ibid Chapter III, article 37

³⁶² Ethical-adviser-at-an-ethics-public-advisory-institution-Participant:L, *PhD Thesis fieldwork* (2012)

and operative rules of the administration and organisation council,³⁶³ operative internal rules of the information committee,³⁶⁴ operative internal rules of the biosecurity commission³⁶⁵ and internal rules of the ethics commission.³⁶⁶ Participant F³⁶⁷ confirms this position:

"It is a general principle that no specific research ethics measures for the protection of children have been provided in relation to samples."³⁶⁸

For underage participants, special attention must be paid beyond the present consent of minors regarding their samples. For example, if data repositories are created for long term use, children's re-consent when reaching adulthood would be highly recommended. In this respect, participant D is certain that:

"Within the National Health Institutes (INS), no differentiation is made between paediatric samples and adult samples. Similarly, the National Paediatric Institute (INP) does not give different treatment to children's samples, from the treatment INMEGEN gives to adults' samples."³⁶⁹

Significant limitations can still be found, and further legislation is required to determine whose consent should prevail, confidentiality, risk benefit ratios, storage periods and children's objection to participate.

4.2.3.1.5 Administrative regulation on biobanks

The Federal government has accepted the challenge of elaborating upon a *Norma Oficial Mexicana* (NOM) in terms of pharmacogenomics, through the Supplement of the National Programme of administrative norms' standardisation 2013, published on the 23

³⁶³ INMEGEN (National Institute of genomic Medicine), *Reglas de Integración y Funcionamiento del Consejo Técnico de Administración y Programación del INMEGEN (INMEGEN's administrative council's integration and operation rules)* (2007)

³⁶⁴ INMEGEN, *Reglas Internas de Operación del Comité de Información del Instituto Nacional de Medicina Genómica* (INMEGEN 2006)

³⁶⁵ INMEGEN (The National Institute of Genomic Medicine), *Comisión de Bioseguridad, Reglas Internas de Operación (Biosecurity Commission's internal operation rules)*

³⁶⁶ INMEGEN The National Institute of Genomic Medicine), 'Reglas internas de la comisión de ética (Ethical Commission's internal rules)'

³⁶⁷ Legal-researcher-at-a-public-research-institution-Participant:F

³⁶⁸ Ibid

³⁶⁹ Responsible-of-the-ethics-department-at-a-public-biobank-Participant:D

September 2013 in the Official Journal of the Federation (DOF). Pharmacogenomic studies are related to personalised medicine, as these aim to identify genomic variations, which allow therapeutic targets to be selected and identifying more precisely individuals at risk of adverse reactions to particular medicines. This new obligatory rule has established general requirements for the use of genetic data protection, in terms of efficacy and risk of some medicines. However, this new administrative norm does not cover biobanks.

Lara and Arellano, in an article published by FORBES Mexico³⁷⁰, propose changes to the regulation of biological samples through administrative norms. They have suggested that this administrative change could be the basis of further legal reforms for biomedical research,³⁷¹ although this is questionable since the nature of NOMs is focused towards technical management parameters. Importantly, Arellano and Lara have recognised that the development of areas such as pharmacogenomic studies will signify “an exponential increase of biobanks, since biomedical research relies on opportune access to quality biological samples and their suitable management.”³⁷²

4.2.3.2 Relevant local legislation

Federal law gives each state its own legislature in accordance with the following general principles. Legislation consists of rules of law made by the Federal Congress (Mexican Parliament), either directly in the form of statute (sometimes referred to as ‘primary legislation’) or indirectly by those other authorities on which the congress has conferred the power to legislate (delegated, subordinate or ‘secondary’ legislation).³⁷³ It is

³⁷⁰ César Lara and Alberto Arellano, ‘Farmacogenómica: Un cambio para el sistema de salud (Pharmacogenomics: a change for the health system)’ Forbes, Mexico <<http://www.forbes.com.mx/sites/farmacogenomica-un-cambio-para-el-sistema-de-salud/>> accessed 3 November 2013

³⁷¹ Ibid

³⁷² Ibid

³⁷³ Carroll 4

therefore assumed that according to the constitution, “the powers not expressly conferred by this Constitution upon federal officials, are understood to be reserved to the [local Mexican] States.”³⁷⁴

Biobanking guidelines are available at the Mexican Federal level, and therefore work as the foundation for local regulations. In Mexican law, it is expected that each Mexican state administers local regulation reflecting federal regulation. This has not always been achieved. In the light of Mexican Law, no local regulations would be expected without a federal background. However, related rules were identified in the Code for criminal procedures from Mexico City and the local rules for genetic data bases for the State of Chihuahua: *Ley Reguladora de la Base de Datos Genéticos para el Estado de Chihuahua*. These came into effect in 2009, signifying progress but also confusion due to the inconsistency that such regulation does not have a federal basis, as would be expected, taking into account the Mexican legal system’s rules.

Regarding this situation, Participant J has inferred that the aforementioned law was provisionally implemented due to the creation of a criminal data base with forensic purposes in the state of Chihuahua. This law, however, is too generic, for instance, it is not established who will provide the information for such a database. The currently emerging local databases could end up feeding a national security database called ‘*Plataforma México*.’ This should not happen in the absence of clearly defined national authorities to resolve this. In addition, it appears that even children are participating and it is not clear at what point the data should be destroyed.³⁷⁵

³⁷⁴ The Mexican Constitution (Mex)

³⁷⁵ Datap-protection-expert-at-a-public-research-institute-Participant:J, *PhD Thesis fieldwork* (2012)

These are two examples in which no correspondence is identified between a federal and a local rule. Both are independent.

1. The code for Criminal Procedures from Mexico City (1931) (*Código de Procedimientos Penales para el Distrito Federal*) Art. 149 protects genetic data. The disposition of germ cells is considered to be illicit when it is performed against the purposes for which the donor has granted authorisation.
2. The local legislation from Chihuahua defines the term 'biological sample' as any biological material, originated from human tissues, susceptible to preservation and capable of containing information regarding a person's genetics.

Therefore, it would be expected that the corresponding sanctions were initially implemented at the federal level, but this has not happened. Only the local Code of Penal Procedure for Mexico City protects genetic data. In Ingrid Brena's point of view, this creates "an obscure law."³⁷⁶

4.3 International law

The incorporation procedure of international legal rules in Mexico consists of a procedure described in the constitution.

*"This Constitution, the laws of the congress and all the treaties in accordance with the Constitution, signed by the President, approved by the senate will be supreme law of the Union. Hence, the judges of each state will follow the Constitution, laws and treaties. International treaties are binding for local entities, despite possible contradictions that the Constitution or state (local) laws may have."*³⁷⁷

Firstly, international treaties need to be signed by the President to become part of the Mexican legal system. Secondly, they need to be approved by the Senate; thirdly they are returned to the President for confirmation and finally, the incorporation becomes official through publication in the Official Journal of the Federation, *Diario Oficial de la Federación* (DOF). Completion this process makes international rules part of the national legal system and consequently binding. Therefore,

³⁷⁶ I Brena, 'El negocio de los genes (The business of genes)' *Guía internacional de la Bioética* <<http://www.bioeticas.org/bio.php?articulo260>> accessed 20 December 2011

³⁷⁷ The Mexican Constitution (Mex)

international treaties have a higher status in the legal hierarchy than federal laws but not higher than that of the Constitution.

According to the Supreme Court's current interpretation of Article 133 of the Mexican Constitution, international treaties rank second. Addressing the question of the hierarchy of the Mexican legal norms, in 'International treaties are hierarchically above the laws and under the federal constitution',³⁷⁸ it was held that "only the Constitution is the Supreme Law," adding: "This Supreme Court of Justice considers that international treaties are placed on a second plane immediately below the Fundamental Law and above the federal and local law."³⁷⁹ In the court's opinion, placing treaties in second rank is justified because they reveal "international commitments [which] are assumed by the Mexican State as a whole, and [which] commit all of its authorities with respect to the international community."³⁸⁰ Potential application of international biobanking instruments for Mexico would first require an investigation of the instrument. A treaty is not the same as a convention, a protocol or a UNESCO declaration. Participant F explains:

"We have to see the hierarchy of those instruments, whether it is an agreement or treaty and whether it has been signed. If it was ratified by the senate, it is mandatory in Mexico. The situations with no ratification tend to be more problematic. Other instruments could be considered, such as declarations and the international custom. This is not automatic, needs interpretation. The Ministry of Health or the National Bioethics Commission could do it."³⁸¹

It has been noted that Mexico has looked for guidance in international documents. In addition, Mexico has signed documents

³⁷⁸ C Martin, D Rodriguez and J Guevara (eds), *Derecho Internacional de los derechos humanos (International Law on Human Rights)* (Fontamara 2004) 159

³⁷⁹ Ibid

³⁸⁰ *International treaties are hierarchically over the federal laws and under the federal constitution (Tratados internacionales se ubican jerarquicamente por encima de las leyes federales y en un segundo plano respecto de la constitucion federal)* 903483 2810 Pleno Novena Época Apéndice 2000 Tomo I, Const, PR SCJN, P 1958 (Suprema Corte de Justicia de la Nacion (Supreme Court of Justice of the Nation) SCJN)

³⁸¹ Legal-researcher-at-a-public-research-institution-Participant:F

regarding scientific goals and participants' rights, including the International Covenant on Economic, Social and Cultural Rights (1976)³⁸² and the Universal Declaration on Bioethics and Human Rights (2005).³⁸³ Both are international standards that Mexico, as a signatory, is bound to support.³⁸⁴

In the year 2001, the Congress recognised that international collaborations in research were highly desirable in the Proposal for the Decree that modifies the General Health Law referring to the human genome (*Iniciativa de Decreto que adiciona la Ley General de Salud, referente al genoma humano*).³⁸⁵ This participation would be founded on documents, such as the Universal Declaration on the Human Genome and Human Rights (1997), the Council of Europe for the Protection of Human Rights and Human Dignity, and the agreements on Human Rights and Biomedicine (1997).

The Organisation for Economic Cooperation and Development (OECD)³⁸⁶ has stated that “the advanced knowledge of genes and complex cell processes is one of the main elements involved in the 2030 bioeconomy;”³⁸⁷ and Mexico, as an OECD signatory, must take part. The international norms specific to biobanks of human biological materials, associated data and corresponding genetic testing are relevant as they provide specific guidance. However, the main motivator for the country to adhere to the OECD was more economic rather than scientific.

³⁸² The International Covenant on Economic, Social and Cultural Rights

³⁸³ The Universal Declaration on Bioethics and Human Rights

³⁸⁴ Mexico joined the ICESCR on the 23 of March 1981

³⁸⁵ Cardona

³⁸⁶ Barahona and Ayala

³⁸⁷ The Organisation for Economic Cooperation and Development OECD, ‘The Bioeconomy to 2030: designing a policy agenda ’ International Futures Programme <<http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/thebioeconomyto2030designingapolicyagenda.htm>> accessed 11 March 2012

One of the main challenges in Mexico is “to strike an appropriate balance between freedom of researchers and the interests of participants and the public,” a matter included in the OECD report.³⁸⁸ First, it is vital to establish regulations for the main interests in research, the participants’ interests (welfare, respect for human dignity and justice) and for the researchers’ interests (freedom and justice). The main benefits of genomic medicine in Mexico are health-care benefits. However, these are still seen as long term goals in Mexico. According to the OECD, it would be worth fostering public participation by community consultation. The operators of the Guidelines for Human Biobanks and Genetic Research Databases HBGRD (2009)³⁸⁹ require that access requests include a scientifically and ethically appropriate research plan, and provide further details in this respect. The formulation of guidelines should be clear, flexible, amenable and general enough to be applied to different biospecimen resources, as it has been established by the NCI best practices in the USA.

Privacy is recognised in several international conventions signed by Mexico. The Universal Declaration on Human Rights (1948) and the International Covenant on Civil and Political Rights (1996) state that: “No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence.” These instruments are legally binding, under the Mexican Constitution.³⁹⁰ The Mexican panorama requires further analysis towards a basic regulatory model and legal effectiveness.

³⁸⁸ The Organisation for Economic Cooperation and Development OECD, ‘Key Outcomes’ (The OECD/HUGO Symposium on Genomics and Bioeconomy, Montpellier, 17 may 2010)

³⁸⁹ The Organisation for Economic Cooperation and Development OECD, *Guidelines for Human Biobanks and Genetic Research Databases (HBGRDs)* (OECD Guidelines, 2009)

³⁹⁰ The Mexican Constitution (Mex) Article 133

4.3.1 International treaties and conventions to which Mexico is a party

The role of international law is essential within new governance. International law documents are “extremely important either to affirm common principles (UNESCO) or to standardize practices (OECD).”³⁹¹ However, international law adherence is more ethically oriented and works “as a reference for scientists and regulatory bodies, and although their violation cannot, in any circumstances, lead to direct sanctions, they can influence the adoption of more binding texts.”³⁹² International rules are the result of an increasing amount of work from the international community. Their incorporation into national rules can be achieved in various ways; some have challenged the traditional methods of solving conflicts between international and internal rules. In most Latin-American countries, the incorporation (adoption) into internal law is facilitated by constitutional law.³⁹³ Direct or automatic incorporation of international treaties is common in Latin America.³⁹⁴ Mexico also follows this procedure. The category of a law or statute depends on recognition by a formal authority. In Mexico, any international frameworks will become compulsory once they are adopted through a specific ratification process.

4.3.1.1 Statutory recognition of international sources

Broadly speaking, statutory recognition comes from a documentary source (generally written) encouraged or adopted by parliamentary action. Additionally, the compliance of the law needs enforcement actors, with oversight power from a direct formal legal

³⁹¹ Rial-Sebbag and Cambon-Thomsen 123

³⁹² Ibid 124

³⁹³ Mac-Gregor217

³⁹⁴ HF Guerrero Rosales and MA. Solórzano Betancourt (eds), *Incorporación del derecho internacional de los derechos humanos al sistema jurídico mexicano (Incorporation of international law of human rights to the Mexican Legal System)* (Comisión Mexicana de Defensa y Promoción de los Derechos Humanos (Commission for the defence and promotion of human rights) CMDPDH 2008) 45

authority. This can be delegated. The senate is responsible for the approval of treaties and diplomatic conventions. The adopted International Law in Mexico is considered to be internally legally binding.

In the opinion of Elizarrarás,³⁹⁵ the discretionary criteria of international conventions impact on the ineffectiveness of such instruments at the internal level. International treaties have the same binding level as the constitution in Mexico, but Elizarrarás believes that declarations are the future of multilateral agreements. Nevertheless, it is the responsibility of each country to be prepared to adopt international guidelines. International documents, such as those from UNESCO, have been partially followed by Mexico, however, other factors (politics, social and economic issues) have also been influential. The delay in the human genome regulation is an example of a bioethics topic that is influenced by a range of factors.

4.4 Concluding remarks

The Mexican context presents a difficult social and political situation that affects the regulation of diverse topics, especially those unexplored in relation to science and technology. In the middle of difficult times that affect the health system, the only way to obtain knowledge involves institutional communication. Institutional coordination between academia and policymakers could provide the guidance needed for the scrutiny of legislative proposals, commissioned research, consultations, and spearheading public engagement and educational initiatives.³⁹⁶ With coordinated interaction, the government can obtain precise knowledge on the differentiation among bioethical issues, like that of biobanks. Once clear knowledge is available, it would be possible to develop specific regulation. This does not mean that the regulation of biobanks needs to

³⁹⁵ Vázquez-Elizarrarás

³⁹⁶ Gibbons 324

be exhaustive; “the diversity of practices could produce greater result than the attempts to control them exhaustively.”³⁹⁷

Although there is a relationship between human cloning and human genome research, both topics are completely different. Elizarrarás³⁹⁸ explains this confusion was caused by the lack of knowledge of the legislators; something regretful that “must be corrected now.” The approval of the reforms of 2011 was related to issues taken out of context, i.e. human cloning and the manipulation of stem cells from embryos,³⁹⁹ which should have been material for the elaboration of different proposals. Participant F suggested that deciding whether articles on genetics apply to biobanks is a matter of interpretation, whereas some articles are specific.⁴⁰⁰ The provision of procedural guidance in Mexico will only be achieved if it is determined who will take enforcement responsibilities. However, the creation of any procedures has to be made carefully, since bureaucratisation processes could end up hampering the scarce research.⁴⁰¹

The rationale of a fit-for-purpose proposal should be led by both expertise and realism regarding the particular barriers of the legal system. By tradition, Mexico has intended to regulate every single area. There are plenty of related biobanking rules. Nevertheless the law is not applicable.⁴⁰² Furthermore, there are categories, such as the human

³⁹⁷ Ibid 338

³⁹⁸ A Cruz Martínez, ‘Cárcel a quien conserve embriones, pide plan de reforma a la ley de salud (Prison to those who keep embryos, asked by planned reform to the General Health Law)’ *La Jornada* (Mexico City, 1 September 2011) Sociedad y justicia (Society and justice) <<http://www.jornada.unam.mx/2011/09/01/sociedad/036n1soc>> accessed 30 September 2011

³⁹⁹ Ibid

⁴⁰⁰ Legal-researcher-at-a-public-research-institution-Participant:F

⁴⁰¹ G Jiménez-Sánchez, J Frenk and G Soberón, ‘El poder transformador de la genómica en la economía global (The transforming power of genomics in the global economy)’ *Este país, tendencias y opiniones* <<http://estepais.com/site/?p=34614>> accessed 3 November 2011

⁴⁰² Datap-protection-expert-at-a-public-research-institute-Participant:J

genome and population biobanks, which may require further attention. The analysed reports fuel concerns that neither the research participants nor the general Mexican population would benefit from such research.

Although important principles have been established for a more modern regulatory framework, in order to ensure that genomic medicine will successfully contribute to improve healthcare in the population of Mexico, biobanking guidelines are still inconsistent. The evidence of regulatory inconsistencies in biobanking has now established the grounds for an extensive ethical analysis, which should work as the basis for future legal frameworks. Looking at the choice of encouraging an integral and inclusive biobanking law, rather than partial reforms, would be of help.

5. Legal holes and weaknesses: fieldwork analysis

5.1 Introduction

This chapter discusses how far the current Mexican legislation governs biobanking, identifying any inconsistent areas and the main failures that have prevented Mexico from optimising the benefits of biobanking. It will describe partial controls, followed by a discussion of their limitations, initially through a detailed legal analysis in the search for functional biobanking rules. The most significant expert opinions will be analysed. This chapter also identifies specific elements to help integrate the perspectives from both biobanks and governance, which according to Hawkins and O'Doherty, determine the legal effectiveness.⁴⁰³

The first section will identify elements of governance which can be considered as indicators of consistency. How these areas are perceived by stakeholders will provide insights on the state of different areas of governance requiring attention. The complexity of biobanking is associated with the diversity of practical areas involved. According to Kaye et.al, "different types of research will tend to use different kinds of biobank, both with respect to data and samples, in relation to the nature of research collaborations they call into existence."⁴⁰⁴ This is quite common: "There is a huge variety of laws and regulations which have relevance for biobank research."⁴⁰⁵ In this context, relevant regulatory areas to be analysed in the subsequent sections are: human tissue, informed consent, data protection, health research, and finally, potential sanctions.

⁴⁰³ A. K. Hawkins and K. O'Doherty, 'Biobank governance: a lesson in trust' (2010)

29 *New genetics and Society* 315

⁴⁰⁴ Kaye and others 285

⁴⁰⁵ AL McGuire and RA Gibbs, 'Currents in contemporary ethics' (2006) 34 *Journal of Law, Medicine and Ethics* 810

5.1.1 Statements on the effectiveness of Mexican biobanking governance

This section presents the responses from several stakeholders on whether biobanks are effectively regulated in Mexico. In order to identify weaknesses on the current biobanking rules, 15 participants were asked whether biobanking rules were effective. (See Table 1 in annex p. 1) The following data was obtained:

Two participants (K and L) said they did not know. Participant K (law maker) said he would need to study the topic more deeply to provide an answer. Participant L (Bioethics adviser) said he was not a law expert, and did not have knowledge of biobanks from a legal perspective. Out of the remaining thirteen participant responses to the question, seven responded that biobanks are not regulated effectively. Out of the seven negative responses, one said that regulation in biobanks is non-existent. From the remaining seven, six said that they are regulated, not effectively but partially. These six participants described the regulation as: partial, unclear, spread, ambiguous, covered by other laws and ineffective. No positive answers were obtained. Participant D “witnessed a discussion at the National Institute of Respiratory Illnesses (INER) to decide the fate of seventy year old samples. Obviously, there was no informed consent or the possibility to obtain it. The samples could be used for scientific research or disposed of, kept by a single institution or shared. This situation reminded me a case from Iceland, where samples dating from 1916, were allowed to be used.”⁴⁰⁶ Participant B⁴⁰⁷ recognised that the collection currently preserved at INMEGEN was created specifically for the HapMap study, the first genome wide genotyping effort of a recently admixed population in Latin America. However, since the study was concluded, the fate of the samples is no longer clear. Should the samples be discarded?

⁴⁰⁶ Responsible-of-the-ethics-department-at-a-public-biobank-Participant:D

⁴⁰⁷ Researcher-at-a-public-biobank-Participant:B

According to Gibbons, samples with no clear purpose “can predate contemporary biobanking norms or principles.”⁴⁰⁸ This is concerning in Mexico, where fieldwork shows that no laws have been enacted specifically in relation to biobanking. Ambiguous guidance regarding sample treatment is expected to cause clashes where there is a contra-position of rights among researchers and participants. These responses reveal great concerns pointing to an apparent lack of regulation and public information, with the potential for further consequences. If laws are weak, institutions are confused due to the absence of guidance as to how to proceed.

5.2 Tissue regulation

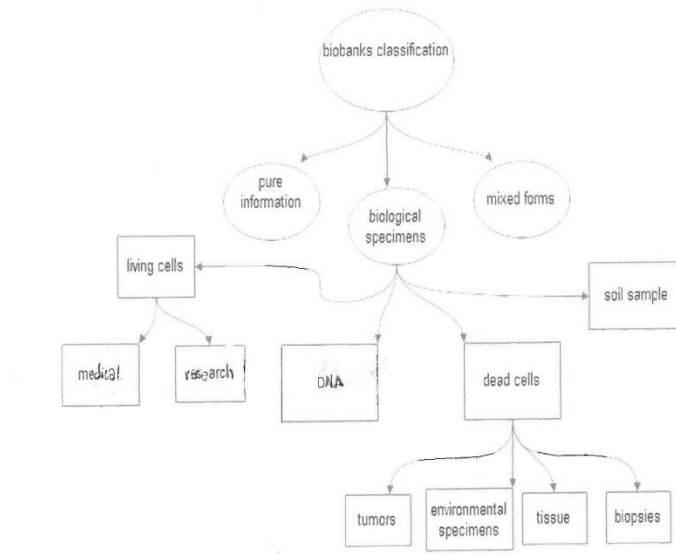
The legal status of human tissue has been an issue for consideration over the last decade, making it essential to determine who has rights over tissue samples, how they can be used and under what circumstances.⁴⁰⁹ The law has traditionally regarded human tissue samples as having no legal status. However, the development of new technologies and the increasing importance of biological samples in medical research has given human tissues a new value and importance. Ingrid Brena’s results on surveying biobanks pertaining to sample ownership revealed that 8 out of 14 biobanks considered the sample as their property, 3 biobanks regarded the donor as unique proprietor and 3 biobanks affirmed that the samples do not have an owner.⁴¹⁰ It is concerning that 50% of the surveyed biobanks consider they are entitled to property rights which could lead to illegal commercialisation. The commercialisation of human tissue is prohibited under article 22 of the Regulation on Sanitary Disposal of Human Organs, Tissues and

⁴⁰⁸ Gibbons 330

⁴⁰⁹ P Martin and J Kaye, ‘The Use of Biological Sample Collections and Personal Medical Information in Human Genetics Research, Issues for Social Science Research and Public Policy’ (Background paper for Wellcome Trust workshop on ‘The Collection of Human Biological Samples for DNA and Other Analysis’) 37

⁴¹⁰ Brena, ‘Biobanks in Mexico, legal aspects (Biobancos en Mexico, Aspectos Juridicos)’

Cadavers (1985). The use of eggs and sperm are covered independently. The content of biobanks can be extremely varied, as shown in the diagram below.⁴¹¹ Fundamental rights can be involved in more ways than just genetic practices.



Tissues and cells are typically the object of biobanks. The currently enforced Mexican norms dealing with the donation of cells, organs and tissues were initially based around organ transplantation⁴¹² and were not concerned with samples for research. They were not originally designed to provide a regulatory regime for research using human tissue. Hence, organ donations could only be used for transplantation purposes. However, in 1997, the term 'cell' was included in the regulation regarding the disposition of organs, tissues and their compounds. The definition of concepts, such as cells, tissues, and what is understood to comprise

⁴¹¹ IBMT, 'Innovative Technologien für die Biomedizin' (*Fraunhofer-Institut für Biomedizinische Technik*, 2006) <<http://www.ibmt.fraunhofer.de/>> accessed 13 March 2012

⁴¹² 'Federal Regulations for the Control of Organs, Tissues and Cadavers of Human Beings' ('Reglamento Federal para la Disposición de Órganos, Tejidos y Cadáveres de Seres Humanos')

artificial reproduction, is included in the General Health Law Rules on Health Research.⁴¹³

Marcia Medrano highlighted that such reform came because of the boom in genetic experimentation at that time. Genetic experimentation would be covered by the section entitled “Disposition of organs, tissues and their compounds.” Additionally, it was stipulated that improper use of organs, tissues, cells and cadavers from human beings, would be against the law and public order.”⁴¹⁴ In the opinion of Medrano,⁴¹⁵ by 1997, the reform was a very superficial framework.

The current minimum guidelines on transplantation, however, cannot be directly applied to biobanking. The General Health Law needs to differentiate between organs and tissues. Each of them requires specific rules since each of them lead to different legal consequences. For example, storage periods are not the same for population biobanks, clinical biobanks or cord blood biobanks;⁴¹⁶ tissues commonly used for research (such as bone marrow, blood, skin and synovial fluids) involve different ethical issues depending on the potential to reveal sensitive genetic data. Ethical decisions should recognise such differences. Inconsistencies of rules for collecting DNA samples between different national regulatory agencies and also between ethics committees may further hamper prospective studies in this area.⁴¹⁷

⁴¹³ Reglamento de la Ley General de Salud en Investigación Científica (Rules of the General Health Law on Scientific Research)

⁴¹⁴M Muñoz de Alba Medrano, ‘ La Ley General de Salud: La Biotecnología en la normatividad Mexicana ¿Podemos estar tranquilos? (The General Health Law: Biotechnology in the Mexican normativity, can we stay calm? ’ (1998) 96 Anuario Jurídico Nueva Serie, IJ UNAM 96

⁴¹⁵ Ibid 103

⁴¹⁶ VM Serrano-Delgado, B Novello-Garza and E Valdez-Martinez, ‘Ethical issues relating to the banking of umbilical cord blood in Mexico’ (2009) 10 BMC Medical Ethics 2

⁴¹⁷ MD Theilade, LE Knudsen and J Renneberg, ‘Regulatory requirements for inclusion of pharmacogenetic testing in applications for clinical trials’ (2001) 12 The Regulatory Affairs Journal 92

The minimum legal requirements cover extreme situations, such as selling tissue and the commerce of organs, which are prohibited. In order to benefit a larger number of Mexicans, it has been stipulated that organs and tissues must not be taken outside the country. Recently, informed consent became compulsory for donations and the management of biological samples, tissues and cells.⁴¹⁸ According to a preliminary report by University Central Hospital from Asturias, “Encephalic death in Ibero-America, preliminary inform” (*Muerte Encefálica en Iberoamérica*),⁴¹⁹ Mexico is one of the 7 Ibero-American countries with no guidelines or recommendations by scientific societies regarding organ donation.

One Mexican legal stakeholder (Participant G) made the point that differentiating between biological samples can be relevant. “There have been arguments between supervisory and research public institutions. Researchers support the position that DNA is not blood, but something purified from blood.”⁴²⁰ This situation emerged when the supervisory institution requested the research institution ‘to bag’ DNA for transport purposes, as they considered it was blood. “First it is necessary to investigate how blood is defined by the law. It has been required that blood is “bagged” when transported. But DNA cannot be bagged.”⁴²¹ Participant G hinted at the legal consequences originating from this, “hence, technically, DNA would not require an authorisation to be transported outside the country because blood does not require authorisation for this.”⁴²²

⁴¹⁸ LGS

⁴¹⁹ D Escudero, *Encephalic death in Ibero-America, preliminar inform (Muerte Encefálica en Iberoamérica, informe preliminar)* (Coordinación de Transplantes, Hospital Universitario Central de Asturias, 2007) 2

⁴²⁰ Responsible-of-the-legal-department-at-a-public-biobank-Participant:G

⁴²¹ Ibid

⁴²² Ibid

5.2.1 Post mortem tissue

Another relevant topic is tissue from the deceased. The General Health Law has stated that cadavers must be treated with respect and dignity. However, no specific ethical guidance has been provided on the fate of samples from deceased donors in biobanking. The main principle for Mexican organ transplantation is altruism; in this case the families of diseased donors are intended to apply the mechanisms for voluntary donation or the denial of donations at the moment of death. Biobanking implies a different treatment for samples from deceased donors which generally depends on informed consent from the donor when he/she was alive.

5.3 Informed consent

There are also inadequacies in the regulation of consent requirements for research projects in Mexico. Protection for research participants' autonomy is essential. Informed consent is mentioned in the General Health Law, Rules of the General Health Law, local rules on health, rules for health services at the National Institute for Social Security (IMSS), official administrative rules (NOMS), National Commission for the Certification of Health Centres (CNCES) and rights of patients guidelines (CONAMED). Apart from legal guidelines, the administrative guidelines and the NOMs⁴²³ establish ethical requirements for informed consent. As a whole, the specific cases which require signed and written informed consent include hospitalisation of psychiatric patients, surgical intervention, fertility treatment, participation in research projects, any diagnostic procedures implying physical, emotional or moral risk, invasive procedures, procedures which produce physical or emotional pain, and socially invasive procedures which can provoke exclusion or stigmatisation. In applicable cases, the document will be filed as part of

⁴²³ Norma Oficial Mexicana del Expediente Clínico (Official administrative rule for clinical files)

the subject's medical records. The General Health Law Rules on Health Research cover informed consent as follows;

Article 20 Informed consent is the written agreement in which the research subject or his/her representative agrees to participate in the research, with full knowledge on the procedures, their nature and the risks; with capacity of freedom of choice and with no coercion.

Article 21 For informed consent to exist, the research subject (or his legal representative) must receive a clear and complete explanation, so he/she can understand, at least, the following:

- Justification and research objectives;
- Procedures to be used and their purpose, including the identification of experimental procedures;
- Discomfort and expected risks;
- The benefits that can be observed;
- The alternative procedures which could be of benefit to the subject;
- The guarantee of receiving an answer to any question and clarification on any doubt about the procedures, risks, benefits and other aspects related to the research and the treatment of the subject;
- The freedom to withdraw his/her consent at any point and stop participating in the study, with no risk of prejudice to continue his/her treatment;
- The security that the subject will not be identified, and confidentiality of the data related to privacy will be maintained;
- The commitment to provide the subject with updated information during the study, even when this could affect the subject's will to continue his/her participation;
- The availability of medical treatment and compensation to which the subject could have the right, by the health institution, in case of damage directly caused by the research;
- If there are additional expenses, these will be covered by the research funding.

Article 22 Informed consent will be written and must meet the following requirements:

- It will be explained by the main researcher, containing the above mentioned information and following the administrative rule made by the Ministry;
- It will be revised and, if this is the case, approved by the Ethics Commission of the health institution;
- It will indicate the names and addresses of two witnesses and the relation that they have with the research subject;

- It must be signed by two witnesses and by the research subject or his/her legal representative (if this is the case). If the research subject does not know how to sign, his/her finger print will be printed, and another person designated by him will sign; and
- The informed consent will be duplicated. One will be for the research subject and the other for his/her legal representative.

Article 23 In case of research with minimal risk, the Ethics Commission, with justified reasons, will be able to authorise that the informed consent can be obtained in a non-written way. In case of research with no risk, it will be able to allow the researcher to be exempt from the requirement to obtain informed consent.

Article 24 If there was a relationship of dependence, ascendance or subordination between the researcher and the research subject that affect him/her granting his/her consent, the informed consent will be obtained by another member of the research team, independent of the relationship of researcher-research subject.

Article 25 When it is necessary to determine the mental capacity of an individual to grant his consent, the main researcher must evaluate his understanding capacity, reasoning and logic capacity, according to the parameters approved by the Ethics Commission.

Article 26 When it is alleged that the mental capacity of a subject had varied through time, his/her informed consent (or that from his/her legal representative) must be certified by a professional group with recognised scientific capacity and moral standing in the specific areas of research, and an observer independent from the research, in order to secure the suitability of the mechanism to obtain consent and validity through the research.

Article 27 When a psychiatry patient is in an institution for being an 'interdiction subject' (the UK equivalent would refer to 'someone who has been sectioned, or detained, under the Mental Health Act'), apart from complying with the previous articles, it will be necessary to obtain the approval of the corresponding authority.

Clearly in the case of the normal informed consent, it is only intended that specific information be provided making it clear that the study is voluntary. The different types of informed consent constitute a wide topic, in which types can be summarised in the requirement for "either broader, initial consent procedures or multiple requests for consent

over time.”⁴²⁴ “How that consent process should be carried out and using what information will vary from study to study and consent seeking in biomedical practice is known to be variable and selective.”⁴²⁵ In terms of standardisation, Manson and O’Neill have stated that consent forms and procedures do not need to be treated as a trivial matter, rather the contrary.⁴²⁶ A standardisation of consent types is at risk of being oversimplified and far from being effective, it would be inadequate to cover the variable and selective nature of biomedical consent.

In terms of the provision of consent, despite the 2011 amendments to the General Health Law, the regulation of informed consent does not provide further details on biobanks. Hence, either blanket or single purpose consent for this situation would be admitted. It has been written in the law that individuals need to be able to understand their right to withdrawal. For this reason, the participant’s right to withdraw participation can be assumed. Nothing has been said of the sample’s fate if withdrawal occurs, which suggests that further guidance on the terms and conditions for withdrawal are required. It is necessary to clarify the traditional consent mechanisms for complete protection of participants. Anonymised samples are the main source of biomedical research.

If a participant from the Mexican research project on ancestry HapMap decided to exercise his newly guaranteed right, it would be too late; the samples are anonymised before the research starts.⁴²⁷ Under the new additions, anonymisation is a non-regulated activity that would prevent participants from exercising their ‘right to know.’ The regulation of consent should cover essential matters, such as secondary uses of data, identification mechanisms, e.g. anonymity and coding, re-contacting

⁴²⁴ DM Secko and others, ‘Informed consent in biobank research: a deliberative approach to the debate.’ (2009) 68 Soc Sci Med 781

⁴²⁵ Manson and O’Neill 192

⁴²⁶ Ibid 191

⁴²⁷ Responsible-for-the-research-department-at-a-public-biobank-Participant:A

participants, participants' withdrawal, the return of results to participants, accessibility and implications. Clear informed consent guidance would benefit not only participants, but researchers, for instance, it has been shown that information provided to participants to avoid accusations of discrimination positively impacts on participation rates.⁴²⁸

5.3.1 Governance perceptions on informed consent

Basic consent requirements “far from being ethically fundamental, presuppose other more basic ethical and legal standards.”⁴²⁹ The following are examples of how stakeholders perceive the governance of informed consent, not necessarily in terms of biobanks, but based on how these could indirectly be covered by existing guidelines. (See Table 7 in annex p.8)

For most participants, informed consent is currently not covered or too generally governed in terms of biobanking. The approach taken by the CNB institution (currently responsible for the governance of informed consent) is too general and is unfit for biobanking purposes. A typical misunderstanding of consent happens when it is seen as “a stamp of approval for medical practice.”⁴³⁰ The current goals of the Mexican CNB's are centred on encouraging informed consent to be seen as a process, not a document.⁴³¹ Informed consent must reflect patients and their families' motivations for participation since the proliferation of genetic testing involves knowledge on the genetic component of their risk for disease, as well as risk perceptions, preferences and level of involvement. The availability of these choices must be established in the original informed consent.

⁴²⁸ Cambon-Thomsen, Rial-Sebbag and Knoppers 375

⁴²⁹ Manson and O'Neill 78

⁴³⁰ B Prainsack and E Buyx, 'A solidarity-based approach to the governance of research biobanks' (2013) 21 *Medical Law Review* 88

⁴³¹ Legal-adviser-at-an-ethics-public-advisory-institution-Participant:H, *PhD Thesis fieldwork* (2012)

Even when the creation of the CNB was focused on health care and research, it seems that more attention has been focused on health areas rather than research. According to the Commission's guidelines,⁴³² informed consent is an instrument for respecting a person's autonomy in research and health areas, consisting of a continuous process which involves health staff and patients. However, some aspects have been left behind, especially in research. In the words of Participant I, "there is nothing on biobanks but in clinical areas, it is necessary to differentiate between medical and research consent which would be applicable to biobanking."⁴³³

Guidelines by the CNB present an imbalanced focus; they are mostly directed to patients, leaving research subjects unprotected. "Consent will be used by health staff in order to inform a competent patient on illnesses, therapeutic procedures, diagnostic procedures, risks, benefits and feasible options,"⁴³⁴ and "the informed consent document is the evidence that a doctor has provided information to a patient, who has understood such information."⁴³⁵ The legal qualification of the person in charge might not be the same when samples are obtained within the healthcare context or within the research context."⁴³⁶ Another observation is that the Commission's role is purely advisory, and even under this governance hierarchy it cannot invigilate or ethically advise the numerous ethics committees in the country.

⁴³² Comisión Nacional de Bioética (National Bioethics Commission) CNB, 'Consentimiento informado' [http://www.conbioetica-mexico.salud.gob.mx/interior/temasgeneral/consentimiento_informado.html](http://www.conbioetica-mexicosaludgobmx/<http://www.conbioetica-mexico.salud.gob.mx/interior/temasgeneral/consentimiento_informado.html)> accessed 2 October 2012

⁴³³ Responsible-of-the-Genetics-department-at-a-public-ethical-advisory-institution-Participant:I

⁴³⁴ CNB

⁴³⁵ Ibid

⁴³⁶ Cambon-Thomsen, Rial-Sebbag and Knoppers 1118

Informed consent is not seen as a protective element for research subjects but as a protective measure for patients. Ethical guidelines by the CNB for biobanks should cover both health services and research areas, since both of them deal with biological samples. There may be types of research that do not represent any hazard to patients, but these must be regarded as exceptions and only official guidelines should decide on exemptions to informed consent.

5.4 Federal legislation on data protection

In terms of National Law, the Mexican Constitution guarantees data protection through a 'right to information', which is to be enforced by the Mexican State. Hence, private information and personal data will be protected according to the law: "all persons will have free access to public information without the need for justification or proving interest;"⁴³⁷ and all persons will have free access to their personal information and will be able to correct misinformation.

Personal data is regulated by the Mexican Federal Law on Transparency and Access to Public Government Information (*Ley Federal de Transparencia y Acceso a la Información Pública Gubernamental*) (2003) (LFTAIPG) which sets forth general principles of public information laws. It should be noted that this legislation applies exclusively to governmental institutions. The Federal Law on Protection of Personal Data Held by Individuals (*Ley Federal de Protección de Datos Personales en Posesión de los Particulares*) (2010) includes a definition of personal data, the regulation of personal genetic data as a sensitive matter, and the protection of personal data and responsible subjects. The Statutes for the Protection of Personal Data (*Lineamientos de Protección de Datos Personales*) (2009) were enacted by the Federal Institute of Access to Public Data (*Instituto Federal de Acceso a la Información*) (IFAI) in order

⁴³⁷ The Mexican Constitution Article 6

to protect the personal data stored in electronic databases and related networks.

In 2010, the Federal Law on Protection of Personal Data Held by Individuals was enacted with no clear constitutional basis. It should be noted that genetic data is sensitive data, and the latter is covered by the Statutes for the Protection of Personal Data. “Sensitive data is any information that affects the most intimate sphere, or whose misuse can cause discrimination or involves related risks for the individual.” According to article 3-IV, the information contained in Mexican biobanks is a sensitive matter. Biobanks’ typical uses, consisting of storing samples and associated data, range in scope from small hospitals and research centres to large national organisations. Inconsistencies with respect to data protection in Mexican law reflects an absence of integrated policy.

Both scientific and academic communities in Mexico are aware that the genetic research boom and have questioned how data from sample donors is managed.⁴³⁸ However, there are no rules that respond to the specific needs of sharing samples, citizens’ participation, sample donation and research in general.

One suddenly has the dilemma of whether to rescue the existing framework, just amend it, or ‘wipe the slate clean’ and encourage a new instrument. The 1987 modifications to the General Health Law came as a necessity to regulate blood banks. Diseases such as AIDS were proliferating and more controls on blood transfusion were required to avoid HIV infection spreading. Then the rules on disposition of organs, tissues, transplants and so on, emerged from demands to control blood and organ donation.”⁴³⁹

It is fair to say that a framework that comes from 1987 cannot deal with the present situation.”⁴⁴⁰ Participant D agreed that “it seems contradictory that after 10 years of public and private biobank

⁴³⁸ Notimex,

⁴³⁹ Responsible-of-the-ethics-department-at-a-public-biobank-Participant:D

⁴⁴⁰ Ibid

proliferation, no concrete answers have yet been found”. Federal regulations provide no specific biobanking guidelines, only one related local regulation has been identified.⁴⁴¹ Evidently, biobanking legislation is applied in an inconsistent manner with no uniformity. The current health legislation, including the latest reforms, constitutes partial controls for biobanking, which is in some cases, a reference for potential legal interpretation.

5.4.1 Data protection perceptions applicable to biobanks

In the opinion of Participant J, the currently enforced data protection regulations’ confusing effects are partly due to “the inclusion of genetic data in the coverage by LFTAIPG on personal data; and to this framework’s failure to cover data preserved by private institutions.”⁴⁴² The Statutes for the Protection of Personal Data regulate data held by private institutions, but “it is not clearly specified whether this includes genetic data in any of the 9 articles on personal data.”⁴⁴³ This is subject to interpretation and if we interpret that personal data includes genetic data, the consent for the use of such data is assumed by opposition, in other words, if no-one makes clear their disagreement on further uses, it may be used; it is open. However, in the case of public institutions, consent for further uses must be stated. In the opinion of the data protection expert (participant J), the information preserved by public institutions seems to be better supervised, through periodical inspections of the institutions.⁴⁴⁴ Hence, biobanking should be covered by both public and private data protection regulations.

⁴⁴¹ Ley reguladora de la base de datos geneticos para el estado de Chihuahua (Rules for genetic databases for the state of Chihuahua) (Mex)

⁴⁴² Datap-protection-expert-at-a-public-research-institute-Participant:J

⁴⁴³ Ibid

⁴⁴⁴ Ibid

Participant A also believes that it has not been specified whether personal data includes genetic data.⁴⁴⁵ Similarly, participant G understands that “IFAI rules do not apply. IFAI protects personal data, in which genetic data is not included. As far as I know, this has not been defined.”⁴⁴⁶ However, participant C believes that IFAI rules may apply to biobanks. “We have general rules. At the moment, individuals dealing with personal data are requested to declare it. However, there is much to do on genetic data, operation, defence mechanisms, inspection mechanisms, data access and rectification.”⁴⁴⁷ This is participant I’s clarifying opinion:

“The current legislation on personal data has not been explicit enough to clarify what samples contain health data. These are sensitive due to the genetic data contained and need different protection. That should be emphasised; we have to go deeply and be more protective with samples containing genetic data, rather than just health data. The data protection systems, both public and private, involve some obligations but not policies on biobanks.”⁴⁴⁸

For participant O, the problem is not simply regulation; “data protection is starting to be carried out. However, people doubt that the government can keep their data safely. Databases were the subject of illegal trading in Mexico City markets not long ago.⁴⁴⁹ Participant J added that nearly one year after the Law on Data Protection for Private Individuals was enacted, it is not clear whether the law has been effective. “It is too little time to know if the law is complying with initial expectations.”⁴⁵⁰ In participant J’s opinion, an expert authority for protecting personal data (clinical data, biometric data) and regulation for

⁴⁴⁵ Responsible-for-the-research-department-at-a-public-biobank-Participant:A

⁴⁴⁶ Responsible-of-the-legal-department-at-a-public-biobank-Participant:G

⁴⁴⁷ Legal-researcher-at-a-public-research-institution-Participant:C, *PhD Thesis fieldwork* (2012)

⁴⁴⁸ Responsible-of-the-Genetics-department-at-a-public-ethical-advisory-institution-Participant:I

⁴⁴⁹ Expert-on-Bioethics-Philosophy-and-Law-at-a-Public-university-Participant:O

⁴⁵⁰ Dataprotection-expert-at-a-public-research-institute-Participant:J

biobanks are absent at the moment. Participants D and E agree with the idea that biobank transparency has not been included by the IFAI.⁴⁵¹

Ingrid Brena has stated that the Statutes for the Protection of Personal Data, which regulate data sharing and the management of personal data, are applicable to genetic data “because of its content.”⁴⁵² This argument could be challenged from a constitutional basis; it is sustained by the Mexican Constitution that the purpose of LFTAIPG (2003) applies exclusively to governmental institutions. Therefore, data protection of biobanks in Mexico, a challenging topic that requires integral governance, is not governed as such by the current Mexican data protection laws.

5.4.1.1 Data protection mechanisms

Dr. Brena conducted a survey as part of the 2008 International Colloquium ‘Biological samples and biobanks for biomedical research’;⁴⁵³ in which 14 questionnaires were completed by various biobanks in Mexico. The findings showed that it was not clear how the confidentiality of genetic data for research purposes would be achieved without established procedures. According to the study, all 14 biobanks store biological samples and protect the confidentiality of their participants following various procedures. For example, samples are anonymised and only the codes remain available for the samples. These codes can reveal the place where the sample comes from, the participants’ gender, even the specific population of origin, but never the name of the person. Two biobanks reported that they dissociate all personal data by the end of the

⁴⁵¹ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

⁴⁵² I Brena, ‘Privacidad y confidencialidad de los datos genéticos (privacy and confidentiality within genetic data)’ Boletín Mexicano de Derecho comparado <<http://biblio.juridicas.unam.mx/revista/pdf/DerechoComparado/123.5/cnt/cnt7.pdf>> accessed 06 May 2013

⁴⁵³ Brena, ‘Biobanks in Mexico, legal aspects (Biobancos en Mexico, Aspectos Juridicos)’

project.⁴⁵⁴ There are access restrictions to the freezers where the samples are kept and not all of the staff have access to the samples. All the surveyed biobanks asked for informed consent from participants. However, in two biobanks, where research is centred on purposes other than those stated in the initial informed consent, no re-consent was requested. By 2008, it was practically optional for biobanks to follow data protection guidelines. Of the fourteen biobanks, only one was found to use systematic controls to protect data; another biobank complied with the ‘existing data protection national law’. This single biobank reported to be following general data protection guidelines, which in principle are binding only for governmental institutions.

5.4.1.2 Data and sample sharing

The problem of inconsistency extends to the protection of participants’ privacy and confidentiality. Sample and data sharing is not regulated and it is not clear how this would happen. For instance, Participant B commonly faces dilemmas on sample treatment in various circumstances:

“I don’t know what happens with the samples if the researcher that started a project leaves the institute and goes abroad. What happens if the funds were from the government? How to establish a protocol, benefit sharing between participants and researchers, publications? It would be good to have some standards at the national level. Each institute has rules but in the end everybody is free to do what they want to do.”⁴⁵⁵

Participant A, for example, emphasises that currently, each institute holds the “ownership” of samples stored.

“Regarding the Cancerology biobank, even if I had a good research project, I will not be able to access their tissues or their patients, it is just cancerology. They may have patients’ consent to prevent sharing the samples with institutions which have nothing to do with cancerology. There are particular concerns of particular institutions and the samples of their own patients...For the release of previously collected samples, INMEGEN requires a detailed research project.”⁴⁵⁶

⁴⁵⁴ Ibid

⁴⁵⁵ Researcher-at-a-public-biobank-Participant:B

⁴⁵⁶ Responsible-for-the-research-department-at-a-public-biobank-Participant:A

The main principles regarding procedural standards for data sharing policy “should be transparent, equitable, practicable and give clear and consistent decisions.”⁴⁵⁷ This is one of the main principles followed by the UK Medical Research Council (MRC).

5.4.1.3 The impact on governing data protection on the national economy

Lina Ornelas, General Director of Classification and Personal Data at IFAI reported in 2012 that one of the advantages of the Federal Law on Protection of Personal Data Held by Individuals has been attracting foreign investment into the country.⁴⁵⁸ The recent law has unified data protection criteria at the national level. Clinical trials are reportedly an area in expansion. The IFAI representative highlighted that “medical expenses are cheaper in Mexican currency than in Euros, for example, and the trials would be more protected by the aforementioned data protection law for individuals.” Additionally, these measures should avoid foreign investors being able to process data in jurisdictions where the law is more relaxed or the taxes lower. This makes Mexico reliable for international investment, since data protection is a great concern among democratic nations these days.

New sanctions have been implemented and, as a result, the IFAI will be able to impose fines of up to \$3 million dollars (if offences are repeated with sensitive data) and establish self-regulation for private companies, including corporative rules. The impact this would have on the Mexican economy has created great expectations:

“If there is an independent regulatory framework and authority, such as IFAI, European countries could invest in Mexico. Current trading agreements request us to provide a suitable level of data protection. When Argentina was regarded by Europe as a safe destination for data

⁴⁵⁷ Medical Research Council, *Principles for access to, and use of, MRC funded research data* (MRC policy on research data-sharing, 2011) 8

⁴⁵⁸ E Camacho, ‘Proteger datos atraerá capital foráneo: IFAI (Data protection will attract foreign capital: IFAI)’ *El Universal*
<<http://www.eluniversal.com.mx/finanzas/93225.html>> accessed 22 February 2012

*protection, this country received more than \$1 billion dollars through direct investment per year, mainly on clinical data. This is what Mexico is after.*⁴⁵⁹

To a lesser extent, the IFAI representative stated that the law was also designed to protect individuals. “In 2011, we received complaints by individuals that several companies were not protecting their data well enough. Anomalies were detected and people did not want their data be disclosed with no controls.”⁴⁶⁰

5.4.1.4 Data protection on health research

Current legal regulations regard genetic data as sensitive. However, no ethical guidance is provided on how sensitive data protection should be achieved within biobanking research. In Mexico, both public and private research deals with sensitive data, which may need more protection mechanisms and guidance than just the general rules from the Federal Law on Protection of Personal Data Held by Individuals (2010).⁴⁶¹ This is highly problematic since clinical data management needs to be safely stored under appropriate conditions, due to the potential for identification of individuals from databases linked to recruitment. Not only is research subjects and patients’ data at risk of being unlawfully disclosed, but also those associated with their family members. Specific guidance is required as research is designed to generate knowledge rather than individual data, and “research laboratories are not necessarily held to the same standards as clinical laboratories.”⁴⁶² The original consent for the study needs to establish what approaches will be taken regarding the disclosure (or non-disclosure) of individual genetic research results, for example, the return of results, re-contact processes, and the conduct and dissemination phases of the

⁴⁵⁹ Ibid

⁴⁶⁰ Ibid

⁴⁶¹ Ley Federal de Protección de Datos Personales en Posesión de Particulares (Federal Law on Protection of Personal Data Held by Individuals)

⁴⁶² N Lockart, “Ethical and Legal Implications of Return of Research Results to Participants in Biospecimen Studies” (ELSI Congress, South Carolina, April 2011)

follow-up study. The required guidance on health research data protection could be introduced by institutional codes of ethics.

Research ethics for privacy is governed by article 16 of the General Health Law rules for health research.⁴⁶³ Individual privacy of research subjects will be protected within research involving humans, by identifying such individual subjects only if they authorise it and only if it is required by the research results. LRECs (Local Research Ethics Committees) have the authority to decide on privacy matters related to biological samples. The definition of health data encompasses genetic data too. It has also been suggested by Kosseim et.al⁴⁶⁴ that data should be protected within research areas and regarded as sensitive data because they can reveal racial and ethnic origins.

Currently anonymisation approaches have been used to protect the participant beyond initial consent from unintended identification and to enable the broader use of data. However, anonymisation involves significant disadvantages, which include the impossibility to fully anonymise large amounts of clinical data. Menasco⁴⁶⁵ has concluded that a great number of anonymisation attempts have resulted in limited use and an imbalanced cost of the clinical study. Of particular relevance are concerns related to the use of data by third-party researchers who have potential access to sensitive data. The criteria followed by Mexican regulations cover general aspects of privacy and consider that the risk of privacy violations for individual sample donors or genetic discrimination does exist but is insignificant. IFAI could be responsible for biobanking data protection but it has limited competence, due to the unclear coverage of its public transparency rules.

⁴⁶³ Rules of the General Health Law on Scientific Research (Reglamento de la Ley General de Salud en Investigación Científica)

⁴⁶⁴ P Kosseim, M Letendre and BM Knoppers, 'Protection genetic information: A comparison of normative approaches ' [2004] GenEdit 1

⁴⁶⁵ Manasco 25

5.5 Current guidance and institutions on health research

This section will identify the most relevant ethical guidelines, consisting of research ethics principles. These are gathered from the procedural rules as well as the General Health Law, outlining their reform towards more specific principles. The current involved institutions will be introduced.

Relevant rules for research involving humans are provided by article 14 of the secondary legislation ‘General Health Law Rules for Health Research.’⁴⁶⁶ The ethical rationale of research relies on ethics committees rather than on enforced rules. The main rules for research involving humans are provided by primary legislation overseen by the National Ministry of Health, through the General Health Law article 98. The scientific and ethical justification for the research include the following criteria: previous experimental basis on animals, the impossibility to obtain scientific results by other means, high probabilities of benefit over predicted risks, request for the written informed consent of the research subject or his representative, participation of experienced health professionals, the committee’s approval, and approval by the manager of the health institution.

The General Health Law Rules for Health Research, which are secondary legislation, state that protection for research subjects is based on principles of “human dignity, human rights and welfare.”⁴⁶⁷ Mexican regulation normally establishes principles in primary Acts, for example, the General Health Law and its procedural rules on health research. The fact that a secondary legislation establishes principles and not procedures is unexpected. If the principles are included in a regulation for procedures, there is no ‘place’ to include the expected procedures to comply with the

⁴⁶⁶ Rules of the General Health Law on Scientific Research (Reglamento de la Ley General de Salud en Investigación Científica)

⁴⁶⁷ Ibid Article 13

protection of human dignity. This disproportional responsibility is normally expected to be established by rules. Instead, this fundamental prerogative has been delegated to ethics committees. Therefore, all institutions which depend on the public health sector have ethics committees for supervision purposes such as for the authorisation of research projects. “Some biobanks require approval of their protocol and their informed consent documents from the research ethics committees. Nevertheless, once the research is underway, the committees, in most cases, do not carry out any supervision of the biobank or the research.”⁴⁶⁸ According to the General Health Law Rules, health research through clinical trials can only be authorised by the Mexican health authority, that is, COFEPRIS.

Although the approved reforms show significant progress, specifically in the human genome area, it seems that the rest of the related areas still present legal gaps (e.g. the regulation of data protection within scientific research). In Mexico, this framework, the Regulation on Scientific Research, intends to avoid undermining human rights in scientific research:⁴⁶⁹

- a) Respect to human dignity, protection of human welfare and other rights are the criteria that must prevail in any research that involves humans (article 13).
- b) The Ministry of Health will be in charge of the evaluation of research activities in the national territory (article 5-IV).
- c) Research in humans must be based on previous research in animal labs or in other facts whenever it is not possible to obtain that knowledge by other means (article 14-I, III).
- d) Research in humans requires approval from the Commissions of Ethics, Bio-security and Research (article 14-VII).

⁴⁶⁸ Casabona and Simons 277

⁴⁶⁸ *Lithuanian Law on Ethics of Biomedical Research*

⁴⁶⁹ Rules of the General Health Law on Scientific Research (Reglamento de la Ley General de Salud en Investigación Científica)

- e) For human research, the informed consent from the research subject, legal representative or the Ministry of Health, is indispensable (articles 14-V, 20, 21, 36 and 43) (with the exceptions of articles 17-III and 23).
- f) For human research within communities, the responsible researcher will have to obtain, apart from the individuals' consent forms, the approval from health and civil authorities within the community (article 29).
- g) In research where under 18s participate, it must be secured that similar studies have previously been performed with adults and with animals, except when the aim is to study particular conditions in new-borns or other particular ages (article 35).
- h) Research in pregnant women must be preceded by previously performed studies in non-pregnant women that prove safety, except from those specific studies that require such a condition (article 44).
- i) For research in subordinate groups, one of the members of the population who will participate in the study must take part in the Ethics Commission (article 58).
- j) Research in clinic pharmacology must be preceded by previous finished clinic studies (article 67).
- k) Authorisation from the Ministry will be required for experimental research in individuals and communities and in that which implies construction and management of recombinant nucleic acids (articles 31, 62, 65, 69, 71-73, 88 and 102).
- l) Ethics, Bio-security and Research Commissions will be constituted in all those institutions where health research is performed (articles 99, 104, 109, 105, 110, 106 y 111).

The General Health Rules for Health Research classifies research risks into minimal, medium and high.⁴⁷⁰ The potential risk of discrimination tends to depend on the type of research being carried out. Participant F remarks that this classification

“refers to physical questions, not emotional. For example, I have seen research protocols on obesity, they are ‘just questions,’ but questioning someone on overweight issues is conflicting; this may result in negative

⁴⁷⁰ Ibid Article 17

*consequences. It must be determined who will respond in such cases; the biobank or the researcher? Who will respond for the data?*⁴⁷¹

With respect to professional operation requirements, the UNAM study reported that ten biobanks were asked for their research protocols. It was found that out of these ten biobanks asked by the Ministry of Health assistance regarding governance, two of them follow the “NOM for the management of biological materials and international guidelines” (2005). Only one biobank follows the guidelines of the University of Cambridge to store brain tissue. In the opinion of Ingrid Brena, frameworks like NOM are not sufficient for the operation of biobanks. The 2011 reforms⁴⁷² could definitely make a difference if they presented concrete procedures.

The role of access to health care has a great impact on biobanking. Patients may not evaluate their participation objectively if they feel they have no choice but to participate in a trial, which can be through sample donation, or to obtain a medicine or a treatment they need. Participation in a research project might be the only choice for a patient to receive treatment, a situation aggravated by illiteracy. 8% of the Mexican population are illiterate and it has been calculated that 19% of patients of the General Hospital (Mexico City) reflect these statistics. The General Hospital provides health care for poor people who do not have a job (employed people are assisted by ISSSTE or IMSS) or people who cannot afford private medical treatment. Some people in Mexico are illiterate in Spanish since they speak other indigenous native languages.⁴⁷³ Poverty and illiteracy are important factors to consider when enrolling subjects for clinical trials, particularly in a developing country like Mexico.⁴⁷⁴

⁴⁷¹ Legal-researcher-at-a-public-research-institution-Participant:F

⁴⁷² , *Decreto por el que se adiciona la fracción IX Bis al artículo 3o.; se adiciona un Título Quinto Bis y su Capítulo Único; y el artículo 421 Ter de la Ley General de Salud. (DEGREE which adds section IX Bis to article 3, the title "V bis" and its unique chapter and article "421 Ter" of the General Health Law)*

⁴⁷³ Comisión Nacional de Bioética (The National Commission of Bioethics) 75

⁴⁷⁴ Virk 22

5.5.1 Reforms

The parliamentary reform, which encouraged these new committees, was enforced in December 2011.⁴⁷⁵ Some biobanking issues should hypothetically be solved by a bio-safety committee; the biosafety committee was responsible for the regulation of the use of ionic radiation or genetic engineering techniques. Since these committees are covered by the General Health Law, the committees' remit can't be extended to other areas involving biobanking, for example clinical trials by the pharmaceutical industry.

“The national health care centres (public, social or private) will have the following committees;

- A hospital bioethics committee for the solution of problems regarding medical attention (for the analysis, discussion and support of decision making of bioethical problems within clinical practice and health teaching). These committees will permanently promote institutional ethical guidance for members of staff.
- If health centres perform research on humans, a committee of ethical research will be responsible for the evaluation of research protocols. It will provide ethical recommendations and institutional guidelines for health research. Recommendations will be reviewed.

Hospital and research committees must follow the enforced legislation and the criteria established by the National Bioethics Commission. The committees will be multi-disciplinary, and these must be formed by medical staff with different areas of expertise: psychology, nursing, social work, sociology, anthropology, philosophy or legal professionals. Members of staff should have bioethics training. Each committee must have representatives from the population groups involved in research, covering a gender quota.”⁴⁷⁶

⁴⁷⁵ , *Decreto que incluye el artículo 41 bis y reforma el artículo 98 de la Ley General de Salud (Decree which includes article 41 bis and amends article 98 of the General health law)*

⁴⁷⁶ LGS

This is evidence of the “patchy” methodology regarding health research. The amendments to the General Health Law from 2011⁴⁷⁷ led to a great number of research ‘commissions’ having their original registry invalidated. Research Commissions for Research, Ethics and Bio-security before this are not valid since they were not established under the current legislation. Many Committees have formed with diverse titles according to their established function i.e. ethics committees, hospital bioethics committees, ethical clinics committees, bioethics sub-committees and research ethics sub-committees.⁴⁷⁸

Hospital committees must follow the parameters given by article 41 *bis* of the General Health Law,⁴⁷⁹ while health research is covered by article 96 of the same regulation.⁴⁸⁰ Accordingly, health research involving humans requires the creation of a research committee, an ethics committee or a bio-safety committee, depending on the activities performed by the institution. The committees must be formed by a minimum of three scientists with broad experience in health research; no detailed description of the professional background of the members is provided. This applies only to health institutions.

5.5.2 Involved key governing institutions

According to Lipset, legitimisation is “the capacity of the system to engender and maintain the belief that the existing political institutions are the most appropriate ones for the society.”⁴⁸¹ When legitimacy cannot be sustained, the only way to inspire a sense of reliance among citizens is suitable implementation of policies. Nevertheless, the current

⁴⁷⁷ Decreto por el que se reforman y adicionan diversas disposiciones de la Ley General de Salud (Decree amending various dispositions of the General Health Law)

⁴⁷⁸ MJ Khoury and others, ‘Challenges in communicating genetics: a public health approach’ (2000) 2 *Genet Med* 87

⁴⁷⁹ LGS

⁴⁸⁰ *Ibid*

⁴⁸¹ SM Lipset, *Political man, the social basis of politics* (New York: Doubleday ed, 1960) 77

implementation of biobanks in Mexico has led to confusion regarding alternatives for biobanking practices, starting by directly involved institutions. Involved key governing institutions are as follows:

5.5.2.1 The National Council for Science and Technology (CONACYT)

The National Council for Science and Technology (*Consejo Nacional de Ciencia y Tecnología*) (*Conacyt*) was created by Congress as a public and decentralised organism of the Public Federal Administration, responsible for the elaboration of science and technology policies in Mexico.

5.5.2.2 The National Institute of Genomic Medicine (INMEGEN)

The emerging discipline of public health genetics in Mexico aimed to maximise the benefits of genomic medical advances.⁴⁸² Based on this principle, General Health Law and the regulations concerning the national health institutes were modified in order to create INMEGEN in 2004. The creation of The National Institute of Genomic Medicine was based on the conception of genomic sovereignty in Mexico.⁴⁸³ INMEGEN, as the official centre for genomic medicine, is intended to interact with the Mexican Parliamentary Congress.

However, the operation of INMEGEN in Mexico has been associated with politics to an excessive extent, a fact that has delayed the social legitimisation on the institution, which will depend on rules reconciling the interests of the public and industry fairly. The pharmaceutical industry is involved and towards this, the protection of human dignity is an essential principle of political ideology.

⁴⁸² Khoury and others 199

⁴⁸³ E Schwartz and A Mendez, 'The law of Genomic Sovereignty and the protection of "Mexican genetic patrimony"' (2012) 2 *Medicine and law* 284

5.5.2.3 The Federal Commission for the Protection against Sanitary Risk (COFEPRIS)

COFEPRIS was not specifically created for biobanking purposes; however, it is fundamental for the current operation of biobanks at legal and ethical levels. It is part of the National Ministry of Health, and is a decentralised organisation with technical, administrative and operational autonomy. Its purpose is to protect the population against sanitary risks through sanitary regulation, control, and promotion under a unified leadership, with a view to providing unity and homogeneity to the policies determined. The initial objective of the Commission was extended to a public policy, with the intention of preserving the population's health more efficiently.

5.5.2.4 The UNAM (National Autonomous University of Mexico) and other academic institutions

Another significant governance area within the Mexican public sector are the academic research institutions. A representative example is the UNAM, which develops most of the academic research in the country. Most academic institutions have had no choice but to found research committees for general evaluation on procedural compliance regarding the management of biological samples. Diverse ethical guidelines, including international, integrated self-regulatory frameworks, followed in the absence of specific official ethical guidelines for research.

UNAM ethics guidelines recommend “the reading of the Universal Declaration of the Human Genome and Human Rights UNESCO,⁴⁸⁴ genetic data protection UNESCO⁴⁸⁵ and published documents by the committee of the Human Genome Project HUGO⁴⁸⁶ with no analyses on

⁴⁸⁴ The Universal Declaration on the Human Genome and Human Rights

⁴⁸⁵ UNESCO International Declaration on Human Genetic Data

⁴⁸⁶ Human Genome Organisation, ‘HUGO’ (2016) <<http://www.hugo-international.org/>>

how these international guidelines could be applicable to the different operation of institutes related to biobanking activities.

An example of principles followed by the Biomedical Research Institute at UNAM follows that: “research must be led by qualified researchers in the area, with the participation of clinical researchers familiarised with the pathological purpose of the study”⁴⁸⁷ and “all protocols must be previously evaluated by the committee specialising in research with humans, which involves the participation of biomedical staff, in order to carry out research involving humans.”⁴⁸⁸ The participation of researchers as members of the committee is recommended only if it is complemented with ethics expertise in biomedical research.

An example of a sanction framework can be taken from one of the biobanks within the UNAM Institute of Biomedical Sciences, which has a Committee of Scientific Integrity, responsible for dealing with accusations of unethical activities regarding research. Presumably, this includes biological samples. The committee is responsible for initiating investigations on ethical misconduct and deciding what cases should proceed. If it does not proceed, the allegation has no effects. If it proceeds, the committee produces a report which is taken to a university council for a final resolution.

5.5.2.5 The National Bioethics Commission (*Comisión Nacional de Bioética CNB*)

The National Commission of Bioethics was established in 1992 by a group of academics in order to discuss issues related to Bioethics. It was created in order to establish public health policies in relation to bioethics. One of the main responsibilities of the commission is to encourage public and private medical institutions to use bioethics

⁴⁸⁷ UNAM

⁴⁸⁸ Ibid

committees and the registration of such ethics committees,⁴⁸⁹ not for official monitoring purposes but for consultation and study purposes. Since 2005, it has been recognised by a presidential decree as a more independent body in operation, although its budget still comes from the Ministry of Health. The institution was intended to encourage a bioethical culture in Mexico, and its mandate is directed to activities in public policy, infrastructure and public awareness. It is the official body responsible for defining national policies on bioethics and consultation. Nevertheless, the Mexican Commission of Bioethics does not provide biobanking guidelines. (See Table 3 on annex p. 4)

5.5.2.6 Ethics committees

The first institutions entitled to deal with biobanking risks in Mexico are ethics committees; “the ethical review board bears the primary responsibility for setting up requirements for the coding and secure handling of information.”⁴⁹⁰ Hence attention to ethics committees is fundamental.

As a result of current Mexican health regulations being primarily based on medical grounds, the 2011 reform focused on health institutions, rather than those for research. By the end of 2012, a year after the reform, committees were still in the process of regularisation and their role was seen as one of ethical advice, rather than oversight. Hence, biobanks are still far from being a priority subject of ethical attention from an independent research focus. (See supporting fieldwork statements on Table 4 annex p. 5)

⁴⁸⁹ Comisión Nacional de Bioética, ‘Comités Hospitalarios de Bioética (Bioethics Hospital Committees)’ (*Comisión Nacional de Bioética (National Bioethics Commission)*, 2 August 2013) <<http://www.conbioetica-mexico.salud.gob.mx/interior/registrocomites/chb.html>> accessed 3 September 2013

⁴⁹⁰ M Hansson, ‘Building on relationships of trust in biobank research’ (2005) 31 *J Med Ethics* 417

For example, Participant L recognised it is now compulsory that health (not research) institutions must have ethics committees, which are generally multi-disciplinary.⁴⁹¹ However it is not yet clear if this will apply to research institutions. Participant N said there was no certainty if this was the case with research committees.⁴⁹² Participant C⁴⁹³ recognised that the recently enforced guidelines were only published for committees created and operating within hospitals. Only Participants H and M show more optimistic views on the committees. (See supporting fieldwork statements on Table 4 annex p. 5)

One of the largest health institutions, IMSS, the health care and social security provider for 50 million Mexicans,⁴⁹⁴ was founded in 1943.⁴⁹⁵ IMSS has a system of 335 Local Research Ethics Committees (LRECs),⁴⁹⁶ whose regulation is covered by the IMSS Medical Research Handbook.⁴⁹⁷ IMSS has a National Health Research Council (CIS) which is the governing body that coordinates all activities in the Institute related to research on health at the national level. CIS has 54 health research centres and units located strategically in different states across Mexico, namely: 13 epidemiology and health services research units, 16 clinical epidemiology research units, 20 clinical research units, and five biomedical research centres.⁴⁹⁸

⁴⁹¹ Ethical-adviser-at-an-ethics-public-advisory-institution-Participant:L

⁴⁹² Bioethics-expert-at-a-public-legal-research-institution-Participant:N, *PhD Thesis fieldwork* (2012)

⁴⁹³ Legal-researcher-at-a-public-research-institution-Participant:C

⁴⁹⁴E Valdez-Martinez and others, 'Descriptive ethics: A qualitative study of local research ethics committees in Mexico' (2006) 6 *Developing World Bioethics* 96

⁴⁹⁵ Garduño-Espinosa and others 333

⁴⁹⁶ Valdez-Martinez and others 96

⁴⁹⁷ Mexican Institute of Social Security IMSS, *Manual de Investigación Médica en el IMSS (IMSS Medical Research Handbook)* (IMSS Internal handbook, 1999)

⁴⁹⁸ Mexican Institute of Social Security IMSS, 'Coordinación de investigación en salud (National Council for Health Research)' (*IMSS*)

<<http://www.imss.gob.mx/profesionales-salud/investigacion/etica>> accessed 10 October 2013

Other public health institutions have established their own ethics codes, such as the Institute of Security and Social Services for the State's Workers (ISSSTE): ISSSTE's ethics code for research in family medicine. ISSSTE is the health care institution for government workers in Mexico, and performs substantial biomedical research which involves biobanking at a national level. For example, it is leading several current national projects on Alzheimer and Parkinson diseases.⁴⁹⁹

LRECs, according to the IMSS handbook, must be formed by at least three executive directors; the term for this position is 3 years and can be extended for a second period⁵⁰⁰. Apart from LRECs, the IMSS depends on the National Commission for Scientific Research to evaluate the ethics of scientific research proposals. The composition of IMSS committees is normally expected to be cross-cutting, that is, to include lawyers, ethicists and laypersons as active members. LRECs were designed to make the necessary changes for the benefit of science and participants' protection in a balanced way. According to this regulation, the purpose of LRECs is to evaluate each research project performed within the IMSS, scrutinise research proposals (in terms of scientific validity and methodology), report irregularities (due every six months), and protect research subjects' rights and welfare.

Every research project must follow an established procedure, beginning with a project submission to the committee secretary's office. The secretary's office designates Executive Directors to the committee as internal scrutinisers for each project. The result of each individual evaluation is passed on to the rest of the committee before plenary meetings, which are led by a Chair Executive Director. Following the

⁴⁹⁹ S Casillas Mendoza, 'Erogación de más recursos a investigación, entre los retos de la siguiente administración federal (More resources for research: amongst the challenges of the following federal administration)' *Cambio de Michoacán* (Michoacán, 24 July 2012)

<<http://www.cambiodemichoacan.com.mx/vernota.php?id=178974>>

⁵⁰⁰ Garduño-Espinosa and others 333

plenary meeting, the secretary sends the main researcher an integral assessment, including outstanding issues within the research protocol. The main issues regarding public institutions will be analysed in chapter 7 (7.3).

5.5.3 Rules for private companies

In Mexico, the pharmaceutical industry is not governed by specific rules. However, there are controls for the development of pharmaceutical research. These are authorised from the corresponding authorities (in this case COFEPRIS) and the informed consent of the research participants. The rest of the regulatory framework consists of self-regulatory powers to the pharmaceutical companies' own committees. Research proposals are evaluated by the pharmaceutical industry committees which have been authorised by COFEPRIS. The principal investigator for the project is proposed by the company, and the company is also responsible for verification "that the research project complies with the requirements established by the General Health Law and applicable regulations."⁵⁰¹ However compulsory ethical controls seem to be insufficient, and it is not clear who is responsible for many issues.

In 2005, the National Chamber of the Pharmaceutical Industry (CANIFARMA) approved the creation of the Council of Ethics and Transparency for the Pharmaceutical Industry (CETIFARMA). The latter institution is intended to "strengthen the development of a socially responsible and transparent pharmaceutical industry."⁵⁰² CETIFARMA

⁵⁰¹ *Acuerdo que establece los lineamientos que deberán observarse en los establecimientos públicos que presten servicios de atención médica para regular su relación con los fabricantes y distribuidores de medicamentos y otros insumos para la salud, derivada de la promoción de productos o la realización de actividades académicas, de investigación o científicas. (Agreement which establishes the guidelines for public health establishments to regulate relationships with pharmaceutical distributors and makers, derived from product promotion, academic or research activities)*

⁵⁰² CETIFARMA, 'Consejo de ética y transparencia de la industria farmacéutica (CETIFARMA)' (CETIFARMA, 2013) <<http://www.cetifarma.org.mx/>> accessed 12 May 2013

has two ethics codes: the Code of Ethics and Transparency of the Pharmaceutical Industry,⁵⁰³ which provides the ethical framework for the members of CETIFARMA, and the Code of Good Practice for the Promotion of the Pharmaceutical Industry,⁵⁰⁴ which aims to promote the compliance with ethical conduct in research activities, development, production, promotion and distribution of medicines. Section 4.9⁵⁰⁵ provides the ethical criteria which members must follow within clinical research, however, the adherence to these instruments is voluntary.

CETIFARMA codes are non-binding self-regulatory instruments, whose sanctions may be warnings, membership withdrawal and fines. Only some serious cases will be reported before the sanitary authorities. Self-regulatory agreements are common instruments signed between the national representative of the pharmaceutical industry in Mexico: CETIFARMA and COFEPRIS. For instance, both parties have signed an “agreement on the actions to be followed regarding self-regulation on health production inputs and advertising ethics.”⁵⁰⁶ These ethics topics tend to be agreed for regulatory purposes.

According to the CNB, one of the greatest concerns with pharmaceutical clinical trials is sponsorship, since “unacceptable misconduct has already occurred.”⁵⁰⁷ This could be related to the fact that it is optional for pharmaceutical companies to establish their own rules in sponsorship. Frequently, public projects have limited funding to develop their own research. Hence, there should be supervision to ensure that no pressure is involved when public institutions accept external collaboration

⁵⁰³ National Chamber of the Pharmaceutical Industry (Cámara Nacional de la Industria Farmacéutica) CANIFARMA, *Códigos de la industria farmacéutica establecida en México (Codes of the Pharmaceutical Industry Established in Mexico)* (Consejo de Ética y Transparencia de la Industria Farmacéutica 2009)

⁵⁰⁴ Ibid

⁵⁰⁵ Ibid

⁵⁰⁶ CETIFARMA, ‘XXV Sesión Grupo Compliance CANIFARMA ’ (XXV Sesión Grupo Compliance, Mexico City, July 23 2012)

⁵⁰⁷ Comisión Nacional de Bioética (The National Commission of Bioethics) 75

because it is the only way to develop research. In relation to funding research trials, it has been established that public institutions, which develop research projects, must follow applicable regulation which has not yet been determined. The fact that health institutes sign agreements on research collaborations with industry (including international industry) is ethically risky but partly justifiable.

5.5.3.1 Private institutions

A great issue, which may not be obvious within biobanking, is the ethical practice of pharmaceutical industry activities in Mexico. The OECD has recognised that “regulations still hold back the interaction between scientific researchers and business.⁵⁰⁸” Biobanks are established for research purposes mostly in connection with clinical drug trials. Pharmacogenomics,⁵⁰⁹ nowadays a common pharmaceutical activity, consists of studying how genetic factors influence different responses to drugs. There can be a great range of responses which depend on elements, such as the toxicity level of the drug, human metabolism, age, alcohol intake, interaction with other drugs, smoking, infections and other factors.

The public sector of research involving biobanking presents various risks, which could be significantly increased within the private sector where economic interests become involved. The ability to sequence the whole of the human genome facilitated the study of new genetic factors determining the response to drugs, which can be disclosed through biological samples. Hence, a great number of the responses of the human body to a new drug can be investigated through biological samples, including those with genetic and non-genetic content.

⁵⁰⁸ OECD, *Getting it Right OECD Perspectives on Policy Challenges in Mexico* (OECD, 2007)

⁵⁰⁹ AK Dubey and others, ‘Understanding the Essentials of Pharmacogenomics- The Potential Implications for the Future Pharmacotherapy’ (2008) 2 *Journal of Clinical and Diagnostic* 682

Generally those with genetic content are the main objects of ethical interest, due to the sensitive information which may be potentially disclosed.

5.5.4 Federal Sanctions

The rationale for Federal sanctions is in Article 101 of the General Health Law, which provides the basis to sanction: “those who perform research involving humans against this law and applicable regulations will be subject to the corresponding sanctions.” One would expect to find the definition of applicable rules in the General Health Law and its procedural rules on health research. However, this is not the case. Article 130 of the General Health Law’s procedural rules is repetitive in terms of the primary regulation of the General Health Law and this makes the sanction rules more complicated.

“The corresponding sanctions will be for those who perform research involving humans and use pathological microorganisms (or the biological material in which such microorganisms are present), construction and management of recombinant nucleic acids.”⁵¹⁰ Sic

Article 130 then confusingly continues with a list of nuclear material commonly used in hospitals which can be hazardous, and pointing out that misuse will be subject to sanctions. The article does not mention the corresponding sanctions other than those related to misuse of radioactive material. No references relevant to biobanking are explicitly stated. It can be assumed that the corresponding sanctions would be imposed by the national health authority COFEPRIS. This commission is an administratively independent institute, which belongs to the National Ministry of Health. As an authority, it is currently responsible for administrative sanctions in the case of “non-compliance with legal dispositions, rules and additional applicable regulations” and for

⁵¹⁰ LGS

“determining safety, preventive and corrective measures for which it is competent.”⁵¹¹ Different assumptions could be made on biobanking, and it’s not clear what type of committee will have the competence to decide on sanctions in these cases. Hypothetically, if a collection of samples involved genetic information, a bio-safety committee should be responsible for deciding on cases in which rules allegedly have been breached, something nearly impossible to prove because of the absence of specific rules. Even if the allegation on unethical biobanking was considered, it is not clear what sanctions would be applied and by whom.

There are no clear sanction frameworks which go beyond general sanctions. It would be extremely complicated to prove misuse of biological samples under the statement, “the commercialisation of organs and tissues is a legal offence.”⁵¹² This general statement was initially enacted for transplantation purposes; it is too broad to include the commercialisation of tissue samples for research purposes. It is not known how violations of human dignity are constituted, and it would be necessary to emphasise the topic, i.e. specific biological donations, and the area of law responsible for the establishment of the so called “corresponding sanctions.” Participant I does not believe that the current articles on the human genome are applicable to biological samples, as these have a particular genetic focus.⁵¹³ Other questions on the effectiveness of the Mexican health law provisions could emerge, for example, nothing has been said regarding the practicalities of accessibility. So far, the proposals, modifying the General Health Law, have been implemented in regard to accessibility and knowledge of an individual’s genome. The regulation for this right was included in 2011. However, legal mechanisms, such as those for an individual to exercise

⁵¹¹ Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios COFEPRIS (Rules of the Federal Commission for the Protection against Sanitary Risk rules)

⁵¹² LGS Article 327

⁵¹³ Responsible-of-the-Genetics-department-at-a-public-ethical-advisory-institution-Participant:I

the *right to know or not to know*, have not been established, for example, participants should be able to decide if they do not want to know about a predisposition to an illness, or when they do not want to know the results of a genetic test, so they can request that that information is withheld.

Initial regulation on general issues is normally the basis for later, specific regulation. Therefore, the human genome regulation should have been derived from a more general regulation, i.e. biobanks.

5.6 Summary on identified problems in the current Mexican regulation of databases and/or biobanks

- **Identification of the problem (what the main problem is)**

The main problem can be seen under two important perspectives: lack of specific regulation and partial regulation.

- **Lack of specific regulation**

Biobanks, as a legal subject, are not regulated in Mexico. Analysis of the current legislation has revealed that this is a problem for stakeholders that work in the major fields of tissue samples⁵¹⁴ or data protection or both.⁵¹⁵

The main instrument in which biobanks are currently believed to depend on is the General Health Law.⁵¹⁶ It was created in 1984, intending to cover the emerging aspects of health research at that time. The major fields of tissue and associated data, are weakly covered by the following derived rules: The Regulation on Sanitary Disposal of Human Organs, Tissues and Cadavers (1985),⁵¹⁷ the Regulation on Scientific Health

⁵¹⁴ See page 151

⁵¹⁵ See page 161

⁵¹⁶ LGS

⁵¹⁷ 'Federal Regulations for the Control of Organs, Tissues and Cadavers of Human Beings' ('Reglamento Federal para la Disposición de Órganos, Tejidos y Cadáveres de Seres Humanos')

Research (1987),⁵¹⁸ the regulations put forth by the National Institutes of Health Law (2000) and the Regulation on Scientific Health Research (*Reglamento de la Ley general de Salud en materia de Investigación para la Salud*) (1986).

- **Partial regulation**

The problem is that the available rules are not only unclear, but incomplete and enforcement instruments are absent. Insufficient regulation has led to the opening of legal interpretation, making it difficult for stake holders to resolve the constant problems in the operation of biobanking. This creates a situation in which it is impossible to determine the legality of an activity.

- **The regulation of genetic information: a relevant example**

The regulatory situation on genetic information, an essential aspect of biobanking, clearly illustrates how difficult it can be to find legal guidance on the subject. None of the above mentioned derived rules cover genetic data specifically. Interestingly, some aspects of genetic information are specifically regulated by the Federal Law on Protection of Personal Data Held by Individuals (2010).⁵¹⁹ This is unexpected, as the main legal body on which biobanks currently depend, as mentioned above, is the General Health Law. Hence, genetic information is partially covered by a law intended to regulate transparency on private data and was not designed to cover health research.

- **So, does the problem relate to biobank or databases or both?**

Both areas are seriously affected. The regulation of genetic data is incomplete. Data protection within scientific research has not been

⁵¹⁸ Rules of the General Health Law on Scientific Research (*Reglamento de la Ley General de Salud en Investigación Científica*)

⁵¹⁹ *Ley Federal de Protección de Datos Personales en Posesión de Particulares* (Federal Law on Protection of Personal Data Held by Individuals)

considered and most important aspects are not covered as a result. For example, the terms "health data" or "genetic data" have not been differentiated from other types of data.

Current laws on personal data have not explicitly set forth what types of samples (blood, saliva, tissue) contain health data, even when "in biobank research it is not the tangible features of biological samples that are at issue but informational content."⁵²⁰ Mexican data protection laws refer to personal data processing in general, failing to specify biological samples used in research.

The regulation of associated samples should belong to the General Health Law, which covers some aspects but not the essential ones. The General Health Law covers some types of human tissue, (blood, blood components, hematopoietic stem cells and derivatives) but only for population studies.⁵²¹ Other types of research are not mentioned. Health regulations have not determined whether it is lawful to obtain samples from children. The Law on Health Research establishes that: "When the minor's mental capacity and psychological state allow it, acceptance must be obtained to become a research subject, after explaining to him what is intended."⁵²² This will be open to interpretation as the statement is ambiguous.

Nothing has been enacted regarding binding research controls on biobanks e.g. authorising bodies or mechanisms for authorisation requests. The law also fails to specify data protection operations, inspection, data access, rectification or sanction mechanisms. Presently, health research authorisation is under the Mexican health authority

⁵²⁰ European Commission 38

⁵²¹ LGS Article 317 *bis* 1

⁵²² Reglamento de la Ley general de Salud en Materia de Investigacion para la Salud (The Ministry of Health Rules of the General Health Law on Health Research) Chapter III, article 37

COFEPRIS, specifically created for dealing with sanitary risks. Committees, being covered by the General Health Law, lack competence for dealing with clinical trials by the pharmaceutical industry which is currently self-regulated.

- **What is the effect of the problem for biobanking or research use of health databases?**

Current rules were enforced on accessibility and knowledge of an individual's genome, without legal mechanisms, to exercise individual rights such as the right to know or not to know. Anonymisation, for example, is a non-regulated activity that would prevent participants from exercising their 'right to know.'⁵²³ Secondary uses of data, identification mechanisms, e.g. anonymity and coding, re-contacting participants, participants' withdrawal, the return of results to participants, accessibility and implications are important aspects on tissue and associated data, which remain completely open to interpretation.

There are significant risks within biobanking for research subjects. These require specific standards which cannot depend on variable interpretation e.g. conservation periods and secondary uses of samples. Sanctions are non-existent. These are sensitive due to the genetic data contained and need different protection.

Sensitive data, understood as that which can reveal racial and ethnic origins, should be protected within research areas, since both public and private research use it. Stronger protection mechanisms relying on general ethics committees with limited legal power are required.⁵²⁴

These matters are important for the individual as well. For example, a person could be discriminated against, regarding work, if their ethnic

⁵²³ See page 156

⁵²⁴ Khoury and others⁸⁷

group was found to have certain health traits. It could also increase their health insurance costs, or remove the option of obtaining health insurance altogether. If a person does not have a right to know or not to know about their genetic data, they may be informed of an impending chronic illness in the future and that knowledge could cause that person's mental health to decline.

- **Situation of the problem within the legal system: at what level in the Mexican structure does the problem occur?**

Due to the structure of the Mexican legal system, the absence of biobanking regulation occurs at both federal and local levels. This is because the regulation of a topic at the federal level impacts on the state level, which has an implicit obligation to regulate on the topic accordingly. The states can follow federal regulations while local legislatures work on specific state rules. For this reason, the role of federal regulations is substantial. Hence it is not acceptable that current primary (federal) regulations show failures such as regulated principles with absent procedures. These constitute the rationale for the states to legislate.

Currently, the only rationale for any federal sanctions derived from biobanking is article 101 in the General Health Law, which very broadly states that research involving humans against the law will be sanctioned. If primary rules are not specific, sanctions cannot be specific either. Their application can remain open, once again, to interpretation. Some specific sanctions have been stated for the use of pathological microorganisms.⁵²⁵ However, no context has been described and no enforcing mechanisms for such sanctions have been mentioned. If this happens at the federal level, no more can be expected at the state level.

⁵²⁵ LGS

Presently, even federal guidance is not sufficient as a basis to regulate biobanks. For example, it is currently compulsory that health institutions must have ethics committees. However it is not yet clear if this will apply to research institutions. This results in confusion for states attempting to regulate according to the federal law.

5.7 Concluding remarks

This chapter, based on both desk based and field research, comprised the analysis of relevant ethical guidelines. These were contrasted with practical issues in biobanking. Planned interviews with members of relevant institutions complemented the current research and identified areas that need urgent legal improvement.

The governance of biobanking has not entirely been solved in Mexico. The additions planned in the 2001 initial proposals⁵²⁶ reflected the constitutional principle but with no further guidance. Nothing has been enacted on research controls, e.g. authorising bodies or mechanisms for authorisation requests. The issue on the “prohibition of discrimination” included in the Mexican constitution was raised in 2001. Not even the 2011 reforms on the human genome have resolved elemental concerns. Practice shows with such a great range of situations, that only well motivated legislation will cover it, for example, the main drive for the legal work is currently focused on national development and economic goals. Tissue rules are relevant for the regulation of biobanks, however, the current coverage in Mexico is not based around human tissue for research and hence is not sufficient.

Most of the rules for research involving humans are not fit for purpose. New rules have been included through amendments rather than new regulations, such as Acts. This has resulted in an extremely complicated patchy framework, where the rules applicable to a particular

⁵²⁶ Cardona

area are not covered by a single body, but by different regulations that do not distinguish between principles and the ways to achieve them, a differentiation that would normally be expected within the Mexican legal system. This is the case with biobanks, they are not specifically regulated. It is very difficult to say whether biobanking legal guidance is available. Determining the availability of biobanking guidance currently depends on variable interpretation criteria. The “Overview of the Legislation on the Human Genome in Latin America and the Caribbean”,⁵²⁷ which focused on the human genome, concluded that “after analysing the current Mexican laws (constitutional, health and criminal law) which could be applicable to the human genome, we conclude that Mexican rules have been surpassed by science. Deficiencies are huge and the absence of specialised laws is creating confusion.”⁵²⁸

A great number of potential risks could breach the founding principles of research bioethics in areas which are not obvious and go beyond physical damage; the implications of biobanking belong to this category. There are significant risks within biobanking for research subjects. These require specific standards which cannot depend on variable interpretation e.g. conservation periods and secondary uses of samples. It is not defined how long samples can be preserved and what secondary uses are allowed. Sanctions are perceived in Mexico by biobanking stakeholders as non-existent: “To the best of my knowledge there are no sanctions.”⁵²⁹ Sanctions are not defined. This has to be developed in accordance with other legal codes. It needs to be defined

⁵²⁷ Alya Saada and Diego Valadés (ed), *Panorama sobre la legislación en materia de genoma humano en América Latina y el Caribe (Legal panorama on the human genome in Latin America and the Caribbean)* (National Autonomous University of Mexico, Latin American and Caribbean bioethics network of UNESCO 2006)

⁵²⁸ Ibid

⁵²⁹ Ethical-adviser-at-an-ethics-public-advisory-institution-Participant:L

whether this will consist of a fine or will be included in the penal code; sanctions are necessary too.⁵³⁰

⁵³⁰ Responsible-of-the-legal-department-at-a-public-biobank-Participant:G

III. IMPLEMENTING CHANGE

6. European examples: What can be gained from the European experience?

6.1 Introduction

This chapter highlights the importance of international experiences as a source of help in the design of effective legal biobanking guidelines in Mexico. More specifically, it analyses the legal situation of Mexico in the light of the European experience. This analysis also aims to identify the weaknesses that could affect future legislation. Recently, a number of European countries have developed a comprehensive framework for addressing biobank expansion within ever-growing scientific and biomedical research communities. The analysis will be achieved by reviewing the flaws of current biobanking regulations in Mexico, comparing them with experiences from Europe, which was in a similar position approximately twenty years ago.

6.1.1 The BTCure project

From September 2011, I started an academic collaboration with the project BTCure, an extensive European consortium which investigates new therapies for the treatment of Rheumatoid arthritis. One of the main challenges of this academic-industry funded consortium has been the exchange of data and samples across Europe. Participating institutions, whose samples are intended for sharing as part of the project's scientific activities, manage tissue banks under the different legislations of each country involved. My participation in 'work package five' consisted of the development of guidelines for Rheumatology biobanks in Europe.

Under the BTCure project, the legal frameworks of the 27 member countries of the European Union (2012) and Switzerland were analysed

in depth evaluating the state of each country regarding legal rules on tissue banks. Different aspects, such as informed consent, data protection, data protection mechanisms and data sharing were evaluated. The data obtained, under previous authorisation by Dr. Frederique Ponchel (responsible for the BTCure work package), was used for the development of this chapter.

The first section of this chapter justifies the analysis of relevant pieces of European legislation, explaining how they would help resolving specific issues within the Mexican context. Mexican biobanking provisions, which fail to satisfy consistency requirements, will be compared with several European countries' frameworks in order to identify which may be best suited for Mexico. National frameworks vary widely from country to country. This chapter argues that several European provisions regarding data protection and sharing, such as Directive 45/46/EC,⁵³¹ can serve as guidelines for international research collaboration currently taking place between Mexico and Europe.

The second section of this chapter will pay special attention to specific issues, including legal competence and subjects of regulation, informed consent models, exclusions and exceptions, consent from minors, the legal effects of tissue biobanking in practice, such as the regulation of post-mortem tissue and the regulation of data protection, including sensitive data, data protection mechanisms and data sharing. Oversight will also be emphasised, which is a major concern to strengthen regulatory bodies and procedures.

⁵³¹ Council & Parliament Directive 95/46/EC, 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

6.1.2 Background on international cooperation

There are reasons and incentives encouraging governments to keep up to date with international harmonisation. Robin Bunton⁵³² has pointed out, in respect to the related issue of ‘genetic governance’, that regulation is not merely a local and national issue, but also a transnational issue. International cooperation consists of the transfer of resources, knowledge and experiences among governments, public entities and the private sector. These bodies aim to achieve of common objectives in order to share common benefits, i.e. economic development and social welfare. Global and political dynamics are constantly creating pressure on harmonisation schemes.⁵³³ In some cases, this is the result of international organisations’ decisions at various levels (regional, governmental or non-governmental). Ethical norms from international codes are widely accepted; an operative programme on health research has stated that “there is no research activity which does not find an answer in international documents.”⁵³⁴

The European Council Recommendation on Human Biobanks and Genetic Research Databases (2009) highlights “the importance of issues, such as access.”⁵³⁵ Various international guidelines have provided further parameters for the management of biobanks. These guidelines have different binding levels. The International Covenant on Economic, Social and Cultural Rights has been fostered in terms of economic cooperation and scientific research, based on the principle of reciprocal benefit. The first paragraph of article 24 of the Universal Declaration on the Human Genome and Human Rights points out that countries mostly promote information sharing and the free circulation of scientific and technological knowledge.⁵³⁶

⁵³² Bunton and Peterson 190

⁵³³ J Maschke and TH Murray, ‘Ethical Issues in Tissue Banking for Research: The Prospects and Pitfalls of Setting International’ (2004) 25 *Theor Med Bioeth* 144

⁵³⁴ (The-Mexican-Ministry-of-Health)

⁵³⁵ Council Recommendation on Human Biobanks and Genetic Research Databases

⁵³⁶ The Universal Declaration on the Human Genome and Human Rights

Other European directives have also been encouraged, providing ethical guidance at a regional level. Despite the existence of basic principles in a general European framework, each Member State is responsible for implementing specific laws on the ethics of biological material for research. The European law is intended to be respectful of the national laws of Member States and “such an approach also allows Member States to adopt more stringent measures, which reflect differing national socio-cultural, economic and political priorities.”⁵³⁷ The European directive 2001/20/EC on good clinical practice in the conduct of clinical trials,⁵³⁸ and the directive 2005/28/EC on human tissue and cells,⁵³⁹ are relevant examples. The former directive on good clinical practice in the conduct of clinical trials has stated that clinical trials on medicinal products for human use must be based on an “informed and free decision.” The directive also provides guidance on the protection of minors and individuals who are incapable of giving their informed consent. The European directive 2005/28/EC on human tissue and cells, has established basic principles regarding the donation of cells and tissues, which must be free and based on minimum information provided to donors.⁵⁴⁰

Internationally, biobankers are developing voluntary standards to address concerns about inconsistencies in the collection, storage and retrieval, and distribution policies of biobanks.⁵⁴¹ Currently, in terms of

⁶ J Hunt and CJ Wallace, ‘Governing the body: Examining EU regulatory developments in Relation to substances of human origin ’ (2005) 27 *Journal of social welfare and family law* 434

⁵³⁸ Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

⁵³⁹ Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products

⁵⁴⁰ *Ibid*

⁵⁴¹ G Laurie and T Caulfield, *Biobanks Information Paper* (National Health and Medical Research Council, 2010) 12

science and technology, it is not sustainable for developed countries to develop knowledge, skills and products, and then to make this available to poorer countries. This is why so many developing countries, especially the emerging economies, are focusing more on local innovation, invention and commercialisation, to break the cycle of dependency.⁵⁴²

International studies present advantages if implementation is developed to take into account the unique characteristics of each country. Past mistakes should assist future improvement. Most interviewed participants agree that the impact of implementing frameworks, based on the international experience, would be positive if adequately done. (See Table 6 in annex p. 7) At the European level, the provision of common explanatory biobanking guidelines, in addition to general directives, would be essential. In principle, there are quite a few features that are shared by the regulatory instruments enacted so far. These could therefore represent a starting point of common and coherent principles for biobanks.⁵⁴³

National coordination of Mexican biobanking is more complex from the international perspective. As reviewed in chapter 4, in Mexico, international declarations are not strictly compulsory. Nevertheless, there are challenges to be overcome. In this case, a significant problem is the inconsistency of Mexican institutions' interpretation.

6.2 Why Europe?

The European experience has been chosen for examination for several reasons. It resembles the Mexican experience in the sense that, similarly to Mexico, the European Union has general instruments which can be applicable to biobanks. The current challenges at the European Union level are centred on the recognition of international diversity to be

⁵⁴² NyikaS26

⁵⁴³ European Commission 41

discussed across national hubs, “in order to develop good solutions, avoid duplication of effort, and facilitate international collaborations.”⁵⁴⁴ The case of Europe was chosen due to the diversity of biobanking legislations, which are currently the object of joint efforts to reach standards to facilitate international collaborations involving biobanking. Mexico can learn many lessons, including those involving the implementation of laws, procedures and stakeholders’ consensus to ethically maximise the potential of samples.

6.2.1 Guidelines based on human rights

Several European countries have effectively implemented international guidelines into their national laws. Some of them evolved from situations similar to the current Mexican biobanking framework or followed similar routes resulting from more general perspectives, e.g. human rights. The regulation of human rights in Europe is related to the emergence of biobanking regulations. Salter and Jones maintain that “the rights-based discourse of biobanks is part of a predominantly international bioethical debate of policy statements, interest and legitimation, which impact to produce common agendas at the national levels.”⁵⁴⁵ This can help as a reference that improving human rights in Mexico can have a favourable impact on better ways to regulate biobanks in Mexico. This has been the case with data protection rules; “when drafting the Directive, the European Union legislators clearly envisaged a rather more robust human rights based system of personal data protection.”⁵⁴⁶

The Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of

⁵⁴⁴ I Budin-Ljøsne and others, ‘ ELSI challenges and strategies of national biobank infrastructures ’ (2012) 21 *Norsk Epidemiologi* 159

⁵⁴⁵ B Salter and M Jones, ‘Biobanks and bioethics: the politics of legitimation’ (2005) 12 *Journal of European Public Policy* 725

⁵⁴⁶ A Charlesworth, ‘Implementing the European Data Protection Directive 1995 in UK Law: The Data Protection Act 1998 ’ (1999) 16 *Government Information Quarterly* 225

Biology and Medicine⁵⁴⁷ is the basis for safeguarding the rights of human subjects in relation to scientific progress within Europe. This convention stipulates general principles that are supplemented by additional protocols. In the run up to the adoption of the 1998 Data Protection Act, the Data Protection Registrar praised the Government White Paper for recognising in its proposals the concept that individuals were entitled to a right of privacy with respect to personal data deriving from the right of respect for their private life contained in Article 8 of the European Convention on Human Rights.

6.2.2 The European Union background on biobanks

The use of biological samples in research has been addressed by some European countries as part of their healthcare national agendas, such as research for healthcare and diagnosis. This fact presupposes adequate health systems and conditions. However, every country prioritises health needs differently. “It is necessary to recognise that the developing world presents greater challenges from those of the developed world in terms of substance and structure.”⁵⁴⁸

The evolution of biobanking regulations in Europe has been largely spurred by the expansion of research activity and the priority given to biobank regulation. Emerging economies, following a delayed but similar expansion in research, are just now confronting the often precarious balance between their home-grown legal framework and related legal and ethical issues.

European consensus was required for effective proposals, initially at the local level. Inconsistent policies may result in unfair treatment and contribute to risks of regulatory capture, in other words, the unfair

⁵⁴⁷ The Universal Declaration on the Human Genome and Human Rights

⁵⁴⁸ Nyika S26

preferential treatment of a public institution towards particular groups of interest.

Both Mexico and the European Union are still in the process of adopting a fit-for-purpose legislation for biobanking research. On the other hand, the European Union can be a specific illustrative example for Mexico, and in particular, the situation of each member state. The effectiveness of biobanking in some countries has proven to be dependent on the urgency to regulate practical situations effectively. Not all European countries have responded with similar solutions, or at the same pace. For example, in contrast to from the rest of Europe, “it can be stated without exaggeration that the legal framework in France has been continuously evolving ever since legislators became aware of the importance of biobanks.”⁵⁴⁹ The European Commission⁵⁵⁰ recognises the variety of regulations resulting from biobanking activities in Europe. Two main positions are explained: “either specific legislative acts are adopted focusing on biobanks’ activities (Iceland⁵⁵¹, Estonia⁵⁵², Hungary⁵⁵³, Sweden⁵⁵⁴, Spain⁵⁵⁵ and Belgium),⁵⁵⁶ or provisions about biobanks or bio-collections are integrated into broader administrative and legislative instruments (France⁵⁵⁷ and the United Kingdom).”⁵⁵⁸

⁵⁴⁹ V Commin, ‘Legal issues surrounding French research-focused biobanks’ in C Lenk and others (eds), *Human Tissue Research A European Perspective on the Ethical and Legal Challenges* (Oxford University Press 2011) 110

⁵⁵⁰ European Commission 39

⁵⁵¹ Icelandic Act on Biobanks no 110/2000

⁵⁵² Estonian Human Genes Research Act RT I 2000

⁵⁵³ Hungarian Parliamentary, Act No XXI on the protection of human genetic data and the regulation of human genetic studies, research and biobanks

⁵⁵⁴ The Swedish Biobank Act

⁵⁵⁵ Spanish Act 14/2007, on Biomedical Research

⁵⁵⁶ The Belgium Law regarding the procurement and use of human body material destined for human medical applications or for scientific research purposes

⁵⁵⁷ French Law N° 2011-814 on Bioethics, JORF n°0157

⁵⁵⁸ UK Human Tissue Act

6.2.3 Pioneering biobanking legislation in Europe

Europe is a world leader in the development of biobanking infrastructure to support research, it makes huge investments each year to support such initiatives,⁵⁵⁹ and in individual aspects of health by specific regulation on topics like confidentiality of genetic data.⁵⁶⁰ Europe involves great commonalities in the nature of challenges that it is facing internationally.⁵⁶¹ This resembles the Mexican overview in various topics. However, as Favale and Plomer have stated, “these issues are often not straight forward to address. Even when the same moral principles tend to be the ethical basis of biobanking guidelines universally, such principles are differently interpreted, enforced and implemented in each country.”⁵⁶²

Several European countries, such as Spain, are pioneers of specific legislation for human biological samples. Additionally, some countries follow similar legal systems to that of Mexico (Civil Law), including Spain and France. In many cases, however, the rules on the use of biological samples for research purposes have to be pieced together taking into account a number of different regulatory instruments.”⁵⁶³ The Mexican biobanking framework did not emerge uniformly but in fragments, a situation comparable with that of France, where the regulation of biobanks does not fall under the purview of a specific law but rather is scattered in several pieces of legislation.⁵⁶⁴ The number of specific authorisations required from the Ministry of Research

⁵⁵⁹ European Commission 5

⁵⁶⁰ I Brena, ‘La perspectiva latinoamericana en la Declaración Universal de Bioética y Derechos Humanos (The Latin American perspective in the Universal Bioethics and human rights declaration)’ in I Brena and G Teboul (eds), *Hacia un instrumento regional interamericano sobre la bioética, experiencias y expectativas (Towards an inter-American regional instrument on bioethics, experiences and expectations)*, vol 501 (UNAM IJ 2009) <<http://biblio.juridicas.unam.mx/libros/6/2673/2.pdf>> 321

⁵⁶¹ Budin-Ljøsne and others 155

⁵⁶² Marcella Favale and Aurora Plomer, ‘Fundamental disjunctions in the EU legal order on human tissue, cells and advanced regenerative therapies ’ (2009) 16 *Maastricht journal of European and comparative law* 94

⁵⁶³ European Commission 39

⁵⁶⁴ Budin-Ljøsne and others 156

of various biobank activities, including exporting and importing samples, proved generally disadvantageous. The French legislator recently provided biobanks with a relatively interconnected legal framework,⁵⁶⁵ which manages to regulate the administrative status of a biobank from the moment that it is created until the moment that it stops functioning.⁵⁶⁶ “Although Europe and Latin America appear to be similar with regard to normative elements, the level of involvement of competent authorities in ethics reviews and the enforcement of regulations differs among countries.”⁵⁶⁷

6.2.3.1 The role of population biobanks in European regulation

Several European countries, similar to Mexico, encouraged legislation based on population biobanks. The Mexican biobanking framework emerged from a source similar to that described in Europe. The first biobanking related rules were an attempt to establish a legislative framework for the emerging population studies by the HapMap Project, a comparable situation with Estonia’s first attempts “to establish a legislative framework and codify law in the genetic era.”⁵⁶⁸ In the case of Estonia, legislation has been motivated by the sudden creation of large biobanks, which promptly motivated rules fit-for-purpose on this matter. With the aim of establishing the necessary institutional and organisational framework for the Estonian Genome Foundation, the Estonian government adopted the Human Genes Research Act⁵⁶⁹ in December 2000 which came into force at the beginning of 2001. The Estonian Human Genes Research Act “is an example of those frameworks created

⁵⁶⁵ Commin 69

⁵⁶⁶ The French Public Health Code

⁵⁶⁷ E Lamas and others, ‘A comparative analysis of biomedical research ethics regulation systems in Europe and Latin America with regard to the protection of human subjects’ (2010) 36 J Med Ethics 751

⁵⁶⁸ J Sándor and P Bárd, *The legal regulation of biobanks National report: Estonia* (GeneBanc 2009) 4

⁵⁶⁹ Hungarian Parliamentary, Act No XXI on the protection of human genetic data and the regulation of human genetic studies, research and biobanks

for practical reasons, and it has already served as a model for other countries intending to launch their own genome projects.”⁵⁷⁰

Mexican regulation of the human genome presents essential and structural issues. The HapMap project was a practical reason for the creation of a framework, which was also inspired by political reasons. The enforcement of the initial human genome law project was delayed almost fourteen years due to political arguments. In the words of a legal ethics expert who worked on the project, General Health Law articles “did not make any difference in the regulation of practical areas.”⁵⁷¹ The 2011 reforms⁵⁷² “were the result of copying and pasting parts of the Universal Human Genome Declaration.”⁵⁷³ The law makers felt pressure to avoid ‘falling behind’ in comparison with other countries implementing the declaration.

6.3 Specific regulation subjects

6.3.1 Informed consent models and their implications

Based on current research ethics within the European framework, each Member State has adopted consent models based on its own specific needs. How this is achieved varies from country to country. Currently, no common standard has been established for informed consent at the regional level. The diverse standards applied by each nation are subject to debate. A clear example of such variation consists of the different procedures following the adopted informed consent model in each country.

⁵⁷⁰ A Nõmper and K Kruuv, ‘The Estonian Genome Project. – Society and Genetic Information’ in J Sándor (ed), *Society and Genetic Information: Codes and Laws in the Genetic Era* (CEU Press 2003) 213–225

⁵⁷¹ Science-and-Technology-Commission-Participant:K

⁵⁷² (Parliamentary-Health-Commission) and (Parliamentary-Science-and-Technology-Commission)

⁵⁷³ Science-and-Technology-Commission-Participant:K

Based on the current basic research ethics principles provided by the European framework, all European countries have rules on informed consent. The European consent criteria vary significantly and some national rules are more open than others. “Some biobanks require approval of their protocol and their informed consent documents from the research ethics committees. Nevertheless, once the research is underway, the committees, in most cases, do not carry out any supervision of the biobank or the research.”⁵⁷⁴ This is not the case in countries such as Lithuania, where a double scrutiny of biomedical research is necessary. First, as biobanking typically involves biomedical research, approval has to be received from the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee, as laid down in Article 12 of the Law on Ethics of Biomedical Research. Secondly, according to Article 10 of the Data Protection Law for collecting and storing medical data, it is necessary to obtain a notification from the State Data Protection Inspectorate. As to the former procedure, Article 15 lays down further rules on the receipt and examination of applications.⁵⁷⁵

The sponsor or the principal investigator of the biomedical research has to submit an application to the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee. The documents must be examined and a reasoned approval or a refusal must be issued within 45 calendar days from the registration of the application, and after payment of all the fees for biomedical research expert examination. According to Article 16 the Lithuanian Bioethics Committee and the Regional Biomedical Research Ethics Committee not only issue approvals, but also have the right to invalidate them in cases where there is evidence of non-compliance with the requirements of ethics of biomedical research. In such cases the sponsor, the principal investigator of biomedical research and the heads of health care institutions where the

⁵⁷⁴ Casabona and Simons 277

⁵⁷⁵ , *Lithuanian Law on Ethics of Biomedical Research*

biomedical research is being conducted must ensure that biomedical research is immediately terminated. An appeal is possible.

According to German law, a patient–doctor relationship only exists between a biobank and a sample donor if the sample was taken in order to treat or diagnose a disease. Outside of a therapeutic or diagnostic context, that is, if the sample was taken purely for research purposes, only the process of physical extraction of the sample itself represents an intervention that falls under medical professional regulations. General consent is established as the rule for further use of uncoded non-genetic health related personal data. However, if the requirements for consent and information cannot be met, biological material or health related personal data may exceptionally be used for further research, *inter alia*, if it is impossible or extremely difficult to obtain consent.⁵⁷⁶

The aspiration to offer a distinctive answer and to resolve Mexican normative questions thus poses a number of challenges: Informed consent is one of them. In Mexico, it is not clear whether the consent obtained initially covers only the research project which motivated the sample donation, or whether it can be extended to further research projects. The rules governing this topic are not condensed into a single section but are distributed amongst various sections which do not make reference to the others. There is no interconnection. Three main consent issues, where no single law covers the wide scope of consent related to biobanking, can be identified as follows:

1. The general aspects of Mexican consent are vague on which aspects could be improved through defining appropriate rules for

⁵⁷⁶ BS Dörr, ‘Research with human biological material and personal data in biobanks: legal and regulatory framework in Switzerland’ in C Lenk and others (eds), *Human Tissue Research A European Perspective on the Ethical and Legal Challenges* (Oxford University Press 2011)102

the diverse issues associated with informed consent for example, genetic material cannot be used for aims different to those which motivated their acquisition.⁵⁷⁷ However, this article only applies to genetic material, which is not expressly defined by the law. Genetic material is understood as any source of DNA.⁵⁷⁸ It can be inferred that the informed consent for non-genetic material can be used for any type of research, even if this was not initially consented to.

2. The Federal Commission for the Protection against Sanitary Risk (COFEPRIS) needs to review and scrutinise the informed consent, but no scrutiny parameters have been provided. The section mentioning that “the health institution will do this” is ambiguous.⁵⁷⁹ The ambiguity caused by too wide interpretation margins could deprive research subjects of autonomy rights over the sample donated. These rights go beyond basic physical safety rules and discrimination risk by insurance companies. Of particular relevance are concerns related to the potential use of data by third-party researchers who access the data, including concern that the data might be put to inappropriate uses, for example, that attempts might be made to identify individuals or that data might be used for research incompatible with the scope of the original consent.
3. Even when the creation of the CNB was focused on health care and research, it seems that more attention has been focused on informed consent for health areas. Guidelines by the CNB present an imbalanced focus, and are mostly directed to patients, leaving the interests of research subjects unprotected.

⁵⁷⁷ LGS Article 317 Bis

⁵⁷⁸ Ibid Article 317 Bis

⁵⁷⁹ Ibid Article 317 Bis I

The Mexican position is theoretically that of a specific consent, but unlimited interpretation causes a greater risk for participants. A suitable informed consent form for biobanking research needs to be designed, reflecting all the variables associated with the research type, rather than just the requirements of any consent form.⁵⁸⁰ If a particular type had to be chosen for Mexican biobanking research, blanket consent is not recommended. "Ambiguous consents for future research are not ideal."⁵⁸¹ Hence, the inclusion of the main aspects related to the fate of samples and data is always preferable. A concise, interconnected framework is believed to work; information does not need to be excessive since "more information will not always support better-informed choices."⁵⁸²

The most important issue in the Mexican context is to define whether informed consent is specific or broad. It could be of help to review other frameworks, such as those from Switzerland and France. In Switzerland, consent is given in a general form, allowing further use of samples and data for future research projects as a rule,⁵⁸³ whereas in France, consent to sample storage is for a single specific research purpose through a narrow consent, as it is set down by 2004 Bioethics Law.⁵⁸⁴ Data can only be retained for a minimum period of time necessary to serve the purpose for which they were initially obtained, and should be destroyed immediately afterwards. This stipulation also refers to all medical and personal data associated with the biomaterials so that, once a biobank has ceased to exist, there would be no legal basis for further

⁵⁸⁰ Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

⁵⁸¹ E. Wallace and 'BM Knoopers, 'Harmonised consent in international research consortia: an impossible dream?' (2011) 7 *Genomics, society and policy* 43

⁵⁸² Manson and O'Neill 191

⁵⁸³ Swiss Federal Law Involving Human Subject Bundesgesetz über die Forschung am Menschenv (Humanforschungsgesetz, HFG)

⁵⁸³ *ibid*

⁵⁸⁴ French Law N° 2011-814 on Bioethics, JORF n°0157

use of its database.⁵⁸⁵ However, an exemption to this rule may be possible, which permits transfer of the data in anonymised form to another research institution.⁵⁸⁶

6.3.1.1 Consent of vulnerable population

This section examines the ways in which persons considered as vulnerable can participate in research under specific protective measures. Regarding international instruments, even when inferences can be made, their binding power is relative and protection of vulnerable people must not depend on relative rules.

The provision in law of consent by proxy, in the case of children or other vulnerable individuals involved in a research, is a regional European rule.⁵⁸⁷ At the national level, Spain provides detailed rules, as far as minors and disabled persons are concerned (BMRA 2007, art. 58.5),⁵⁸⁸ and Article L. 672-5 of the French public health code⁵⁸⁹ prohibits the extraction of tissue, cells and other human body products in under aged people without a therapeutic purpose. According to the recommendations of the Austrian bioethics commission, in the case of a minor, consent must be sought from his or her legal representative until he or she has attained the capacity to consent (as a general rule at the age of 14). Storage and utilisation of samples donated by minors who have reached legal maturity is only permissible if the test person gives his/her consent.

At the present time, most genetic studies around the world require parents to voluntarily provide a cell sample from a child. It is likely that parents will increasingly be asked to involve their newborn children in

⁵⁸⁵ J Simon and others, 'A legal framework for biobanking: the German experience' (2007) 15 Eur J Hum Genet 531

⁵⁸⁶ The German federal data protection law ('Bundesdatenschutzgesetz', BDSG) Article 40

⁵⁸⁷ European Commission 41

⁵⁸⁸ Spanish Act 14/2007, on Biomedical Research

⁵⁸⁹ The French Public Health Code

gene therapy programmes, or for drug testing in pharmacogenetic studies. The former might go beyond minimal risk, but the latter is less likely to do so.⁵⁹⁰ Criteria are different according to the situation and degree of risk. In the opinion of Knoppers, research into carrier status should be delayed until a minor is competent to consent to the test.⁵⁹¹ As discussed in chapter 5, the consent of underage Mexican persons is included in the Federal Civil Code and, specifically, conventions on the rights of children. There are ethical rules for medical research in humans with incapacity conditions under Mexican civil law. However, the provided rules are not protective enough as many aspects are not covered.

6.3.1.2 Withdrawal of consent

Withdrawal of consent with no negative consequences for the research subject is covered by Mexican legislation. However, it is worthwhile to explore further the implications of this subject. A general provision by the European Commission consists of the possibility of free withdrawal, which often entails destruction (where possible) of the relevant biological sample(s) along with any personal information relating thereto; in some cases, by a specific request of the participant data subject.⁵⁹² Nevertheless, withdrawal is not always possible at all stages of the research process. “Consent to research may be withdrawn by the donor ‘unless such data are irretrievably unlinked to an identifiable person’ and that the data and biological samples should be dealt with in accordance with the wishes of the donor unless they are irretrievably unlinked.”⁵⁹³ In Switzerland, there is a standardised right to withdraw consent, which applies to pseudonymised samples and data and their future use. When consent is withdrawn, samples must be destroyed. The UK Biobank provides a sliding scale of withdrawal options reaching from

⁵⁹⁰ BM Knoppers and others, ‘‘Children and incompetent adults: consent and safeguards’’ (2002) 3 *Nature Reviews Genetics* 223

⁵⁹¹ *Ibid*

⁵⁹² European Commission 42

⁵⁹³ UNESCO International Declaration on Human Genetic Data 7

“no further contact”, “no further access” and “no further use”, whereas in Sweden researchers may still make use of the data even after the materials’ withdrawal.

Withdrawal from research is a basic ethical requirement to be included in any consent form; the right to decide to withdraw participation from a research project without consequences for the participant.⁵⁹⁴ The ‘right to withdraw with no consequences’ implies, in several cases, the destruction of biological samples. However, this option may no longer be feasible at all phases of the study; the sole destruction of the sample may not stop the use of the associated data analysis at advanced stages of the research.

6.3.2 Tissue

In order to reflect all the variables associated with the research type, biobanking guidelines should be developed for the type of tissue to be used depending on the project. As observed with regulations, such as those from the UK, determining the legal consequences depends on whether the tissue contains genetic information. Any potential further use of tissues must be established in advance; such as sample donation to a biobank for future research. “Prospective collection of samples for genetic research is an appropriate opportunity to deal with pertinent ethical and practical issues, rather than as and when the issues manifest as roadblocks for the research.”⁵⁹⁵ Potential unexpected situations and exceptions need to be covered, for example, retention periods of collected samples. If the consent forms do not allow retention after a certain number of years, collection of new samples would have to be collected “at the expense of time, funding and dissemination to the scientific community.”⁵⁹⁶

⁵⁹⁴ P.H.J Riegman, ‘TubaFrost 1: uniting local frozen tumour banks into a European network: an overview ’ (2006) 42 *European Journal of Cancer* 2683

⁵⁹⁵ Nyika 112 s

⁵⁹⁶ Wallace and BM Knoopers 37

Mexican biobanks use cerebral tissue, heart tissue, skin cells, blood plasma, brain spinal fluid, DNA, RNA, immortal lymphocytes, cellular lines and bone marrow fluid across several public biobanks in national health institutes, social security institutes, universities and technological institutes.⁵⁹⁷ Current guidelines set forth in related legal areas cannot be directly applied to biobanking. The General Health Law needs to differentiate between the different purposes of organs and tissues, and whether they will be used for transplantation or research purposes. As legal consequences vary considerably, each requires its own specific rules. The current minimum guidelines on transplantation cannot be directly applied to biobanking.

The UK's regulatory structure separates tissues and cells on the basis of their assumed biological 'riskiness'.⁵⁹⁸ The relevant material described as: bile, blood, bone marrow, bones/skeletons, brain, breast milk, buffy coat layer (interface layer between plasma and blood), cells when blood is separated), CSF (Cerebrospinal fluid), cystic fluid, faeces, foetal tissue, fluid from cystic lesions, hair (from deceased person), joint aspirates, mucus, nail (from deceased person), nasal and bronchial lavage, non-blood derived stem cells (i.e. derived from the body), non-foetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes), organs, pericardial fluid, platelets, pleural fluid, primary cell cultures (whole explant/biopsy present), pus, saliva, skin, sputum (or phlegm), stomach contents, teeth, tumour tissue samples, umbilical cord blood stem cells and urine. Non-relevant materials are: antibodies, sperm, RNA, lysed cells, gametes, artificially created stem cells, serum, nail (from living person), hair (from living person), embryos (outside the body), extracted material from cells, e.g.

⁵⁹⁷ Casabona and Simons 261

⁵⁹⁸ S Weber, D Wilson-Kovacs and C Hauskeller, 'The regulation of autologous stem cells in heart repair: comparing the UK and Germany' in C Lenk and others (eds), *Human Tissue research A European Perspective on the Ethical and Legal Challenges* (Oxford University Press 2011) 165

nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids, cell lines, DNA, eggs, embryonic stem cells (cells derived from an embryo), cells that have divided in culture, breath condensates and exhaled gases.

6.3.2.1 Post mortem samples

According to the Irish human tissue bill, no hospital post-mortem examination should be carried out and no tissue retained for any purpose whatsoever without authorisation. The bill also covers consent procedures for the use of tissue from the deceased donors for the purpose of research. The bill contains several other provisions pertaining to research. When consent is given for organ and tissue removal and retention as part of the post-mortem examination process, consent for the purposes other than the diagnosis of the cause of death may not be presumed, but must be specifically obtained for research. Tissue from deceased persons may be used for research if the removal, retention and use for the purpose in question are authorised either by an advanced healthcare Directive, by next-of-kin or by a nominated proxy. In contrast, according to Swiss legislation, a small amount of material may be taken without consent from bodily substances removed during a post-mortem or transplantation and will be anonymised for research purposes, provided that there is no documented refusal of the deceased.⁵⁹⁹ In France, donations from deceased persons operates under the presumed consent system with opting-out possible through registration in a computerized national register.

Macklin recognised that the main concern, regarding post-mortem material, is not regarding the dignity of the dead body, but respecting the relatives' wishes and feelings towards that body.⁶⁰⁰ Macklin and Brazier

⁵⁹⁹ Dörr 102

⁶⁰⁰ R Macklin, 'Dignity is a useless concept, it means no more than respect for persons or their autonomy' (2003) 327 BMJ 1420

and McGuinness' support the principle of autonomy of the living, which also involves the deceased and, in the case of biobanking, needs to at least not conflict with a decision made while the person was alive or a family decision.

The General Health Law has stated that cadavers must be treated with respect and dignity. However, no specific ethical guidance has been provided on the fate of samples from deceased donors specifically in research areas. In some cases, the use of biological samples from deceased individuals is expressly regulated,⁶⁰¹ which is desirable.

6.3.3 The relevance of data protection and the European data protection directive

Billie-Jo Hardy et al⁶⁰² have suggested that, whereas data and sample sharing are a primary concern in many developed countries regarding consent in association with privacy and confidentiality, the priorities of developing countries should be centred on the sovereignty of the data and of samples.⁶⁰³

6.3.3.1 Data and sample sharing

"Internationally, issues that rapidly need to be addressed for productive and equitable collaborations include data and sample sharing, research capacity building in developing countries, and rules and guidelines for building and using international repositories containing long-term treatment outcomes in both developed and developing nations."⁶⁰⁴ Clear limitations and specific safeguards should be applied in case biological samples are transferred abroad.⁶⁰⁵

⁶⁰¹ European Commission 41

⁶⁰² Hardy and others s 25

⁶⁰³ Billie-Jo Hardy and others, 'The next steps for genomic medicine: challenges and opportunities for the developing world' (2008) 9 Nature Reviews Genetics s25

⁶⁰⁴ Ibid

⁶⁰⁵ European Commission 41

In most European countries, personal data may be transferred outside the European Union or the European Economic Area only if the country in question guarantees an adequate level of data protection. A recent option to exchange tissue between countries with different regimes, respecting national regulations, is the coordinating “home-country principle,”⁶⁰⁶ which consists of taking the country where the tissue and associated data were collected and which normally corresponds with the research subject’s nationality as the main point of legal and ethical reference. The latter principle does not affect the use of such tissue in the country where it is sent within a research project, “even if that other country has more strict regulations enforced for residual tissue research.”⁶⁰⁷ The home country principle has also been translated as a “home-biobank principle”; the biological material is able to be used following the rules and informed consent initially established by the first biobank. The regulatory regime in which the tissue was collected establishes the use of the tissue.

6.3.3.2 Data protection in Mexico

The concept of personal data is fundamental within data protection. In Mexico, the Law recently incorporated the concept of Sensitive Data. This concept includes sensitive information, such as genetic data. There are penalties in case of non-compliance, as a protective measure against potential discrimination caused by personal data processors, such as telecommunication companies (see Chapter 5).

Legal requirements impact on the development of a common infrastructure for Mexican biobanks and the sharing of data and samples from across the borders. The Mexican General Health Law (article 317) establishes that organs, tissues and cells will not be able to be taken

⁶⁰⁶ EB Van Veen, ‘Tubafrost 3: Regulatory and ethical issues on the exchange of residual tissue for research across Europe ’ (2006) 42 Eur J Cancer 2919

⁶⁰⁷ Riegman 2682

outside of the national territory. Permission for tissues to be taken outside of the national territory will be granted only under specific requirements, except in emergency cases. (Article 317 Bis of the General Health Law).

The original article presents conceptual deficiencies which lead to confusion. It is not clear what requirements need to be satisfied in order for tissues to be taken of outside the national territory and it is not explained what 'urgent' cases mean. This article, strictly applied would only cover blood, blood derivatives and stem cells, since the phrase saying that blood can be a source of genetic material is redundant for study populations. Hence, bone biopsies (and other tissues) for rheumatoid arthritis research and any other research unrelated to population studies can be freely taken outside the national territory. In Europe, this would be impossible.

6.3.3.3 Data protection mechanisms

In Van Veen's opinion, "under certain conditions two-way coded data can be considered as anonymous data under the European data protection directive."⁶⁰⁸ Coding is sufficient to avoid an individual patient being traced back, unless many variables are included, using databases in different locations.⁶⁰⁹

Filter techniques seem to be a suitable choice, for example, privacy enhancing technologies (PET) provide coding techniques which allow donors to be anonymised and still uniquely discernible⁶¹⁰ for tissue to be used in coded form.

"Where it proves impossible to use anonymous or anonymised data or biological samples because of the specific features of the research, such data and samples may be used after being 'coded' (pseudonymised); ad-hoc safeguards are envisaged in some cases to ensure that data and samples are pseudonymised under stringent confidentiality rules (e.g.

⁶⁰⁸ Veen 1438

⁶⁰⁹ Schmidt 2380

⁶¹⁰ Veen 1438

*double code) and the cases are specified in which it may prove necessary to de-code (de-crypt) the information in question.*⁶¹¹

Data protection mechanisms need to be fit for both research and research participation purposes. “It is important for researchers to ensure that the informed consent captures all issues that are of concern to the participants and their communities.”⁶¹² The main identified problem is the insufficient supervision by the Mexican authority to verify the compliance with these minimum ethical requirements.

The transferral of biological material and associated data can be agreed whenever minimal general rules are part of the agreement, such as those provided by the EU directive and in the initial informed consent, providing the participant the choice to accept or deny authorisation for the transferral. The agreement may include: “Sending the samples in a coded form; the obligation, for the receiver of biological materials, to use them only according to the research protocol approved by the Ethics Committee, and return of all the remaining materials to the prior biobank.”⁶¹³ The development and publication of tissue transfer agreements are relevant for matters such as “design issues, for example, the web site, access to the database, coding or labelling of the sample, etc.”⁶¹⁴ These agreements “could have major implications for the conditions on how to work with and exchange tissue samples between the different European countries by law,”⁶¹⁵ as long as they do not contradict local legislations.

Confidentiality in Mexico is covered in the data protection federal laws (LFTAIPG) by the statement that the data subject will not be identified. However, the mechanisms to do this are not specified. In Germany, any transfers must take place in anonymised or coded form. In

⁶¹¹ European Commission 41

⁶¹² Nyika 112 s

⁶¹³ Porteri and Borry 141

⁶¹⁴ Riegman 2682

⁶¹⁵ Ibid

Austria, the donor's identity must not be known to the researchers using the specimens. Non-anonymised data may only be used for different purposes from those originally established under explicit and written consent. Spain and Greece show different postures. Informed consent in Spain is also required for anonymised samples, whereas in Greece anonymised data is non-personal and thus its protection is not within the scope of the Act. The Slovakian legislation follows the option of coding, in which a unique numerical code is allocated to the donor and to the donated tissues and cells. That ensures proper identification of the donor and the traceability of donated material protecting the identity of the research subject at the same time.

Anonymisation would not be the best choice for Mexico due to its limited scientific value⁶¹⁶ and the impossibility to truly anonymise data. Manasco argues that "due to the increasing amounts of clinical and genomic data, the ability to truly anonymise data and samples is impossible."⁶¹⁷ How the Mexican law will apply when data has not been anonymised or made unidentifiable is subject to interpretation.

6.3.3.4 The European data protection directive

The main data protection framework in the EU is the Data Protection Directive 95/46/EC.⁶¹⁸ It has provided a framework for an international approach to protecting personal data privacy and appears to be gaining approval elsewhere.⁶¹⁹ Data protection legal regimes in some countries, even outside of Europe, are based on specific data protection frameworks.

⁶¹⁶ Eriksson and Helgesson 1074

⁶¹⁷ Manasco 25

⁶¹⁸ Council & Parliament Directive 95/46/EC, 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

⁶¹⁹ A Charlesworth, 'Implementing the European Data Protection Directive 1995 in UK Law: The Data Protection Act 1998' (16) 1999 Government Information Quarterly 233

The European Directive 2004/23/EC⁶²⁰ provides general guidance on the exchange of tissues and cells between Member States to ensure the traceability of tissues and cells, subject to meeting the standards of quality and safety. Similar to other research ethics issues, more specific guidelines are needed to resolve ethical questions on data and sample sharing, for example, whether the authorisation to use tissue for research under flexible rules would have to be re-scrutinised if the material is then used in a country with strict rules.

6.3.3.5 Re-contact issues

Data associated with biological samples may involve various ethical implications under the current national guidelines; this is the case with discoveries of a personal informative value. However, genetic information is different from health information. If the research project does not involve individual clinical care and the research findings are not expected to have individual predictive value, the provision of feedback to the patient may not be necessary. These concerns are not unique to pharmacogenetics. Whilst the suitability of particular drug treatment may not be sensitive, the revelation of secondary information about disease predisposition or progression, which may follow test results, has potential adverse employment and insurance effects and implications for relatives.⁶²¹

There are similarities in the current national recommendations on biobanking in Switzerland, Austria and Germany. For example, the specifications regarding donors participating in biobank research consider who should be informed about findings with personal, diagnostic or therapeutic relevance (Switzerland) or findings which are essential to life

⁶²⁰ Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

⁶²¹ A Buchanan and others, 'Pharmacogenetics: ethical issues and policy options' (2002) 12 Kennedy Inst Ethics J 1-15

(Austria, Germany). Other frameworks are different. According to the first report of the Irish Council for Bioethics,⁶²² in some situations it may be extremely difficult or impossible for investigators to re-contact individuals and obtain consent for the use of their archived biological material. This may be the case for large-scale studies involving the treatment of huge volumes of DNA sequence and/or expression data from large numbers of people.⁶²³ Material may have been stored for long periods of time, individuals may have died or become untraceable. In some cases, it might be prohibitively costly to re-contact large numbers of individuals to seek consent, especially for academic-led studies. Therefore, where it is not practical to obtain consent from individuals for use of their archived material, Research Ethics Committees may waive the requirement for consent.

The best option should be decided in terms of research types. In general, the most important ethical aspect is the maintenance of “a strong link between the use of biological samples and the donor’s informed consent.”⁶²⁴ The informed consent form should give precise indications on the identifiability of the biological material and coding modalities. Within some types of research, the potential to know about an individual risk of disease from data associated to a sample is of statistical nature. No prevention is possible; therefore, re-contact is pointless. According to the European Commission, “in research projects there is no responsibility to return results to individuals.”⁶²⁵ Reciprocity would imply participants’ knowledge on how their contribution through sample donation is helping research.

⁶²² Office)

⁶²³ Cho 1

⁶²⁴ Porteri and Borry 141

⁶²⁵ European Commission 53

In Mexico, although “there is a commitment to provide the research subject with updated information obtained during the study,”⁶²⁶ it has not been clearly established whether the research subject is entitled to the right to have any results obtained through research disclosed. In some informed consent forms, the person concerned is asked at the very beginning about his or her desire to be (or not to be) contacted again, while in some others the possibility of being re-contacted is excluded.⁶²⁷ Even when both choices may be ethically opposed, the decision to be made on whether or not to provide feedback to the participant will depend on the nature of the research involved. “Whether such individual feedback is possible will very much depend on the nature and set-up of the research.”⁶²⁸

6.4 Oversight

International ethical oversight requires each country to be responsible to regulating “the nature of the control and bureaucratisation of processes.”⁶²⁹ Not only has regional guidance been followed by Member States, but also national frameworks such as the Dutch Medical Contract Act, which is well known due to its clear structure. Eastern European countries, Lithuania and Estonia, have based their patient rights on the Dutch Medical Contract Act.⁶³⁰ Germany is regulated in terms of oversight under the auspices of one main authority and one main legal instrument, and clinical trials are subject to a more streamlined procedure.⁶³¹ German governance team members talk about regulation in terms of the formalisation of procedures, while the UK team stressed

⁶²⁶ Reglamento de la Ley general de Salud en Materia de Investigacion para la Salud (The Ministry of Health Rules of the General Health Law on Health Research) Article 21-IX

⁶²⁷ Porter and Borry 140

⁶²⁸ Veen 1444

⁶²⁹ Kaye and others 137

⁶³⁰ T Birmontiene, ‘Changes in the Lithuanian health law and the influence of the Netherlands Civil Code’ (2002) 9 *European Journal of Health Law* 381-95

⁶³¹ Weber, Wilson-Kovacs and Hauskeller 165

the emerging nature of regulatory practices and the process of bringing together different actors and agencies in the regulation of their trials.⁶³²

Clinical trials are performed by Mexican public and private institutions.⁶³³ According to the General Health Law rules, health research through clinical trials can only be authorised by the Mexican health authority, that is, COFEPRIS. The institute aims to protect the population against sanitary risks through sanitary regulation, and administrative controls. In contrast to the CNB, COFEPRIS is responsible for monitoring. Due to provisions contained in European Directive 95/46/EC (which is currently under revision), Data Protection Authorities also have an important role in overseeing data, not only within biobanks, but also the use of data and samples by researchers. For example, Data Protection Authorities: have been empowered to identify the rules that can be relevant for biobank research in Italy, have given guidance to stakeholders in Germany, were responsible for monitoring the creation and operation of the Health Sector Database in Iceland, issued an authorisation to the legislators in Portugal on biobanks, were involved in public hearings in the national Parliament of Sweden, and, in some cases, have used their enforcement powers.⁶³⁴

Regarding the oversight of the Mexican human genome, although the legislation describes the conduct to be sanctioned,⁶³⁵ no procedures exist to enforce them. The Mexican legislator has failed in involving the right authorities in the right issues. The Ministry of Health should not involve the National Institute of Genomic Medicine (INMEGEN) as a

⁶³² Ibid

⁶³³M Castellanos, 'Clinical Research in Mexico: An Overview. The conduct of clinical trials in developing countries has received increased attention recently. The outlook in Mexico' Estern Medical, Clinical Research Organization and Consulting Company for Global Biotech's Pharmaceutical and Medical Device Companies
<<http://www.esternmedical.com/information/article06.php>> 1

⁶³⁴ European Commission 44

⁶³⁵ LGS Article 103 7 and 421 *ter*

government assessor and national reference centre to be responsible for the registration of ethical authorisations,⁶³⁶ since the INMEGEN itself needs to be regulated as it performs population studies.

Examples of consistent European practices which could be effectively adopted by Mexico include:

- “Biobanks’ accreditation should be sought with the competent national authorities, usually the Ministry for Health, the Ministry of Research or local pharmacology agencies.”⁶³⁷
- “The creation of a biobank should be notified, and the competent national authorities, including the data protection authorities should accordingly set up registries of biobanks.”⁶³⁸
- “Supervision should be carried out by the competent national authorities alongside the supervision of the national data protection authority.”⁶³⁹
- “Management of biobanks should be committed to a specific individual or entity, usually from the medical (or biological) profession.”⁶⁴⁰

6.4.1 Sanctions

There are no explicit penalties for breaching EU guidelines, in the same way that Mexico does not have clear sanctions in terms of data protection. Even so, responsibility could be placed at the members’ local level. The situation is different at the local level, for example in the UK, where “serious violations of ethical conditions may prompt remedial action.”⁶⁴¹ These include issuing cautions, disciplinary action,

⁶³⁶ Ibid

⁶³⁷ European Commission 40

⁶³⁸ Ibid

⁶³⁹ Ibid

⁶⁴⁰ Ibid 41

⁶⁴¹ Kaye and others 77

professional misconduct, fitness to practiced procedures,⁶⁴² suspension or termination of researcher's or biobanks' funding, fixed and variable monetary penalties, stop notices, compliance requirements, restoration requirements, civil sanctions, conduct audits and criminal prosecution.⁶⁴³ Breaching of the Human Tissue Act or its codes of practice are legally founded reasons for suspension and withdrawing of licenses. "Inspect premises; and stop the use or transfer of human tissues for purposes; or in ways, that are not permitted."⁶⁴⁴ In any case, the physical intervention itself requires the informed consent of the donor. This is the case in Germany, where extraction without informed consent constitutes an act of bodily injury according to 223 of the German Criminal Code.⁶⁴⁵

The sanctions imposed by the Mexican law only consider direct threats to a subjects' personal welfare. The fact that Mexican ethics committees operate with ample discretion and little oversight continues to be problematic. Given that the only requirement for Mexican research ethics committees since 2012 is registration,⁶⁴⁶ no sanctions currently exist for noncompliance. Only a few aspects in relation to biobanking, such as population studies, have been considered for potentially serious sanctions.⁶⁴⁷ "The person who transports organ, tissues and components from living or dead donors outside the national territory (or performs related actions) will receive between four to fifteen years of imprisonment and a fine for 300 to 700 days of minimum wages." The same sanction will apply to that person who performs actions related to the transportation of ADN tissue sources for genomic population studies. If the responsible person is a professional, technician or assistant within health areas, the penalty will additionally involve the suspension of professional activity for

⁶⁴² UK Human Tissue Act s 5 Regulatory UK Regulatory Enforcement and Sanctions Act s42

⁶⁴³ UK Regulatory Enforcement and Sanctions Act pt 3.

⁶⁴⁴ Kaye and others 77

⁶⁴⁵ German Criminal Code 'Strafgesetzbuch', StGB.

⁶⁴⁶ LGS Articles 41 bis and 98

⁶⁴⁷ Ibid Article 317 bis

a maximum of 7 years.⁶⁴⁸ Obtaining separate time-consuming authorisations may not be burdensome for researchers if the law, even when is not comprised in a single framework, is interconnected.

6.4.2 Ethics committees

RECs are the formal bodies that are common to European countries with the purpose of reviewing biobank protocols and the Data Protection Authorities responsible for the oversight of data processing. The ongoing reform on the ethical review process, both in the UK and Europe, focuses on the facilitation of good research; efficiency, effectiveness and proportionality are of key importance, but this has not always been the case.

The UK, at some point, experienced “the failure to give statutory authority to all RECs”⁶⁴⁹ which led to a complex system at the time; “researchers felt stifled by bureaucracy.”⁶⁵⁰ Until recently, the REC system was voluntary and non-statutory. Today, however, “certain RECs – notably, those legally recognised under the Clinical Trials regulations – enjoy limited statutory status and formal authority to give ethical opinions on clinical trials involving investigational medicinal products.”⁶⁵¹ The Mexican situation resembles some of the past experiences of the UK in terms of ethics committees. The IMSS Mexican health department has a system of 335 local research ethics committees (LRECs). The UK Department of Health first recommended that district health authorities establish local research ethics committees (LRECs) in 1975. More detailed formal guidance was issued in 1991. Each local health authority was required to set up at least one, and there were over 200 LRECs in all. By 1997, due to limited guidance and coordination, the LRECs’ review process was often inconsistent; multi-centre researchers faced a diversity

⁶⁴⁸ Ibid Article 461

⁶⁴⁹ M Brazier and E Cave, *Medicine, patients and the law* (Penguin Books 2011) 465

⁶⁵⁰ Ibid

⁶⁵¹ Kaye and others 77

of procedures and outcomes. However, RECs were acquiring independent statutory authority, which was later formally delegated by the UK Ethics Committee Authority (UKECA). Rather than giving all RECs statutory authority (as occurred in some countries), the Ethics Committee authority recognises certain RECs appointed by a range of authorities including: strategic health authorities, the National Research Ethics Service (NRES), universities and independent institutions.

General oversight schemes at the national level are linked to ethics committees, for example the Human Tissue Authority in the UK, which does not have an easily identifiable Mexican equivalent. The Mexican Ministry of Health has been over-loaded with many responsibilities, including biobanking. This is concerning as the Mexican Ministry of Health is, in theory, responsible for the oversight of biobanking. Another level of oversight is undertaken by the institutions where the biobank is based or by the local health authorities which host the biobank.⁶⁵² This could be equivalent to the National Institute of Genomic Medicine in Mexico. Generally, National Bioethics committees are also part of the oversight scheme for guidance purposes, for example, the Mexican National Commission of Bioethics.

Coordination and authority will be key elements in the search for standard guidelines for Mexican biobanking research committees. Research ethics committees should assess the purposes to be achieved when setting up the given biobank. In some cases, ethics committees are required to assess each research project that is expected to rely on biological samples. However, it is rarely the case that the specific issues to be considered by ethics committees are examined in detail, and different approval procedures based on different arrangements are usually envisaged in the individual legal systems.⁶⁵³ Another choice is the

⁶⁵² European Commission 43

⁶⁵³ Ibid 41

possibility of centralisation for ethics committees. At this point, Mexico only has LRECs. Participant M thinks that if each committee has different needs then it is fine that each institution has a committee.⁶⁵⁴ Although LRECs involve some advantages, at the same time, Participant M recognises that there can also be disadvantages: “we have multi-centric research and it is difficult to determine whose committee will scrutinise the project.”⁶⁵⁵ Experience in the UK has shown that the evolution from LRECs to centralised committees was part of a process which proved positive in the end. The same could be experienced by Mexico.

6.4.3 Self-regulation and E-governance

Regarding self-regulation, there is no clear evidence that its role has been determined for most primary European frameworks. The UK has experienced that “self-regulation is only likely to work effectively where it costs business more to breach the self-regulation policy than it does comply.”⁶⁵⁶ These types of agreements partly motivated the 1998 UK Tissue Act. It was necessary to provide a legislative backstop for sectoral self-regulation with clear and effective penalties for non-compliance with the law. “Public pressure for companies to operate in compliance with sectoral codes of conduct, while much touted as a valuable mechanism for facilitating effective sectoral self-regulation, is rarely sufficient by itself to ensure that this happens on a consistent basis.”⁶⁵⁷ Nevertheless, with legislation in place, self-regulatory practices can be acceptable if these do not contradict established rules. According to Kaye et al,⁶⁵⁸ “an inconsistent regulatory framework can also lead to innovation.” A good example is UK Biobank, which has set up its own governance systems to ensure accountability and transparency.”

⁶⁵⁴ Responsible-of-the-Human-Genome-Department-at-a-public-ethics-advisory-institution-Participant:M

⁶⁵⁵ Ibid

⁶⁵⁶ Charlesworth, ‘Implementing the European Data Protection Directive 1995 in UK Law: The Data Protection Act 1998 ’ 233

⁶⁵⁷ Ibid

⁶⁵⁸ Kaye and others 90

Additionally, self-regulation has worked for some (although a small proportion) as a solution in Europe. New ideas for governance have recently gained traction from a collection of frozen specimens to virtual biobanks.⁶⁵⁹ New “e-governance” systems have emerged that allow consortia to function through self-regulation as the result of many initiatives marking the evolution of biobanking. The internet is now used to facilitate collaboration among medical researchers, gaining the consent of participants through web-based tools. One example is the EnCoRe⁶⁶⁰ project, in which “dynamic consent,” was presented as a possible solution for the endless dilemmas of potential future re-consent; the consent of choice where participants are continually updated.

Self-regulation in Mexico has resulted from attempts by those who participate actively and make decisions in biobanking activities and struggle to find uniform and consistent guidance. Normally, an ethics committee decides on the fate of biological samples after their first specified use. For instance, the committee has to resolve ethical controversy which could emerge from further uses, addressing the concerns involving privacy and data protection of participants who are still alive. The choice of re-contacting participants does not resolve the whole situation, it can become too difficult or unaffordable. If samples are anonymised and no privacy risks are involved, the ethics committee could determine that no further re-consent is necessary. Self-regulatory agreements are common instruments, agreed between the national representatives of the pharmaceutical industry in Mexico. However, the way self-regulation currently operates in Mexico has proved problematic, (See case study in Chapter 3) it has worked as a form of self-authorisation that can lead to exploitation.

⁶⁵⁹ YG De Souza and JS Greenspan, ‘Biobanking past, present and future: responsibilities and benefits’ (2013) 27 AIDS 310

⁶⁶⁰ MM Casassa, V Sharma and S Pearson, *EnCoRe: Dynamic Consent, Policy Enforcement and Accountable Information Sharing within and across Organisations* (HP Laboratories 2012) 1-69

6.5 Concluding remarks

Analysing present legislation, which other countries have used to solve similar situations in Mexico, constitutes a way forward for a possible solution. There are still valuable lessons to learn from those countries which have already achieved the necessary frameworks for the use of archived samples, not only for genetic research, but other related biobanking aspects. International biobanking models with the potential for implementation in Mexico require a careful evaluation according to the needs of the national context. For this reason, the interpretation of ethical principles must be based on cultural sensitivities. The selected international governance models must also be sensitive to the needs of the different actors involved in biobanking.

The main lesson to learn from Europe is the need to successfully harmonise external frameworks with local contingencies. Every issue is based on national realities and connected to cultural and ethical perceptions. No foreign regulation can “fit” the unique conditions currently faced by Mexico. That said, many real-world initiatives have inspired fresh thinking, including numerous examples from overseas biobanks.

Mexico has the choice of learning from experiences or looking at processes that have proven effective among common circumstances. Past mistakes should assist future improvement. This chapter has identified some national frameworks to examine, based on contextual and circumstantial similarities. European biobanking frameworks vary significantly, depending on each country’s situation. The unification of biobanking standards in Europe currently remains unclear due to a future consensus that is difficult to envisage at present. European member states are aware of the difficulties of adopting a European standardised legislation for biobanks, but recognise the need to “develop a consistent and coherent legal framework for biobanking that should protect participants’ fundamental rights, in particular in the areas of privacy, data

protection and the use of human tissue in research.”⁶⁶¹ Several identified parameters can lead to effective standards for international sample and data sharing. Some identified actions can be avoided when designing biobanking legal policy, including genetic exceptionalism (especially at the population level) and excessive legal burdens.⁶⁶² Specific, flexible and harmonised agreements are key elements to resolve the ethical and legal issues caused by divergent frameworks, such as those in Europe. International collaboration needs to take into account multidisciplinary aspects. The adoption of consensual guidelines may be an interim solution. There are important lessons to learn from the European experience, but more specifically about the European countries involved. The situation of each of them is different and each of them involves examples of similarities and disparities with the Mexican situation.

Europe has developed a comprehensive framework due to the expansion of biobanks, ethical treatment of tissue, the necessity to share samples and related data, and ever increasing scientific and biomedical research. The current European Data Protection Directive could be relevant in the establishment of basic data protection, in terms of international research collaboration. Most studies in Mexico are multi-centric these days.⁶⁶³ Consistent regulation is important if multi-centre trials are to cross national boundaries. Most European countries have effectively ratified data protection mechanisms, such as anonymisation or coding. However, in the case of more specific issues, such as informed consent, a more careful analysis is still required.

Kaye has stated that biobanking improvement is part of a gradual process. In the UK’s case, “terminology and standards were in a state of

⁶⁶¹ European Commission 48

⁶⁶² Graeme Laurie, ‘Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of the law’ (2011) 130 *Hum Genet* 351

⁶⁶³ Responsible-of-the-Genetics-department-at-a-public-ethical-advisory-institution-Participant:I

development and still emerging and there is considerable uncertainty within the research community.”⁶⁶⁴ Mexico is still in the early stages of a similar process, in which the coordination among stakeholders will play a fundamental role. Even when national collaborations involving research are intended to be equal and more independent, changes for the protection of citizens relate to: academics, judges, law makers, the government, human rights commissions and the wider society. The culture of transparency is essential where research takes place, and recent views relate closely to biobanking and public engagement.⁶⁶⁵ Interviews presented in previous chapters emphasised the need to strengthen coordination among stakeholders. The independence of science and technology relies on the organisational level among Mexican groups, and helps to build the research subjects’ trust towards the decisions made by research teams and biobanks.

Based on the European experience, the issues raised by Mexican biobanking require solutions that are sensitive to its own particular needs. Actions to implement include the development of appropriate ethical and legal attitudes towards the research participants and the value and nature of the research project, on a culturally sensitive basis. The same models used abroad for population studies could be used in Mexico, although Mexican populations participating in such studies are more vulnerable. Researchers have to find out the model or models that would be acceptable in the particular communities where research studies are to be conducted,⁶⁶⁶ which must include social experiences in defence of human rights.

⁶⁶⁴ Kaye and others 4

⁶⁶⁵ KC O’Doherty and MM Burgess, ‘Engaging the public on biobanks: Outcomes of the BC Biobank Deliberation’ (2009) 12 Public Health Genomics 203-215

⁶⁶⁶ Nyika S 21

7. Implementing change in Mexican biobanking

7.1 Introduction

Previous chapters have made evident the absence of a consistent legal framework to govern the data and tissue necessary for research in Mexico, and significant legal inconsistencies have been discovered within Mexican biobanking. The aim of this chapter is to identify the best ways to implement change in Mexican biobanking, proposing ways in which those inconsistencies could be fulfilled. Governance, the conceptual basis of implementation, will also be discussed, in particular the model of reflexive governance will be analysed in order to determine the elements which could strengthen a suitable regulatory proposal.

Priority areas, such as informed consent and data protection, will be focused in on as areas that require major changes in implementation. The role of key governing institutions will be explored in order to evaluate their effectiveness in both public and private institutions. Different degrees of external control and supervision will be highlighted as means to improve implementation. The role of trust will be explored. Finally, a brief analysis of emergent governance measures, as viable options while implementation takes place, will follow.

7.1.1 The role of governance

The etymology of the word 'governance' can be traced back to the Latin term *gubernare*, connoting rule making.⁶⁶⁷ Governance is a multifaceted concept. Robin Bunton and Alan Petersen⁶⁶⁸ suggest that the best governance focus should be inclusive. Gotweis and Lauss have proposed that the role of biobanking governance should be understood as "a strategy for patterning a network of interaction that unfolds within and across a number of different fields including a variety of activities that

⁶⁶⁷ Bunton and Peterson 4

⁶⁶⁸ Ibid 2

go beyond regulatory activities.” These fields can be: science and technology, medicine and health, industry and economy, legal and ethical, and society and politics.”⁶⁶⁹

7.1.2 The model of reflexive governance

Gottweis and Lauss have highlighted the development of new modes of enquiry and models of ‘lay participation’ by policy makers based on public interests.⁶⁷⁰ Biobanking governance can be solely reflexive, through the assurance of long-term social commitment, by encouraging responsive participation from the diverse views of different stakeholders.⁶⁷¹

Models of reflexive governance involves “facilitating mechanisms of mutual learning in addressing genuine dilemmas.”⁶⁷² When these emerge, it is about understanding them and addressing challenges, then working together to meet expectations. Reflexive governance acknowledges legitimate coordination and consequent mutual learning. However, coordination by itself is not sufficient; solidarity and trust also need to be reflected by governance in ethical features, such as informed consent. Reflexive governance, ultimately, signifies the need to encourage legal governance recognising legal boundaries and providing a firm basis for legal action. It also aims to encourage clarification on each stakeholder’s role in cooperative actions. The role of each stakeholder should be equal, following reflexive governance, otherwise it would not be legitimate.

7.1.3 The legitimacy of governance actors

A substantial element of governance consists of the roles of involved actors and their legitimacy. It is about both the people and the

⁶⁶⁹ Gottweis and Lauss 61

⁶⁷⁰ Ibid 194

⁶⁷¹ Ibid 187

⁶⁷² Laurie 351

science.⁶⁷³ Dynamic and interactive research processes involve multiple actors: scientists, health professionals, policy makers, funders, industry and members of the public (including research participants). Bioethical researcher Mats Hansson⁶⁷⁴ argues that the data collected is not only linked to the patient but, in many cases, also to his relatives. This type of family link creates a legitimate interest in areas like efficiency and integrity of biobanks, i.e. governing the storage, use and sharing of samples. Biobanking is associated with those participating directly and with general public. This will be part of the process for long term biobanking legitimisation. “The project’s long term viability could be threatened if biobank’s funders fail to adopt a more open approach and engage not only the project’s participants and stakeholders but the wider public.”⁶⁷⁵ However, “there may also be third parties, such as insurance companies, employers or the police with an interest — which may or may not be legitimate — in gaining information about the diagnosed individual and his or her relatives.”⁶⁷⁶

7.1.4 Public awareness and engagement

According to Salter and Jones, the legitimisation of biobanks’ ethics would not necessarily depend completely on the legal framework. “Traditionally, public support for new technologies has been assured through governmental regulatory arrangements that have relied heavily for their legitimacy on the authority of scientific advice.”⁶⁷⁷ Legitimising processes should consider public awareness as a *sine qua non* element for the materialisation of results in practice. Political will and leadership are expected to be the rationale of public engagement in terms of

⁶⁷³ MJ Murtagh and others, ‘Realizing the promise of population biobanks: a new model for translation’ (2011) 130 Hum Genet 334

⁶⁷⁴ Mats Hansson, *The Use of Human Biobanks – Ethical, Social, Economical and Legal Aspects* (Research Program Ethics in Biomedicine, Uppsala University, 2001) 93

⁶⁷⁵ House of Commons Select Committee on Science and Technology, *The Work of the Medical Research Council* (The House of Commons, 2003) para 63

⁶⁷⁶ Hansson 526

⁶⁷⁷ Salter and Jones 713

organisation. In this sense, within the context of reflective governance, public engagement can work as “an effective means to address a concrete unmet need in biobanking practice.”⁶⁷⁸ Support from the media, along with other forms of knowledge dissemination, is essential and constitute a way to simplify the complexity of interaction processes.

Public engagement by the biobanking community is essential,⁶⁷⁹ as public interest is the main justification for the legal authority’s intervention in biobanking; “law might be called upon both to protect and to promote core interests engaged in biobank practices.”⁶⁸⁰ But in general, public support will be key in overcoming policy and legal obstacles.

7.1.4.1 Public forums, a way to materialise public engagement?

Following O’Doherty and Burgess, when critical issues can be identified in the early stages of their evolution, more attempts can be made to create an appropriate dialogue with stakeholders and the public. This would enable the development of public awareness and public acceptance, favouring anticipatory arrangements such as regulation.⁶⁸¹ Public engagement involves exercises for the public to have a say regarding biobanking policy. The first step is selecting viable exercising options. Public consultation can be used to address criticisms and to enhance informed and more widely representative views of the public interest.⁶⁸²

It is necessary to achieve a reasonable consensus among citizens, and a suitable instrument for this purpose could be public

⁶⁷⁸ Laurie 355

⁶⁷⁹ Hewitt 116

⁶⁸⁰ Laurie 351

⁶⁸¹ O’Doherty and Burgess 213

⁶⁸² PW Hamlett, ‘Technology theory and deliberative democracy ’ (2003) 28 Science Technology and Human Values 122

consultation. The implementation of consultation would require specific mechanisms such as identifying appropriate consultation types and incorporation of the results into policy making.⁶⁸³ Biobanks are expected to develop ways to maintain and attract participation. Knowledge dissemination of realistic health benefits associated with biobanking can be the main tool to incentivise active participation of the population.

The participation of those involved in research biobanks should be acknowledged as equally valuable. From these recommended measures, educational sessions with stakeholders seem more suitable for Mexico at this point. Once participants and patients had proper knowledge, then there could be a more active participation in forums from research to medical expertise. As pointed out by Cambon-Thomsen et al., more biobank openness, balanced with an increasing use of dialogue and public-stakeholder consultation, can lead to the public demand of better controls.⁶⁸⁴

Public forums may be viable for their representation and participation of scientists, industry, government and health and research representatives and the public in general. “To ensure that different perspectives are being considered, ethics and legal expert opinions are now used to complement the opinions of scientists to assess the risks of policies and practice.”⁶⁸⁵ The isolated example of INMEGEN’s open forums (Chapter 3), while it conducted the HapMap project, should be made compulsory to projects of this nature by law. The ‘Mexican HapMap’ showed an acceptable degree of public engagement, which is not a guarantee that every biobanking population project will follow the same self-regulatory steps. Hence, simultaneous encouragement of oversight will be critical for the legitimacy and operation of Mexican biobanks.

⁶⁸³ Salter and Jones 713

⁶⁸⁴ Cambon-Thomsen, Rial-Sebbag and Knoppers 375

⁶⁸⁵ Hawkins and O’Doherty 313

The Mexican legislative congress has also proposed forums,⁶⁸⁶ but these and other academic or medical and scientific areas of expertise, organise purely internal activities, unable to generate an impact on knowledge translation. Forums would be an open space of communication and interaction to discuss the benefits that could be achieved, whether these are aimed at the community, the Mexican population or even mankind, and whether the project could be linked to health programmes. More involvement is required from the scientific community; hence, the organisation of forums should be compulsory for these cases.

7.2 Priority areas

7.2.1 Data protection

Society needs to both recognise the vital importance of personal data and start demanding personal data protection. Data protection laws will only work effectively when data users are willing to be bound by them and there is meaningful enforcement against rogue companies and information pirates.⁶⁸⁷ Hansson has highlighted that the public, when participating in either biomedical or genetic research, consider the importance of privacy in relation to the study itself. Even when the degree of risk involved by biobanking research is minimal, “there is still reason for concern since insurance companies, employers, and other third parties may have a great interest in information acquired through human tissue sampling.”⁶⁸⁸

Operative rules for disputed access would justify the involvement of the judiciary.⁶⁸⁹ An important and viable reference point for these issues would be to make sure that law and policy makers become aware of the

⁶⁸⁶ Science-and-Technology-Commission-Participant:K

⁶⁸⁷ Charlesworth, ‘Implementing the European Data Protection Directive 1995 in UK Law: The Data Protection Act 1998’ 234

⁶⁸⁸ Hansson417

⁶⁸⁹ B Capps, ‘The public interest, public goods and third party access to UK biobank’ (2012) 5 Public Health Ethics 5

topic. The Mexican Congress requires greater expert support. Participant K, a member of the current parliamentary commission for Science and Technology, said that he was “not familiar with information about topics such as biobanks. Data protection has had a very strong impact recently and it has to do with biobanks. There are vulnerable groups to protect.”⁶⁹⁰ Bioethics is not currently a priority in Mexico, which also means that, although biobanking is not the only issue within legislative works, it needs to be attributed to a specific commission.

Participant J has highlighted the need for Mexicans to act sensibly as citizens by understanding the importance of personal data and then demanding personal data protection.⁶⁹¹ If the Mexican population is not aware of the risks involved in the potential abuse of data when donating a sample, then the authorities will not be asked to provide protection.

Law makers may, with careful attention, actually operate and protect participants. This is an argument picked up by leading policy makers, such as Participant K, who claimed not to be well informed regarding the topic but was interested in improving regulatory aspects. “I do not know about biobanks. I would have to have a look. I believe that persons who provide samples (freely or through a payment) need to know and authorise the extent of use of the sample and forthcoming data. Ultimately, it’s their identities.”⁶⁹²

Gerardo Laveaga, IFAI’s commissioner president, has mentioned that “the dispersion of responsible subjects and the little awareness shown by those entitled to privacy and data protection are a couple of challenges to be faced by the IFAI and the legal Mexican community.” IFAI announced that, according to a survey organised by the institute,

⁶⁹⁰ Science-and-Technology-Commission-Participant:K

⁶⁹¹ Datap-protection-expert-at-a-public-research-institute-Participant:J

⁶⁹² Science-and-Technology-Commission-Participant:K

more than 50% of the participants are not concerned, or only a little concerned, regarding the fate of their personal data. “If we consider the amount of institutions dealing with personal data, this is highly worrying.”⁶⁹³

7.2.2 Informed consent: the suitability of a specific model

In terms of communication between participants and biobanks, two elements are needed to reinforce informed consent: specific consent procedures and a closer involvement from participants. “The inevitable decrease in reliance on informed consent and the increasingly obvious inability of researchers to guarantee protection of privacy should be countered by more attention on appropriate governance mechanisms.”⁶⁹⁴

Informed consent contributes to engage participants more fully in the research process. Bioethics literature has constantly emphasised the role of consent procedures preceding the act of donation as a device “that may contribute to instil trust,”⁶⁹⁵ and therefore legitimisation based on autonomy. If the donors’ trust is not obtained by consent and information procedures, such procedures are not necessarily sufficient to prevent irresponsible uses of data biobanks.⁶⁹⁶ Similarly, within medical areas, “several studies have revealed that health providers may not have the skills necessary to critically analyse and communicate genomic information and meaning, suggesting that some are not prepared for the

⁶⁹³ A Morales, ‘ A 50% no le preocupa datos personales: encuesta IFAI (50% are not concerned about their personal data)’ El Universal
<<http://www.eluniversal.com.mx/notas/899033.html>> accessed 28 January 2013

⁶⁹⁴ Hawkins and O’Doherty 312

⁶⁹⁵ Pascal Ducournau and Roger Strand, ‘Trust, Distrust and Co-Production: The Relationship between Research Biobanks and Donors ’ in Jan Helge Solbakk, Søren Holm and Bjørn Hofmann. (eds), *The Ethics of research biobanking* (Springer-Verlag Solbakk. 2009) 2

⁶⁹⁶ Ibid

present flood of new consumers interested in genetic testing,”⁶⁹⁷ for instance.

The current Mexican rules remain inconsistent, fragmented and incomplete, if we take into account that most of the guidelines only cover ‘the human genome’. The legality of some activities is not entirely clear yet, e.g. particular types of consent and the legal qualification of the sample source-person which “cannot be the same when samples are obtained within the healthcare context or within the research context.”⁶⁹⁸ Chapter 5 showed that Mexican informed consent ethical guidelines are based on a predominantly medical focus and “more attention has been focused on health areas.” (5.1.2)

Designing a suitable consent model is not a simple task. The agreement on what model would suit the needs of Mexican citizens remains open to debate. A broad consent model would only be acceptable as long as a social need (such as health) is supported and autonomy respected. This is very difficult to achieve. The main role of informed consent is to determine more specific issues; such as when (re)consenting will be feasible and in what cases findings will be communicated to participants. More inclusive models are required to encourage better communication with research participants; e.g. by honouring their altruism, respecting their autonomy, and promoting trust in the biomedical research enterprise.⁶⁹⁹

Mexican research participants would not yet be ready for a completely broad consent option, at least at present. For participant B, it would be difficult to design a general informed consent process suitable for Mexican biobanks, since “the idea has been to make general

⁶⁹⁷ Lumbreras, Porta and I Hernández Aguado 756

⁶⁹⁸ Rial-Sebbag and Cambon-Thomsen 118

⁶⁹⁹ AL McGuire and LM Beskow, ‘Informed consent in genomics and genetic research’ (2010) 17 *Annu Rev Genomics Hum Genet* 15

recommendations and it would be good if we, researchers, knew the basic points to be covered.”⁷⁰⁰

Participant H thinks it is worthwhile to design an informed consent proforma for collecting research samples that allows the researcher to do further research, “I have witnessed researchers complaining that they cannot re-contact participants; they may not see them again. It is very difficult and that involves the risk of wasting big efforts to collect the sample. We need to find mechanisms to resolve these situations and I think the best way is clarifying that the samples may be used in the future for other projects.”⁷⁰¹ Participant K agrees with the idea that informed consent should be as specific as possible. “If the use is granted to only one institution, only that institution is entitled to use the samples, unless the person authorises further use. Samples cannot circulate freely. For me this is a new concept.”⁷⁰²

The sole change of informed consent forms will not make a significant difference. Informed consent processes should be enhanced by a strong legal rationale in order to ensure a more fair translation of biobanking benefits to society. Changes need to be substantial; informed consent can reinforce public engagement when it is demanded by social involvement.

Significant issues in Mexican biobanks could be resolved through the renewal of current informed consent processes. Participants within specific biomedical research projects need a different consent model from that established for clinical trials. A specific consent model would cover individual results, the right of everybody to know) or not to know their results) and non-discrimination measures. It needs to be preventive and

⁷⁰⁰ Researcher-at-a-public-biobank-Participant:B

⁷⁰¹ Legal-adviser-at-an-ethics-public-advisory-institution-Participant:H

⁷⁰² Science-and-Technology-Commission-Participant:K

flexible but more preventive than flexible. “The scope of consent to future use of research samples should be considered with obtaining of initial, prospective consent to participate in a biobank.”⁷⁰³

7.3 Main institutional issues

According to Rial-Sebbag and Cambon-Thomsen, the inadequacy of traditional regulatory frameworks tends to result in a great governance challenge: the reluctance among lawmakers to define objects and structures, as well as their status, thus creating ambiguity and legal instability in all aspects.⁷⁰⁴ Accordingly, a more active institutional collaboration in policy-making would avoid “policy conflicts, crises and social turbulences.”⁷⁰⁵

Laurie argues that “failing to capture the notion of partnership”⁷⁰⁶ will result in unworkable legislation in practice. Participatory governance, as it has been regarded by Murtagh and Harris, is a simple concept which, in a self-indicatory way, calls for cooperative views, optimising the translation of biobank science into societal benefit as a necessarily transdisciplinary project.⁷⁰⁷ As a result of analysing the context in Mexico, it can be stated that a significant amount of coordinated work is necessary to organise a legitimate agenda involving the public and the private sector. In principle, the most relevant approach is “a multidirectional exchange of knowledge and information among researchers, consumers, professional groups, industry, policy makers and public agencies.”⁷⁰⁸ Such a gradual involvement should eventually influence the translation of personalised medicine projects into practical results. Hence, participation needs to be boosted gradually.

⁷⁰³ Simon and others 828

⁷⁰⁴ Rial-Sebbag and Cambon-Thomsen 115

⁷⁰⁵ Bunton and Peterson 189

⁷⁰⁶ Laurie 352

⁷⁰⁷ Murtagh and others 341

⁷⁰⁸ Lumbreras, Porta and I Hernández Aguado 756

7.3.1 Coordinating governance issues

Coordination implies differentiating among different types of research. It is necessary to recognise that exceptional types of research require more protective measures, for example, those involving indigenous populations. This is part of a new sensitive paradigm within the social and political context of translational science; it should be able to include representatives from the main areas involved. It has been observed that a great number of biobanking projects in Mexico have been carried out in an isolated way, and the different biobanking networks are not coordinated.

The 2004–2009 INMEGEN institutional programme⁷⁰⁹ covered nine strategic points for development, including alliances for the Nationwide Development of Genomic Medicine, the application of world-class genomic technology to common health problems, compliance and investigation on ethical, social, and legal issues.

Not all stakeholders may share the same interests, but all of them aim for knowledge translation. A broad perspective of knowledge translation is referred to as “a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically sound application of knowledge.”⁷¹⁰ As a result of combined actions, it is expected that stakeholders should develop a sense of interactive collaboration towards knowledge translation, including the public. As stated by participant I, “it is important to understand that we will never be exhaustive enough, that coordination is important and we will have some interrelated interests.”⁷¹¹

⁷⁰⁹ G Jiménez Sánchez, *Programa de Trabajo para dirigir el Instituto Nacional de Medicina Genómica* (Fundación Mexicana para la Salud, 2004) 32

⁷⁰⁹ Jimenez-Sanchez and others 1198

⁷¹⁰ Canadian Institute for Health Research CIHR, ‘About knowledge translation and commercialisation’ Canadian Institutes of Health Research <<http://www.cihr-irsc.gc.ca/e/29418.html>> accessed 15 April 2013

⁷¹¹ Responsible-of-the-Genetics-department-at-a-public-ethical-advisory-institution-Participant:I

Hence the different public health institutions would use results obtained from different federal entities. The relationship between different biobanking stakeholders works as a chain, where the actions of a sector will affect or benefit a counterpart. This will be crucial for the creation of fit-for-purpose rules. For example, scientists need to explain the full range of possible choices that samples could be used for after collection; participants are normally interested in the fact that “the sample collection will be owned publicly.”⁷¹² This would in principle, be drawn to the attention of both public and private areas. Whether the institution is public or private affects the potential generation of profit or generation of information for public benefit, and this may be communicated at the initial point of collection.

This proposal is meant to help the enforcement of fit-for-purpose rules beyond ineffective written laws, political discourse and non-transcendent coordination, in which the public opinion tends to be excluded, partly due to collective disinformation on what could be gained socially and to what extent it is desirable. A possible starting point could be achieved by promoting cooperation and participation with biobankers in the design of the information and consent procedures, allowing new devices, possibly on the group or community level, for the debate of broad-scoped issues. Equal regulatory action taken by science, industry and policymakers is desirable without the involvement of excessive politics, which would create an imbalanced situation.

7.3.1.1 Institutional coordination efforts

A coordination effort in relation to the transportation of tissue outside Mexico, involving the health authority COFEPRIS and INMEGEN, was attempted through article 317 of the General Health Law.

⁷¹² Trust and Council 63

Article 317 bis The Ministry, in coordination with the National Institute of Genomic Medicine, as Federal adviser of the government and reference centre in the subject, will register the authorisations on transportation of human tissue outside the country.

However, in the opinion of Participants D and E, this has not been achieved:

“The amendments to article 317 bis have had no determinant impact whatsoever at INMEGEN’s operation. Article 317 bis is part of a block of more articles. The role of INMEGEN is not very clear; apparently it involves a governmental advisory role. Another article was enacted in 2007 on genomic sovereignty, states that it is prohibited to take samples outside the country and then INMEGEN appears as a governance actor to authorise population studies and transport of samples overseas. If that was the case, we would have to have full offices revising applications. That has not happened. An agreement was reached with COFEPRIS, and it is still the only authority in this respect however, it is not specified in a written form. I hope this will be clarified one day.”⁷¹³

Participant G is aware that recently, it was established that INMEGEN would collaborate with the authority through a registry. However, so far, that has not happened. “At some point, the INMEGEN will have to play both a consultation and invigilating role. This will only work through coordination. It will not be possible with an obsolete law.”⁷¹⁴

Several attempts to enhance institutional coordination have proven unsuccessful, such as the plan to strengthening “the contact and exchange data among the national experts”⁷¹⁵ included in the 2001 legislative proposal for the General Health Law. The plan was intended to encourage the study and the development of new research projects, and so that information regarding social, ethical and legal aspects on human genetics would be better understood. However, there seems to be a gap between policy and institutional responses. The existing institutions either fail to deal adequately with the new regulatory issues raised by genomics or they still need to be created to respond to the new policy issues. In

⁷¹³ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

⁷¹⁴ Responsible-of-the-legal-department-at-a-public-biobank-Participant:G

⁷¹⁵ Wistano

Mexico, it is not only researchers who recognise this matter; the OECD⁷¹⁶ had previously emphasised the role of policy in fulfilling legal gaps, which could be closed by the government through policies integrated under the principles of justice that society has chosen to apply.⁷¹⁷

Beyond individuals, the establishment of governance relies on the institutional component. Gibbons suggested that “an institutional body is capable to take part in the resolution of any debates at different scales where oversight, regulation and transparency are too general” and, “where, characteristically, there is less internal and external oversight, regulatory accountability, or transparency.”⁷¹⁸

7.3.1.2 CNB: the key to govern biobanks?

For the time being, it is clear that biobanks are not expressly covered by the commission. Clearly, the National Commission of Bioethics is not an authority. The benefits of the compulsory registration of ethics committees within the commission consist mainly of updates and academic diffusion. However, it could become a more active institution in Mexico. The CNB could provide the biobanking expertise needed to advise policymakers, lawmakers, biobanking professionals, the public and especially, ethics committees. Ingrid Brena pointed out, in this respect, that “it is imperative to implement regulations, national laws and international standards.”⁷¹⁹

Ethics committees could play a fundamental role in biobanking.⁷²⁰ If that was to happen, clearer and more specific advisory guidelines would be highly appreciated by stakeholders. Additionally, more advice and

⁷¹⁶ Jiménez-Sánchez, Frenk and Soberón

⁷¹⁷ C Lyall, T Papaioannou and J Smith (eds), *The Limits to Governance: The Challenge of Policy-Making for the New Life* (Ashgate 2009) 42

⁷¹⁸ Gibbons 324

⁷¹⁹ Brena, ‘Biobanks in Mexico, legal aspects (Biobancos en Mexico, Aspectos Jurídicos)’

⁷²⁰ Ibid

oversight powers are urgently required. A specific biobanking organism is a possibility, but it would take time and great effort to materialise. Meanwhile, if the CNB can provide advice and the COFEPRIS has oversight, both institutions could work together.

Both commissions (CNB and COFEPRIS) could join efforts with research institutions to protect biological samples; this is not far from the *status quo*. According to the recent reform regarding ethics committees, COFEPRIS will remain in charge of the committees' registration. However, this will now have to include the authorisation of the CNB. The guidelines for the structure and operation of committees are being provided by the commission. Participant M,⁷²¹ representative of the CNB, recognised the following:

"We are related to the committees in terms of the registration and training of members; some of them lack knowledge on bioethics and they have started to work on that. The registration is helpful for the commission to identify where this training is necessary and to have records of established committees, especially now that they are mandatory."

The General Health Law was amended 2011 to state that the "...National Health Institutes Regulations basically consist of obligations to carry out clinical and experimental research into fundamental technology development within the area of genomic medicine; this should promote safety measures in its specialised area in order to further the links between national and international institutions."⁷²² This was allegedly planned in order to create a research network in the field of genomic medicine; to foster innovation and technological projects for creating means of diagnosis.⁷²³ According to the initial amending proposal (2001), the 'National Reference Centre' would be in charge of genomic medicine and genetic therapy, and deal with issues related to studies on

⁷²¹ Responsible-of-the-Human-Genome-Department-at-a-public-ethics-advisory-institution-Participant:M

⁷²² LGS Article 7 bis

⁷²³ Omar Moreno, *Genoma humano y derecho, resultados de la investigacion y su impacto en la investigacion juridica (Human genome and the law, results of research and its impact in legal research)* (Palibrio 2011) 198

genomic medicine and its applications.⁷²⁴ The promotion of cooperation among public health institutions will contribute to human development. However, this will be achieved only by coordination encouraged through sound policies.

7.3.2 Main issues within health institutional committees

One of the main unresolved issues in Mexico is the absence of procedures for the enforcement of research ethics rules and, therefore, biobanking. It is necessary to determine the most effective binding level for new policies. Research Ethics Committees (RECs) or Institutional Review Boards (IRBs) are common to most jurisdictions. These bodies are the key decision makers in reviewing and allowing research protocols to proceed and therefore hold considerable power in the research governance and also enjoy wide social acceptance. Any research that is carried out using samples and information from a biobank will be required to seek REC approval. RECs have been responsible for approving the establishment of biobanks.⁷²⁵

Even when LRECs are regulated, a study by Valdez et al⁷²⁶ on the performance of IMSS LRECs revealed that the IMSS handbook is not always followed. The foundation of the committees was not focused on a particular area. According to the study, the two main reasons that led to the foundation of an LREC were 1) Medical managers considered this necessary (11.9%) and 2) To follow established institutional rules (88.1%). Some practices among LRECs reflect that the committees are not specialised in particular topics, and it is common that requests are made for external support with decision making.

⁷²⁴ Ibid

⁷²⁵ European Commission 44

⁷²⁶ E Valdez-Martinez and others, 'Understanding the structure and practices of research ethics committees through research and audit: a study from Mexico' (2005)

74 Health Policy 62

The IMSS study reported that only a few committees are specialised on issues such as the resolution of difficult cases, promotion of professional values, human rights vigilance and the promotion of good medical practice. These expectations reflect the nature of the committees, that IMSS committees and guidelines are more focused on health ethics, which can be partially applicable to biobanking. However, biobanking is more closely related to research ethics but the number of these cases is falling. In contrast, clinical cases have increased; i.e. complaints on medical attention and issues among health staff. 54.8% of the committees in the study reported such clinical issues.⁷²⁷ This has resulted in health committees with different guidance, different forms and different remits.

7.3.2.1 Integration and diversity

The IMSS study reported that 10% of LRECs had less than three Executive Directors and some of them had remained in the position for more than 6 years. Another factor which could negatively impact on the decisions of the committee is the reported absence of key members, e.g. the chair, “at most meetings.”⁷²⁸ Evidence of gender disparities were identified by the study as “professional bias”⁷²⁹ in the committees’ integration, as there were disproportionately more men than women. In addition, less than half of the LRECs held meetings to issue a report of a project’s evaluation. According to Valdez et.al,⁷³⁰ this reflects a lack of interest and commitment within the IMSS LRECs system.

7.3.2.2 Members’ background

The IMSS handbook does not specifically state the academic background required for an ethics membership position. Only 22% of committee members have PhDs. Most committee members hold a high administrative position within the institution in addition to their committee

⁷²⁷ Khoury and others 89

⁷²⁸ Valdez-Martinez and others 65

⁷²⁹ Garduño-Espinosa and others 333

⁷³⁰ Valdez-Martinez and others 65

membership. 50% of the committee members were doctors with a management position.⁷³¹ This is not necessarily negative but could impact on the legal capabilities of the committees. IMSS LRECs tend to concentrate on rules, regulations and the law, and the resolution of a local committee is merely an administrative step which it has to fulfil. More attention should be paid to LRECs' human resources. Valdez et al. suggested that "they may not be sensitive enough to the needs of vulnerable research participants...The sole presence of professionals in LRECs makes these committees less responsive to vulnerable populations when these populations are considered within the selection criteria for research proposals."⁷³² Most discussion of ethical challenges raised by the growth in the number of research biobanks focuses on the assumption that the only ethically relevant interests are those that concern risks to subjects' welfare. Before the IMSS study, "no reliable follow-up studies about the structure and the functions executed by this system of LRECs had been completed,"⁷³³ for instance, only one out of 1000 research projects was rejected, a figure which could reflect superficial assessment.

7.3.2.3 Lack of bioethics expertise

Although the IMSS handbook is intended to deal with health and research ethics, the composition of the IMSS committees is not balanced in terms of expertise. Participant N suggested that a problem is that they have "a few bioethicists." Hence, this number cannot cover the demand for bioethics expertise. Additionally, Participant N raised concern about a lack of knowledge on bioethics. "They need training."⁷³⁴ Other health institutions, including private institutions, follow different rules. The fact that the IMSS performs health care and research, having rules mainly for health care, reflects an imbalance in terms of expertise.

⁷³¹ Khoury and others 88

⁷³² Garduño-Espinosa and others 333

⁷³³ Valdez-Martinez and others 61

⁷³⁴ Bioethics-expert-at-a-public-legal-research-institution-Participant:N

7.4 Proposal

Institutional coordination would be a good step in resolving problems on a national level. It is relevant to mention that these measures depend mainly on further changes to the regulation of research ethics committees. The particular actions to be taken to bring about the transformation of Mexican biobanking governance remain undefined. When social participation is not sufficiently incentivised, particular measures need to be implemented. “For lawyers, recourse to law is a first natural reaction to new social challenges.”⁷³⁵ So far, the legal experiences on biobanking cannot guarantee that the best choice will be formal governance. The two main choices, to be carried out by the public authority, are either encouraging self-governance through professional attitudes of the parties involved or regulating the activity by legal policies.⁷³⁶ A fundamental component of both choices will be information. The implementation of policy would need to incorporate sanctions and other consequences of legal noncompliance.

In the end, powerful alliances of stakeholders, with government, industry and large scientific bodies, have achieved the most recent genomic advances. The regulation of biobanks depends on a firm basis of principles that require further explanation in practice, for example, access to human specimens and data for research purposes. INMEGEN has achieved a good reputation as a result of the organisation of studies currently developed, up to the point where it has been given the authority to approve population studies.⁷³⁷ Nevertheless, this implies potential disadvantages if one institution plays the double role of poacher and gamekeeper, something even more risky than self-regulation.

⁷³⁵ Laurie 350

⁷³⁶ Ibid

⁷³⁷ Instituto Nacional de Medicina Genómica (National institute of Genomic Medicine), *Manual de organización específica del Instituto Nacional de Medicina Genómica (Handbook for the specific organization of the National Institute of Genomic Medicine)* (Secretaría de Salud (The Mexican Ministry of Health), 2011) 31

High-level policy decisions need to isolate, identify, and synthesise the key factors, characteristics, and attributes of biobanks across the board using simplified implementation schemas. A starting point consists of understanding the legal consequences of biobanks, which should be covered by generic simplified frameworks. Only this can provide the basis of any “practical, flexible, theoretically defensible, but readily adaptable instruments that might prove to be useful in shaping, managing, and implementing better biobanking regulatory systems in the future.”⁷³⁸

There should be controls for each of the different types of collections. Some activities are common to biobanks in spite of their purpose, such as collection, storage and release of samples and associated data. Hence, it is vital to determine that the best conceptualisation choice will be inclusive, based on common standards, and, at the same time, specific where exceptions are required. Classification needs to be systematic, accessible, and functional in order to avoid governing guidelines being overtaken by practice. This is one of the first steps to avoid duplication and complexity. Each category needs to reflect “on why the categorical heading, and its sub-components, may be significant for regulatory purposes.”⁷³⁹ The idea that all kinds of biobanks, including forensic ones, should be regulated to protect donors and guarantee the correct working order of biobanks as research tools, is challenged by the idea that “no ‘taxonomic’ list can ever hope to be exhaustive.”⁷⁴⁰

The main objective of a new policy is the provision of inclusive rules, and any potential policy object needs to be taken into consideration, although “certain kinds of biobanks should be ‘ring-fenced,’”⁷⁴¹ or be treated as exceptional. Heterogeneity of biobank categorisation is

⁷³⁸ Gibbons 317

⁷³⁹ Ibid

⁷⁴⁰ Ibid 17

⁷⁴¹ Ibid 322

preferred for regulatory purposes “rather than the generation of a checklist.” Rial-Sebbag and Thomsen remark that the legal effects from a biological sample will differ depending on the context in which they are used,⁷⁴² which will have significant implications. The multifactorial nature of the subject needs to be recognised when new regulations are enabled. Some specific types of collections will deserve more attention due to their nature.

7.5 Ethical guidance or binding rules?

Kaye and others⁷⁴³ have identified self-regulation as a typical failure in general biobanking policies. It has resulted from worrying legitimacy deficits and soft, regulatory techniques. Self-regulation is currently taking place due to the absence of oversight mechanisms to enforce the rules mentioned in the various partially applicable regulations. Self-regulatory practices can be detected in most current Mexican biobanking policies, affecting the execution of research projects. Self-regulation and internal decisions have been the alternative for biobanks up to now as a result of the absence of specific ethical standards.

From the evaluation of the relevant guidance, it is clear that the current framework of ethical guidelines presents weaknesses in the establishment of consistent rules for guiding authorities. Due to the absence of clear standards for research with samples and tissues, the decisions of more than one committee could present considerable variations regarding the same situation. A series of principles depends on interpretations and decisions attributed to ethics committees. The most evidently problematic areas are decision making, composition, operation, potential conflicts of interest and project assessment. Questions to participants on what choice would be suitable for Mexico obtained the following answers: (See Table 5 in annex p. 6)

⁷⁴² Rial-Sebbag and Cambon-Thomsen 379

⁷⁴³ Kaye and others 279

Hence, self-regulatory attempts should be regarded by Mexican law makers as precedents for the creation of specific and stringent laws which respond to the needs of researchers and research participants. A degree of scepticism in this sense is preferable to an excessive reliance on those involved, in such a complex area as biobanking. The promotion of international guidelines, through optional adherence to international codes of ethics on health and scientific research, has taken place since 2001⁷⁴⁴ with a partial response in practice. Mexican researchers would also prefer effective guidance which does not result in hampering administrative procedures.

In Participant A's opinion, laws should not stifle research, and should be constrained to relevant parts of the research.⁷⁴⁵ Hence simplified procedures must be implemented as the alternative to an uncontrolled autonomy, which has not worked for Mexican biobanking. Ambiguity has been used opportunistically, and as a consequence, the organisers of numerous pharmaceutical trials aim to cover a number of requirements with no knowledge on scientific research, which are then evaluated and authorised by committees with the same ignorance on the topic. As a result, "a legal and ethical simulation is performed."⁷⁴⁶

Legitimacy is also based on specific forms of bioethical expertise. As Reich has pointed out,⁷⁴⁷ the current role of bioethics, within policy making and the governance of biobanks, should be based on such specific forms of the knowledge to be legitimated, rather than led by technocratic authoritarian or self-regulatory approaches. The regulatory aspects of biobanking are meant to be complemented by the expertise of ethics committees. Avoidance of exploitation depends on their decisions.

⁷⁴⁴ (The-Mexican-Ministry-of-Health)

⁷⁴⁵ Responsible-for-the-research-department-at-a-public-biobank-Participant:A

⁷⁴⁶ Tamayo 262

⁷⁴⁷ WT Reich, 'Introduction' in WT Reich (ed), *The encyclopedia of bioethics* (Simon Schuster Macmillan 1995)

LRECs have the great responsibility of applying the current rules, self-regulatory principles and international guidelines. This involves evaluating the scientific merit of a project corresponds to ethics committees. For this reason, members of LRECs need special training. They should be aware that these rules and regulations are not powerful enough which to determine whether a decision is right or wrong. Ethical issues will be resolved in a more centralised way if committees' decisions are compulsory.

Institutionalised ethics of this nature may include public concerns within the policy process, while they subordinate those concerns to an isolated defence of individual autonomy. However, "ethical issues concerned with public welfare do not have recourse to individual autonomy, yet a common theme is the legitimacy of decision makers and their policies in relation to the 'public interest'."⁷⁴⁸

7.6 The need for oversight in biobanking

An adequate attempt to start the discussion for what is required may be simpler if we know what should be avoided. In addition, it would be necessary to use ethical knowledge on biobanking to encourage legal enforcement. It is on the Mexican legislators' agenda to become more supportive of medical science: "We will be vigilant of this great advance (the human genome),"⁷⁴⁹ a commitment which is still to materialise.

In the opinion of Gibbons, for biobanking governance, "a dedicated, independent statutory authority could reduce the risk of regulatory capture."⁷⁵⁰ Gibbons recognises that "biobanks may be

⁷⁴⁸ MM Burgess, 'Public consultation in ethics, an experiment in representative ethics ' (2004) 1 *Journal of Bioethical Enquiry* 5

⁷⁴⁹ , *Decreto por el que se adiciona la fracción IX Bis al artículo 3o.; se adiciona un Título Quinto Bis y su Capítulo Unico; y el artículo 421 Ter de la Ley General de Salud. (DECREE which adds section IX Bis to article 3, the title "V bis" and its unique chapter and article "421 Ter" of the General Health Law)*

⁷⁵⁰ Gibbons 324

governed or supervised effectively in many different ways, through structures put in place for overall project governance, day-to-day management, ethical oversight, compliance checking, and enforcement.”⁷⁵¹ However, the required control will depend on the type of biobank. Different ‘types’ of biobanks warrant various forms, degrees of regulation and oversight. The proposed criteria would also take into account the nature of the institution, selecting principles for effective control, and inclusiveness matters. This means that small biobanks should be regulated too. Even though it is not written in law, fieldwork has shown that the current authority responsible for biobanks is COFEPRIS and not the National Bioethics Commission. Only one participant referred to the latter as the current authority, even though committees do not have binding power.

If biobanks continue to come under the regulation of health laws, the oversight would come under the Ministry of Health. In case COFEPRIS retains the oversight of biobanking, it would need more experts and clinical data. Ideally, a new biobanking framework for Mexico would also cover data protection; data protection laws could be used to regulate the IFAI, the current institution in charge of the protection of public and private data, as long as data protection related to biological samples is regarded independently. In this case, the IFAI would have to be coordinated by the institution in charge of general biobanking oversight.

Although COFEPRIS is currently the legal authority responsible for biobanking and establishes regulatory mechanisms for biological matters, many of the functions this institution has to perform have no connection to biobanking. It will be necessary to have a specific authority for biobanks, and one of the first steps would be to create an institution able to control and register biobanks. This has been the case in Spain and in

⁷⁵¹ Ibid 339

UK. (Chapter six compared Mexican and other countries' laws). The creation of a National Registry of Protocols can be envisaged, making sure that rejected research protocols are not actually carried out, even if they find a supporting institution. The CNB cannot take on this role; its purpose has been designed to be purely advisory. Another possibility, though less suitable, is the creation of an organisation dependent on COFEPRIS.

Fieldwork has shown (See Table 2 in annex p. 3) that the national supervision of biobanking can be attributed to COFEPRIS as it is responsible for the "sanitary control of organs, tissues, and human cell donation and transplant."⁷⁵² In contrast to the CNB, COFEPRIS has monitoring responsibilities. Research protocols are meant to be evaluated by the Internal Commission of Health Authorisation in Human Beings within COFEPRIS. Any committees must be registered at COFEPRIS using the "registry of commissions of research, ethics and bio security"⁷⁵³ and applicants are assigned a registration code. COFEPRIS, as a supervisory and scrutinising authority, approved 538 research protocols in 2011.⁷⁵⁴ However, in practice, it has been detected that COFEPRIS has found it very difficult to deal efficiently with protocols involving increased biobanking activities. Participants A, D and E,⁷⁵⁵ agree that the numerous functions delegated to this commission have proven excessive. COFEPRIS' extensive work has been directed to administrative controls to prevent health risks at the national level. The effective control of biobanks is still far away from being achieved; a situation that could justify

⁷⁵² Comisión Federal para la Protección contra Riesgos Sanitarios (Federal Commission for the protection against health risks), *Atribuciones, funciones y características de la COFEPRIS (COFEPRIS' attributions, functions and characteristics)*

(Secretaría de Salud (The Mexican Ministry of Health, 2010)

⁷⁵³ COFEPRIS

⁷⁵⁴ Sánchez,

⁷⁵⁵ Responsible-for-the-research-department-at-a-public-biobank-Participant:A, Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

the creation of an alternative oversight organism or specific subdivision of COFEPRIS.

7.6.1 The need for governance biobanking mechanisms

Governance barriers might come from different perspectives and different interpretations of the main legal issues. Following Bunton and Peterson's focus on governance, the law cannot advance separately from aspects such as policies.⁷⁵⁶ Once the legal background has been provided, the existence of legal issues is evident, such as the level of regulatory response, the role of decision makers, types of measures to be favoured, incentives and restrictions, and the distribution of responsibilities.

A great problem within the Mexican experience has been finding suitable mechanisms in order to avoid contradictory operative rules on public goals. These need to "reflect both substantive and procedural aspects."⁷⁵⁷ Many biobanks are purposefully designed as long term endeavours, ensuring the longevity of the biobank and the continuity of governance policies and mechanisms, fit-for-purpose over time, with respect to both private and public interests that are at stake.⁷⁵⁸

Policy makers are committed to cover as many situations as possible, and scientists and academics need to be equally committed to provide constant feedback to their relevant sectors. The mechanisms need to cover the potential options for tissue samples when the research project has ended. Researchers are interested in avoiding "samples' waste" of preserved tissue, and mechanisms should encourage maximising the use of valuable material for science. If the samples need to be disposed of on ethical grounds, this would also need justification

⁷⁵⁶ Bunton and Peterson 205

⁷⁵⁷ Capps 8

⁷⁵⁸ Laurie 349

mechanisms. For benefit sharing and even the creation of a ‘Mexican biobank’ in the long term, agreements will not suffice. Mechanisms need to be imposed by the governance framework.

Prainsack and Buyx propose the implementation of policy based on solidarity, an element to be analysed in depth in the next chapter, which includes actions and overarching goals of the research biobank, followed by specific requirements to provide:

- Information about the research questions and contexts that the biobank supports at the time of recruitment.
- Information on commercial strategies and interests.
- Statement of future use: the participation agreement should include a statement that the biobank may be used to serve research that cannot yet be envisaged.
- Re-contacting and feedback: participants should be informed what kind of data and information they will have access to.
- A list of risks and benefits insofar as they can currently be foreseen.⁷⁵⁹

Principles are required to reduce ambiguity; hence the publication of biobanking guidelines is essential. Despite significant legal gaps, the current biobanking rules need to start becoming effective through practical mechanisms. Implementation requires:

- The need for a fully transparent process;
- The need to articulate the values that inform decisions
- The need for a scientific case to justify certain choices over others;
- The need for procedures of accountability.⁷⁶⁰

If any of these are absent, institutional coordination efforts are likely to be negatively affected; “it is almost certain that the sense of partnership would be damaged and that would attenuate ideas about the effectiveness of independent scrutiny and public accountability.”⁷⁶¹

⁷⁵⁹ Prainsack and Buyx 84, 85

⁷⁶⁰ Capps 8

⁷⁶¹ Ibid 6

7.7 The role of trust

The effectiveness of a governance framework to protect participants from abuses has an impact on public trust towards the law. The enhancement of socially ethical behaviour can be encouraged by a strong legal framework. Salter and Jones, based on the experience of UK Biobank, point out that scientific advances in genetics are dependent on the construction of novel forms of regulatory legitimacies,⁷⁶² which need to be reliable.

In biomedical research, the aim of creating public trust, of compliance and cooperation has been a primary strategy. The ethical, legal and social implications of prioritisation must not be set aside. It is a priority to find mechanisms for scientists and policy makers to approach research participants and patients more directly. This is one of the greatest challenges within the multi-cultural Mexican context. The lack of standardisation, scope and ethical significance of policies calls for uniform ethical biobanking guidelines. It makes it evident that oversight mechanisms and sanctions are preferred over voluntariness and hence, these should be adopted.

Biobanks are committed to sustain the trust of those who contribute samples.⁷⁶³ “When the public give their samples and information, they have to base their decision on trust; they need to have hope in the biobanks and faith in the biobankers, much in the same way that we have faith in our banker’s skills and honesty, and hope in the interest rate that the bank will be able to offer us.”⁷⁶⁴

⁷⁶² Salter and Jones 725

⁷⁶³ Gotweis and Lauss 64

⁷⁶⁴ P Ducournau and R Strand, ‘Trust, Distrust and Co-Production: The Relationship between Research Biobanks and Donors ’ in JH Solbakk, S Holm and B Hofmann (eds), *The Ethics of research biobanking* (Springer-Verlag Solbakk 2009) 3

Public trust will help to overcome the challenge of upholding citizens' willingness within biobanking.⁷⁶⁵ Reflexive governance can also encourage healthy scepticism as a means to promote trust.⁷⁶⁶ A degree of scepticism should be expected, which is preferable to not having any public response.

7.7.1 The impact of public trust in Mexican biobanking

If at the heart of the biobanking enterprise is the need to promote issues such as trust and the public interest, it is not clear that laws alone can deliver on this task.⁷⁶⁷ Even when Mexico reaches a suitable legal biobanking framework, even the most detailed reforms present limitations beyond legislative technique.

The predominantly legal ambiguity and excessively trusted self-regulation have been partly responsible for the Mexican public being either uninterested or sceptical. It could be observed from Chapter 4 that the legislative debate on genomic research did not receive any public pressure and remained stuck for more than a decade. This and other embarrassing situations have led national to regulators to lose a significant amount of credibility, and therefore trust.

Participant O⁷⁶⁸ emphasised that one of the greatest problems in Mexico is the lack of trust from citizens towards the legal system, an issue to which the media contributed. The participant shared anecdotal facts of the data bases available in a Mexico City flea market known as '*Tepito*'. This situation has made many citizens decline from readily disclosing data. Participant N has pointed out that even strict biobanking laws by

⁷⁶⁵ Ibid

⁷⁶⁶ Laurie 353

⁷⁶⁷ Ibid 351

⁷⁶⁸ Expert-on-Bioethics-Philosophy-and-Law-at-a-Public-university-Participant:O

themselves may not work effectively if there is no trust in the law, especially researchers.⁷⁶⁹

7.7.1.1 Realistic promises or ‘genohype’

In principle biobanks should be trusted as promoters of fair research contributing to public benefit. Normally, “patients have increasing opportunities to obtain information about health care products and services from sources outside the traditional healthcare setting, such as the printed press, television and the internet.”⁷⁷⁰ Breaching subjects’ trust does not necessarily mean allowance of exhaustive exploitation on the information; the difference could consist of previous explanation of the different uses and purposes of information. “The naturally trusting part of the public might not pay attention, not even if the irresponsibility of the goals is revealed in the information sheet.”⁷⁷¹ Trust can be easily broken in a passive way. Omissions take place when the limits of accessibility are not explained.

“Concerns about privacy, intellectual property and possible uses of samples and data, as well as episodes of misadventure or inappropriate use of stored samples challenge biobank managers’ ability to maintain trust and regain it once is lost.”⁷⁷²

Mexican patients read in the newspaper that someone was saved from leukaemia. However they do not know that such achievement took perhaps years, several trials and that some failed.⁷⁷³ Topics such as personalised medicine involve numerous limitations, for instance, time. In a sense, Mexicans might have been given false expectations.

⁷⁶⁹ Bioethics-expert-at-a-public-legal-research-institution-Participant:N

⁷⁷⁰ Lumbreras, Porta and I Hernández Aguado 756

⁷⁷¹ Ducournau and Strand 9

⁷⁷² R McWhirter and others, ‘Practical Application of Participatory Governance for Biobanks’ (ISBER Annual Meeting & Exhibits Sydney Convention & Exhibition Centre (SCEC), Sidney, 2013)

⁷⁷³ Legal-researcher-at-a-public-research-institution-Participant:C

Recently, novelty pieces of international literature have remarked the importance of public trust within biobank research,⁷⁷⁴ highlighting that people may participate in research in the hope to receive follow up examination or treatment.⁷⁷⁵ For a more integral relationship to be accomplished, the biobanking discourse needs to be more realistic; especially when promises are made, participants need to have increased expectations “as doctors come closer to making claims that a drug will work for them as advertised.”⁷⁷⁶ (Public understanding involves knowledge dissemination). Knowledge dissemination in Mexico requires strategically based techniques free of typical sensationalism. Media communications sensationalism has been termed “genohype,” and describes the exaggerated portrayal of the risks and benefits of genetic research and biotechnologies.⁷⁷⁷ Consequent public anxiety can be decreased by realistic and direct information. Similarly, if the limits set up in advance are breached, trust will be undermined. “To fail to use the resource for community benefit would be a betrayal of trust.”⁷⁷⁸

The principle of ‘integrity of purpose,’ aims to promote trust by strengthening the links between biobanks and society. Public trust can be restored through a policy of transparency covering the multiple interests of current and future patients. Biobanking governance needs to promote trust, but at the same time, regulate it. Any relationship based on trust needs coherence and consistency between biobanking promises and the results. Positive popular reactions can be expected only once those involved have true proper knowledge of what can be expected from biobanking and their rights; and once trust is generated.

⁷⁷⁴ Ducournau and Strand

⁷⁷⁵ Cambon-Thomsen, Rial-Sebbag and Knoppers 379

⁷⁷⁶ EM Meslin, ‘The value of using top–down and bottom–up approaches for building trust and transparency in biobanking ’ (2010) 13 Public Health Genomics 409

⁷⁷⁷ Ibid

⁷⁷⁸ Capps 7

7.7.2 Natural trust: an element to enhance

Docornau and Strand have classed a sense of trust as ‘natural’: “a general trust in public medical research and the medical profession.”⁷⁷⁹ The medical nature of some collections will encourage public trust and inspire a sense of responsibility by itself, “*a priori*.” Natural trust is highly desirable in order to achieve efficient enrolment of donors.⁷⁸⁰ The option of natural trust should be transposed from medical, towards the role of the doctor, to expertise grounds, towards ethics committees. However, this initially blind trust involves some risks. Researchers and doctors could act advantageously and the public could act irresponsibly, if a sense of responsibility is not maintained.

The establishment of limits would impact positively on the accessibility of samples, the subject and the group of subjects, by creating a sense of trust. Creating awareness among members of ethics committees from public institutions would also constitute a step in reinforcing the desired natural trust even among those who have developed scepticism.

7.8 Emergent measures

Following Hardy et al, the main question for countries that have not started genomics initiatives is, what are the potential entry points?⁷⁸¹ Even when the purpose of biobanks’ may not be completely certain, new governance needs to be as certain as possible, and preventive measures are required. In the short term, positive steps cannot be provided by instruments other than the law. Laurie⁷⁸² has pointed out that the law is required when the systems have failed. Reflexive governance, through mutual learning, is a state in which the law is not even required; something unrealistic for the Mexican setting. Participant F has pointed out that

⁷⁷⁹ Ducournau and Strand 9

⁷⁸⁰ Ibid 10

⁷⁸¹ Hardy and others 25

⁷⁸² Laurie 354

Mexico requires emergent measures based on governance, supported not only by the engagement of the public, but also all involved stakeholders.⁷⁸³

The law will be helpful to alleviate systematic failure. Some of the measures evaluated could work in the long term and some of them are still emerging. The procedural legal field requires urgent attention, and the enforcement of principles of “independence, oversight and efficiency of control powers, including sanctions⁷⁸⁴” would be a good start. Following the reflexive governance approach, other measures to be taken consist of:

- Designing-in interoperability with respect to scientific and governance approaches.
- Designing-out approaches that are restrictive for sharing, cooperation, flexibility and mutuality,
- Establishing policies and procedures for protection
- Establishing policies and procedures to actively promote the use of the resource in keeping with its original purposes,
- Ensuring the longevity of the biobank through carefully managed access policies and arrangements and stewardship of the resource, and
- Ensuring that governance policies and mechanisms remain fit for purpose over time.⁷⁸⁵

Ethical review boards will play a key role in maintaining public trust,⁷⁸⁶ but can struggle to achieve it without an adequate legal policy, suitable training and expertise. They will be likely to be assigned the resolution of cases unforeseen by the law.

It is essential to raise awareness of participants’ rights in general regarding data protection. An urgent measure to be taken by the IFAI will

⁷⁸³ Legal-researcher-at-a-public-research-institution-Participant:F

⁷⁸⁴ Cambon-Thomsen, Rial-Sebbag and Knoppers 375

⁷⁸⁵ Laurie 349

⁷⁸⁶ PG Shekelle and others, *Maintaining Research Integrity: A Systematic Review of the Role of the Institutional (Review Board in Managing Conflict of Interest* (Evidence-based Synthesis Program (ESP) Center, West Los Angeles VA Medical Center, 2012)

be to remain in contact with associations; proposed activities include the organisation of colloquiums,⁷⁸⁷ in connection with social campaigns to in order to build a sense of culture around the right of personal data protection.

7.9 Concluding remarks

This chapter has identified relevant indicators used to measure consistency in terms of governance, through fieldwork showing insights from different biobanking areas. These indicators point to self-regulatory elements, which are detrimental to biobanking and should currently be avoided. The main detected inconsistencies are associated with deficiency and over-dependence on informal systems. The governance of biobanks in Mexico is ambiguous. According to the analysis, the current governance actors and institutions do not include a fully protective framework for patients and research subjects. This is partly due to the fact that the main motivation for the legal work has focused on national development and economic goals.

Fieldwork has demonstrated that research governance is the main categorical element to enhance biobanking. Research policies should be established for the acquisition of new samples, access to samples for research purposes, for destroying collections when samples have fulfilled their original purpose, if they are no longer suitable for their intended purpose, or if participants request the withdrawal of their specimens. These policies should be clearly described and openly available, where appropriate, to users and potential users of the specimen collections.⁷⁸⁸

Fieldwork has revealed that a number of Mexican stakeholders still feel reliant on modifying the current biobanking structures, rather than creating new ones. However, the Mexican legal framework on biobanking

⁷⁸⁷ Morales

⁷⁸⁸ (ISBER) 10

needs to be replaced in order “to protect and to promote core interests engaged in biobank practices and ensure that the science in question is responsible.”⁷⁸⁹ The view of encouraging a completely new biobanking framework prevails over the choice of reforms.

The model of reflexive governance, an innovative approach relying on mutual stakeholders’ feedback, rather than solely on governance, requires trust schemes, which at the moment, Mexico needs to develop. The main legal deficiencies described through this chapter should initially be a target for legislators; law making is essential since “all biobanks require governance, at least to some extent.”⁷⁹⁰

Even when currently, there are institutions associated with the governance of biobanks, these remain uncoordinated and their attributions disconnected from current biobanking rules. Public institutions, such as INMEGEN, should become a governmental priority in order to achieve common objectives through biobank research. Additionally, more engagement with the public would be highly beneficial. In the long term, formally enforced governance with a strong ethical background can be reinforced by public demands, the building of trust, acceptance and careful political negotiation.⁷⁹¹ In response to socio-cultural challenges, cooperation is essential; it needs to materialise in direct involvement with the public through participatory consultation forums.

Provisional measures should be proposed as a starting point for substantial legal reform. The ever developing political debate around emerging human genome research and the collection of biological materials constitutes justification to reconsider not only regulatory

⁷⁸⁹ Laurie 351

⁷⁹⁰ Gibbons 339

⁷⁹¹ H Gottweis and K Zatloukal, ‘Biobank governance: trends and perspectives’ (2007) 74 Pathobiology 210

practices, but also strategies.⁷⁹² Reflexive governance is the goal for Mexico in the long term, while specific general mechanisms for emerging initiatives are preferable in the short term. “The general point that governance was seen as the solution to concerns raised by biobanks should not be a surprise; rather, it reflects a widely held notion that governance mechanisms mediate relationships of trust in modern democratic societies.”⁷⁹³

⁷⁹² Ibid 207

⁷⁹³ Hawkins and O’Doherty 323, 324

8. Social solidarity and justice

8.1 Introduction

This chapter will investigate the role of social attitudes in legitimising Mexican biobanking regulations, focusing on social solidarity as a form of engagement through collective action. It argues that the latter is a relevant component for the emergence of effective biobanking policies, and it will address the main challenges of a social solidarity approach from a Mexican perspective. Finally, a discussion on the appropriateness of social solidarity as the rationale for biobanking policies will follow.

The first section of this chapter will analyse social awareness and its impact on the current state of Mexican biobanking. The second section will analyse social alternatives to enhance the effectiveness of biobanking rules, exploring the role of solidarity. Literature on solidarity as an element contributing to the effectiveness of biobanks will be included.

8.1.1 The importance of social attitudes

Lumbreras and others support the idea that regulation cannot be understood in isolation, especially when biobanking research is closely linked to social benefit.⁷⁹⁴ Social attitudes have had a significant impact on the implementation of biobanking laws and ethical guidance around the world, including implementation in Mexico. However, Mexico's reasons to regulate biobanks greatly differ from other countries.

Recent discussions in international biobanking are centred on human rights (dignity and more specifically data protection and informed consent⁷⁹⁵). At the level of individual participation, well defined principles

⁷⁹⁴ Lumbreras, Porta and I Hernández Aguado 756

⁷⁹⁵ Ducournau and Strand 136

of autonomy, beneficence and no harm should be upheld, and confidentiality and privacy of information is required to respect the participants and the dignity of human life. These principles have no geographical boundaries and have “common value” to all human beings in every part of the world. Nevertheless, substantive principles alone are not enough to determine policy frameworks. Universally accepted ethical principles of privacy, confidentiality and consent need special considerations in developing countries because their definition is also embedded in the cultural context alongside research ethics.⁷⁹⁶ For instance, Mexico’s predominant bioeconomic views have negatively affected the social side of biobanking.

8.1.1.1 The role of cultural attitudes in biobanking

A range of factors emerge from recognising the need for legislation, in which the most influential ones are historical, cultural and ethical. Historical circumstances have affected cultural contexts to a great extent. The values and culture that are implicit in a particular country may also influence the way that these various elements of governance are enacted.

Christian churches, through the centuries, have asserted their right to express an opinion on medical matters of spiritual importance, while other major religions across the world similarly voice their opinion on matters of medical ethics, some not allowing any use of body tissue due to religious beliefs. In Mexico, small isolated groups of indigenous people may find that the use of data conflicts with religious or cultural understandings about their ethnic, legal or political claims relating to land or items of cultural patrimony.⁷⁹⁷ As stated by Simon et al, community

⁷⁹⁶ Minakshi Bhardwaj, ‘Rich databases and poor people: Opportunities for developing countries’ (2004) 8 TRAMES 103

⁷⁹⁷ RR Sharp and MW Foster, ‘An analysis of research guidelines on the collection and use of human biological materials from American Indian and Alaskan Native communities ’ (2002) 42 Jurimetrics 165

engagement implies recognising the cultural context surrounding biobanks.⁷⁹⁸ In the opinion of Gottweis and Zatloukal, the success or failure of biobanking projects depend on the ability of these to become part of the political and socio-cultural fabric.⁷⁹⁹

Data obtained from interviews has revealed the need to explore socio-cultural elements, providing different insights, for example, Participants D and E have recognised that some people are still fearful of donating body parts for cultural reasons.⁸⁰⁰ Participant L⁸⁰¹ remarked that currently, the most complicated part of biobanking are the cultural issues. Participant O⁸⁰² referred to cultural boundaries regarding the treatment of tissue from the deceased; “in the case of organ donation, there is no social awareness because we have not encouraged it from elemental education. Then, suddenly trying to “force” a culture for organ donation would be discouraged.”⁸⁰³ Planned actions need to be based on awareness of people’s cultural views, for example, on tissue treatments, balanced with knowledge on the implications of sample donations.

A major obstacle that biobanking actors frequently face is the Mexican public seemingly unaware of a number of ethical issues. The population need to be aware of ethical and practical issues in order to subject biobanking to proper scrutiny. The cultural diversity of Mexico means researchers need to be prepared if they are to produce knowledge, but also society needs to be able to respond if they are to use the generated knowledge adequately.

⁷⁹⁸ Simon and others 829

⁷⁹⁹ Gottweis and Lauss 210

⁸⁰⁰ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

⁸⁰¹ Ethical-adviser-at-an-ethics-public-advisory-institution-Participant:L

⁸⁰² Expert-on-Bioethics-Philosophy-and-Law-at-a-Public-university-Participant:O

⁸⁰³ Ibid

8.1.2 Public accountability and awareness

Accountability to the public is a highly desirable element, which demands a degree of reciprocity. “In attempting to address these controversies in biobanks, it is of paramount importance to take into account public perception and trust of biobanks.”⁸⁰⁴ A biobank will be publicly accountable if it acts ethically by recognising and protecting the rights of those involved. Ethical research requires not only recognition of the benefits of personalised medicine, but also the moral issues involved. Biobanking can only be scrutinised publicly if the public are aware of the importance of the ethical aspects. Such recognition can foster public demands. The notion that payment or return of health information can outweigh a person’s privacy concerns may have implications for the ethical enrolment of subjects.⁸⁰⁵ In addition, health research can be seriously affected if fundamental research biobanking structures are not reliable. “If there is a perception that biobanks are not proceeding in a manner congruent with public interests, biobank research may be significantly hindered or prevented.”⁸⁰⁶

Public awareness is necessary to support the accountability of a legal system through public scrutiny. It emerges when a significant number of citizens become interested in a topic, with well-founded political reasons. This interest, generally fostered by a need, starts at the individual level, for example, an individual need for protection against associated risks. Participants D and E agreed that a sense of trust is basic for biobanks to operate and that the legal rules play an essential role in this matter.

Currently, there is a lack of awareness of the value of biobanking in Mexico and the consequences are costly to industry. In general, as

⁸⁰⁴ Hawkins and O’Doherty 312

⁸⁰⁵ DJ Kaufman and others, ‘Public opinion about the importance of privacy in biobank research’ (2009) 85 *The American Journal of Human Genetics* 650

⁸⁰⁶ Hawkins and O’Doherty 312

pointed out by Hewitt, “one additional obstacle to public-private partnerships is the lack of quality assurance in many public sector biobanks.”⁸⁰⁷ In terms of data protection, more overseas attention has been attracting foreign investment into the country,⁸⁰⁸ with regulation in place.

Awareness of limits on prevailing biobanking rules is critical, as biobanking must always be viewed within a larger context. Public awareness may cause a contraposition of interests between industry and citizens. It would be concerning if the creation of rules instead of self-regulation discouraged investment by industry. However, the opposite effect is more likely to happen. If the population is to be interested in the need for human rights protection, first, they need to be aware. The population need to understand the importance of topics such as personal data contained in biological samples. Public awareness can gradually be constructed through public scrutiny of the defence of individual and collective rights. In this particular case, awareness needs to be created on the rights which can be affected by the donation of a sample. Following this, the needs of those involved can then be clearly identified, demanded and be the subject of legal protection.

8.1.2.1 Public awareness attitudes towards biobanking practices

As pointed out by Vaught and Lockhart, in recent years public awareness of biobanking has grown significantly.⁸⁰⁹ However, there are still significant boundaries for the creation of specific biobanking regulations and the most important are the predominant cultural values. Most Mexicans are not aware of the risks when donating a sample; hence, no protection is demanded from the authorities. The public are not aware

⁸⁰⁷ Hewitt 116

⁸⁰⁸ Camacho

⁸⁰⁹ J Vaught and N Lockhart, ‘The Evolution of Biobanking Best Practices’ (2009) 413 Clin Chim Acta 5

of their rights, which slows down reform as it results in ambivalence. Paradoxically the public are unaware of the ethical issues and therefore quite happy with the situation. If they woke up to the potential rights infringements, then there would be more impetus for reform.

Diverse opinions of stakeholders agree on the fact that public awareness in Mexico needs to be encouraged. In the view of Participant L,⁸¹⁰ strengthening awareness on the potential benefits of research amongst the public is a key point for the resolution of too-passive social attitudes. Participant K⁸¹¹ believes that dissemination of information should be carried out at the same time as legal rules are encouraged, as a way to achieve legal compliance. If people are aware of their rights, they will also demand more protection of them.

In the case of tissue sample donations in Mexico, there might not be significant social awareness because it would be unusual. For Participants D and E, Mexican social and political participation currently occurs to a low degree. A citizen's donation of a sample happens because "Mexicans tend to have a 'reverential respect' towards the role of their doctor. Their donation could be encouraged only because "because their doctor told them to do so",⁸¹² not because they are really interested in contributing to science. In the words of Participant N, "the population in general do not always understand the implications of donating a sample. Hence, the need for protection mechanisms is urgent in this respect."⁸¹³ This helps to explain how the relationship between science and society tends to be split in Mexico.

⁸¹⁰ Ethical-adviser-at-an-ethics-public-advisory-institution-Participant:L

⁸¹¹ Science-and-Technology-Commission-Participant:K

⁸¹² Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

⁸¹³ Bioethics-expert-at-a-public-legal-research-institution-Participant:N

Regarding awareness of indigenous communities, research in personalised medicine has been significantly helped by their samples, but they will always be a vulnerable group to protect. Reportedly, it is unlikely that a research team will come back to the community to inform donors of any results. “Researchers do not come back to the sample source to inform them of the publication.”⁸¹⁴ Participants D and E have pointed out that indigenous people tend to ignore their need to be protected and what from.⁸¹⁵

Biobanking research depends on citizens’ willingness to act as donors and allow research on their donated biological samples and personal information.⁸¹⁶ The core challenges of biobanks arise from their diversity, their longevity and the uncertainty that underpins their future direction.⁸¹⁷ Under the principle known as proportionality of action, there can be exceptions to the principle of integrity of purpose if there are enough justified reasons. “Thus, risk to privacy can be seen as acceptable so long as the imperative to share is demonstrated, the benefits to the public interest are articulated, and the relative risks to privacy are minimised.”⁸¹⁸

8.1.2.2 Informed consent, an example of cultural influence

The list of examples showing an absence of public awareness among the Mexican population is extensive; this is the case of informed consent. Although globally debated whether it is just a legal doctrine, the concept of informed consent is a significant ethical concern for developing countries because of the complications of social hierarchy at the level of the nuclear family, the community and the still prevalent paternal attitudes

⁸¹⁴ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

⁸¹⁵ Ibid

⁸¹⁶ Ducournau and Strand 2

⁸¹⁷ Laurie 350

⁸¹⁸ Ibid 49

to medicine where doctor is above the patient. This example also portrays the negative expected result from paternalistic ideologies in the practise of medicine used as coercion, where participants are ignorant about their rights.⁸¹⁹

Participants D and E⁸²⁰ believe that the cultural perceptions on the legal system also influence how people see the informed consent document. In the US they have very long consent forms to avoid being sued. In Northern Europe they tend to be brief as people have more trust in their institutions. “Mexican people will not read a long informed consent document. It needs to be concrete.”⁸²¹

Participant N explained that the poor awareness among Mexicans means participants “just sign the informed consent form because they know it is part of the procedure, nothing else.” In the opinion of participant F, implementing a flexible consent model according to the needs of each biobanking type, “does not mean standardising the informed consent.”⁸²²

If Mexican citizens are unlikely to read a long consent document, other choices need to be available for building awareness, especially in the case of vulnerable populations. It is the responsibility of researchers and health providers to ensure fair research and healthcare activities. The way information is presented has an impact on the public, who may not understand due to expertise or language barriers. An ideal informed consent process will ensure that participants understand all advantages and disadvantages from their participation.

⁸¹⁹ Bhardwaj 97

⁸²⁰ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

⁸²¹ Ibid

⁸²² Legal-researcher-at-a-public-research-institution-Participant:F

Participants D and E believe that “informed consent in Mexican legislation needs to be very specific because of the trust level of people towards institutions.”⁸²³ The absence of social trust on institutions would make specific rules ineffective. Moreover, the Mexican population should be informed of potential scientific benefits that can be achieved through sample donation in a realistic way. In the end, biobanks entirely depend on citizens’ actions and the health of the greater population relies on biobanks. It was emphasised by participants D and E that, compared to other countries, there is much work to be done in Mexico on the area of trust. “Some Mexican researchers had the opportunity to ask Northern Europeans what should happen to their samples, and were surprised by the responses. The interviewees said that the ethics committee should decide on it. In Nordic countries, people are more open to sign an informed consent because they trust their institutions. In developing countries, the trust level of people was lower.”⁸²⁴ In the opinion of Participant O, regarding investment, the level of practical structure in comparison with other countries is significantly poor. “We have no means as databases, we are really behind.”⁸²⁵

Consent must be inclusive and designed according to the needs of the ‘culturally sensitive’ target population. If an indigenous population demands data protection in the same way as other populations, it means that special measures will need to be taken; 1) to make that population aware of the involved risks and 2) to take the necessary measures to protect the group, given its character of vulnerability.

⁸²³ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

⁸²⁴ Ibid

⁸²⁵ Expert-on-Bioethics-Philosophy-and-Law-at-a-Public-university-Participant:O

The following section will discuss whether Social Solidarity can work as the justification for biobanking activities in a country like Mexico, a country whose diversity is not only present in terms of ethnicity but also in the distribution of wealth among the population.

8.2 The role of social solidarity

Collective health depends greatly on social cooperation and interdependence.⁸²⁶ The role of solidarity is unifying in this respect, “a social force which contributes to the sustenance of the unity of a group of people.”⁸²⁷ Similarly to cooperation, solidarity is constructed on the basis of certain beliefs and has a cohesive effect, often considered necessary for the success of a social struggle.⁸²⁸

It is precisely in a context of social struggle that elements of unification are needed. The majority of the Mexican population live under poverty conditions, which need to be helped by focusing on priority fields, such as health. Mexico has the second highest rate of obesity. One out of 11 Mexicans suffer from diabetes, the highest cause of death in Mexico. This percentage is 3 times higher than in Chile. 17% of public health funds are spent in the treatment of this disease. From 1960 to 2012, Mexican life expectancy had gained 2.8 years in men and 3.4 in women. Countries like Japan have gained 7 years in men and 10 in women. The average gain in OECD countries is 4.4 years in men and 5.6 years in women. 6.4% of the IPB is spent on health, in comparison with 9.6% from average OECD countries' IPB. A Mexican spends 249 dollars per year on medicines, whereas an average OECD citizen spends 487 dollars annually. There are 1.7 hospital beds per 1000 habitants; whereas the

⁸²⁶ B Jennings and A Dawson, ‘Solidarity in the moral imagination of bioethics’ [2015] Hastings Center report 37

⁸²⁷ D Heyd, ‘Justice and solidarity: The contractarian case against global justice’ (2007) 38 Journal of Social Philosophy 119

⁸²⁸ Ibid 119

average for OECD countries is 3.1.⁸²⁹ These conditions are not shared by the whole of the population. Some sectors are wealthier than others.

A more comprehensive approach could feed into discussions of compensatory and distributive social justice and, in this way, move towards resolving tensions that currently exist; such as social inequalities. Following Rawls, the role of justice, similar to solidarity, is also cohesive. There is justice when rational and reasonable individuals are constrained by the sense of fairness.⁸³⁰ This can be transposed to international grounds, taking into account that biobanking is an international reality where Mexico already participates.⁸³¹ Whilst this concept of distributive justice holds particularly true in the relationship between the developed and developing world, “a more general principle of compensatory justice would also seem to underlie concepts of benefit sharing.”⁸³² In this sense, the concept of solidarity can help society understand itself better.⁸³³ Benefit sharing is still possible even within disparities.

8.2.1 Criticism to solidarity in literature

However, in the context of contemporary neoliberal societies, the influence of solidarity, by itself, in health and other social affairs, has been considered as weak.⁸³⁴ Solidarity, being mediated by a commitment to an idea or a cause, is in that respect ideological.⁸³⁵ Solidarity can indeed become ideological when there are no realistic conditions that make

⁸²⁹ M Carbonell, ‘El desafío de la salud (The health challenge)’ *El Universal* (Mexico City, 17 May 2012) Opinión

<<http://www.eluniversalmas.com.mx/editoriales/2012/05/58536.php>>

⁸³⁰ J Rawls, “Justice as Fairness: Political not Metaphysical,” 14 *Philosophy and Public Affairs* 123

⁸³¹ See page 53

⁸³² S Wilson, ‘Population biobanks and social justice: Commercial or communitarian models? A comparative analysis of benefit sharing, ownership and access arrangements’ (2004) 8 *TRAMES* 82

⁸³³ Jennings and Dawson 31

⁸³⁴ *Ibid* 32

⁸³⁵ Heyd 119

participants equal in practice. "A society which clearly perceives solidarity, interdependence, mutual risk and benefit, is preferred.⁸³⁶ Solidarity certainly needs to be strengthened by social cooperation and an appropriate sense of legality to fight economic inequalities.

According to Samuel A. Butler, solidarity can be weak when attempting the provision universal healthcare. "Anything that might serve such a role (the provision of universal healthcare) is more properly understood as being grounded in concepts such as liberty, equality or justice than in solidarity."⁸³⁷ Health affairs need the intervention of medical professionals, health policy analysts, and health policy makers. However, this does not only apply for solidarity, but also for justice and liberty. These could also become ideological without the coordination of stakeholders, social engagement and adequate legal rules.

Health is a primary for everybody, despite their social condition. In this respect, the role of bioethics can be helpful. The benefits of medical research must be viewed as solidarity obligations to take social action over social interests. Solidarity must become more widely active and explicit in bioethics analysis and argumentation as it endeavours to shape reasons for obeying norms and rules of common benefit in an open diverse society.

8.2.2 Social solidarity and biobanking

As emphasised previously, biobanking research involves priority areas and the use of diverse techniques, which involve the potential for discovering new therapies for diseases. In epidemiological terms, biobanking is socially oriented (stratified medicine) and individually oriented (personalised medicine). Accordingly, this link emerged from the

⁸³⁶ Jennings and Dawson 32

⁸³⁷ SA Butler, 'A dialectic of cooperation and competition: solidarity and universal health care provision' (2012) 26 *Bioethics* 351

promise of personalised medicine to revolutionise health care by harnessing individual genetic information to improve drug safety and efficacy.⁸³⁸ One of the main targets of the diverse biobanking projects in Mexico has been for personalised medicine to benefit the whole population. The role of the public in biobanking is substantial due to the link between research and improvements in medicine for everybody.

According to Wilson, “all research participants should receive information about general research outcomes and an indication of appreciation”⁸³⁹ Sadly, without adequate biobanking governance, the benefits of scientific research will never reach the poorest. Within biobanking, solidarity aims for the willingness of participants to donate time, samples and information with the only compensation being the knowledge of potentially having helped someone else’s health. “Researchers and patients should be seen as a team, each doing their share to promote the common good of improved health.”⁸⁴⁰ In terms of practicalities, it would appear that, where specific legislation relating to governance of the databases has been enacted, the matters of ethical concern are at least identified and an organisational response stated. This approach acknowledges the importance of the relevant ethical questions, and the relevance to the communities involved, assuming that they are equal.

When participants are not equal, disparities need to be mitigated somehow. A socio-political discourse has been constructed from solidarity, which explains biobanking purposes as “a new process for agreeing to research participation in the form of a participation agreement, including a conceptual shift towards harm mitigation

⁸³⁸ SH Katsanis, G Javitt and K Hudson, ‘A Case Study of Personalized Medicine ’ (2008) 320 *Science* 53

⁸³⁹ Wilson 82

⁸⁴⁰ J Stjernschantz, ‘Changing perspectives in biobanks research: from individual rights to concerns about public health regarding the return of results’ (2009) 17 *Eur J Human Genet* 1547

strategies.”⁸⁴¹ The guarantee that research would improve public health helps to legitimise solidarity in biobanking. “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.”⁸⁴²

8.2.2.1 Social solidarity and ownership

Innovative models of biobanking governance need to support collaborative approaches to improve health systems. Solidarity practices would manifest in biobank governance arrangements that envisage research participants “as partners in research to whom the biobank owes respect and veracity.”⁸⁴³ For this reason, it is relevant to inform participants of the type of research and anticipated findings that will be obtained.

However, the principle of solidarity cannot be implemented in a completely free way. For example, the policy of not providing feedback to research participants may be based on solidarity reasons. This would be acceptable as long as the findings of the health consequences of the person are insignificant. Feedback on samples is not possible in some cases; samples are only used as a source of data, as medical registers are used in epidemiology. “Any benefit that can result from such research is a product not of the samples or registries themselves, but of the intellectual work done by the researchers.”⁸⁴⁴

⁸⁴¹ B Prainsack and E Buyx, *Reflections on an emerging concept in bioethics* (Nuffield Council of Bioethics and Arts and Humanities Research Council 2011) xvii

⁸⁴² Human Genetics Commission HGC, *Inside Information: Balancing Interests in the Use of Personal Genetic Data*. (A report by the Human Genetics Commission, 2002) 16

⁸⁴³ Prainsack and Buyx, ‘A solidarity-based approach to the governance of research biobanks ’ 88

⁸⁴⁴ Stjerschantz 1547

Even when some databases involve free access, property rights are still a matter of ethical concern. Generally speaking, both researchers and participants envisage benefit to the public good, through a contribution to science. While participants agree to donate their samples, researchers have the choice of whether or not to share research materials. The ownership of knowledge or potential knowledge may become an individual or collective right, even in places where social inequalities are present. “The problem with genetic samples is that the research community has traditionally considered the DNA as a gift,”⁸⁴⁵ which is an action of altruism and solidarity, not a ‘loan’ under a specific contract. Ownership issues have become a significant debate, which in the USA recently finished with the prohibitions of human genes patents.⁸⁴⁶ The ethical focus present discussions are taking seems oriented towards the protection of citizens against extreme profit making interests.

No references to intellectual property matters have been made in Mexico. It is very difficult to determine the individual ownership of such samples, and it could be assumed that they are the property of the biobank in which they are being stored. Gerardo Jiménez recognises this as a challenge to “the need for novel funding mechanisms and incentives to innovate and register intellectual property outside of the traditional format that conditions a significant proportion of scientists’ income, creating a legitimate urge to publish results.”⁸⁴⁷

8.2.3 Solidarity as a means to help disparities

Prainsack and Buyx ask whether it is necessary to offer any kind of benefit in exchange for a significant social contribution, for example in sample donation. This should not be misunderstood; this proposal does

⁸⁴⁵ Dalton 1

⁸⁴⁶ *Association for Molecular Pathology v. Myriad Genetics Association for Molecular Pathology Association for Molecular Pathology, et al v Myriad Genetics, Inc, et al* (The United States Court of Appeals for the Federal Circuit No. 12–398.)

⁸⁴⁷ Jimenez-Sanchez and others 1196

not involve changing the sense of solidarity as a principle. Solidarity works as a principle of mutual advantage that Rawls portrayed as social ideal based on social cooperation, "in justice as fairness society is interpreted as a cooperative venture for mutual advantage."⁸⁴⁸

Mexican biobanking requires agreements involving the sharing and exchange of materials between participants from diverse cultural backgrounds, still with interests in common. "Majority and minorities in a multicultural society share the same destiny in many respects, a fact that creates a sense of solidarity."⁸⁴⁹

According to solidarity as a principle, resultant inequalities should improve the least well off.⁸⁵⁰ Chadwick and Berg have suggested that underlying the concept of benefit sharing is the "ethically strong ideal of equal opportunities," which results in the "duty of those who are well off to share with the poor."⁸⁵¹ Justice often implies solidarity when solidarity acts come from injustice towards an individual or oppressed class.⁸⁵² Thus, solidarity is manifest in the struggle of the working class against oppression, the flight of trade unions for the amelioration of working conditions, or the effort of liberation movements of minorities to achieve recognition.⁸⁵³

Solidarity, reinforced by adequate legal controls and mutual engagement, provides protection against exaggeratedly unequal distribution.⁸⁵⁴ It offers a more careful analysis of benefits, costs and other

⁸⁴⁸ J Rawls, *A Theory of Justice* (Harvard University Press 1971) 79

⁸⁴⁹ Heyd 119

⁸⁵⁰ Butler 355

⁸⁵¹ R Chadwick and K Berg, 'Solidarity and equity: new ethical frameworks for genetic databases' (2001) 2 *Nature Reviews Genetics* 321

⁸⁵² Jennings and Dawson 34

⁸⁵³ Heyd 118

⁸⁵⁴ Butler 355

relevant factors that should be considered in the justification for a particular course of action or policy.⁸⁵⁵

Legal governance, recognised as a multidisciplinary element, will face a series of challenges in practice. The main one is designing fit-for-purpose binding rules which guarantee collective protection, for example, by ensuring autonomous participation and protecting the identities of underage and vulnerable participants. For instance, establishing the terms of disclosure of a propensity for illness (discovered through biobanking research) of a particular ethnic group.

Solidarity can work as a transitional feature in order to strengthen the weakened trust of Mexican participants. Issues such as: insufficient public awareness (the prerequisite for public demands on human rights' protection), poor dissemination of knowledge by ethics committees, a weak sense of trust by study participants and an economically focused knowledge translation, can all be alleviated through social solidarity approaches. "When it comes to large-scale biobanks consisting of altruistically donated materials, the purpose of the donation is to enhance scientific knowledge to promote people's health."⁸⁵⁶

"In political terms, population-based genetic biobanks stand at the research frontier where the engagement between regulatory needs and ethical capacities are at their most acute, and where solutions are only just beginning to emerge."⁸⁵⁷ The bioethical agenda must be considered in the same way as health priorities, such as campaigning against chronic diseases. Regulatory efforts in this area are worth the effort from a preventive approach. Genetic research is, in the end, a way to prevent these chronic diseases.

⁸⁵⁵ Prainsack and Buyx, *Reflections on an emerging concept in bioethics* xii

⁸⁵⁶ Stjerschantz 1547

⁸⁵⁷ Salter and Jones 722

“Solidarity involves as deep understanding and interpretation of a lived experience perceived through a distinct cultural and personal lens.”⁸⁵⁸ According to Heyd, caring for others “constitutes a necessary condition for the operation of justice.”⁸⁵⁹ In this dimension of solidarity, it stands for a will to assist others, such as defending a particular “a cultural way of life” or better health conditions to those oppressed.⁸⁶⁰ This implies the recognition of differences among those involved within a multicultural society, in this case the differences that make indigenous communities vulnerable. A sense of identification, which also recognises differences amongst them is desirable.

8.2.4 Is social solidarity the most appropriate?

From the discussion above, solidarity has been considered a potential key factor to boost regulatory efforts, based on citizens’ willingness to cooperate voluntarily, because even the unequal share common interests. Solidarity also supports the idea that the wealthiest should, due their position, commit to help the poorest. However, the role of the law will be essential to help the disparities of a population where some are more vulnerable than others.

8.2.1.5 Vulnerable populations, a separate subject

The great diversity found within Mexican population is a challenge in terms of unification for public engagement. This is clearly depicted in the case of Mexican indigenous communities, who tend not to consider themselves as part of the society. They have historical claims to their own customs and laws. In contrast to the scepticism regarding data protection shown by citizens from the urbanised capital of Mexico, an apparently

⁸⁵⁸ Jennings and Dawson 37

⁸⁵⁹ Heyd 119

⁸⁶⁰ Jennings and Dawson 36

greater indifference can be found amongst indigenous communities. Whitener and others explain how “the ‘genomic goldrush’, created by the fast advancement of knowledge in the area of genomics and the excitement for the possibility of new interventions for chronic disease, has resulted in conflict between indigenous communities and researchers.”⁸⁶¹

Regarding indigenous communities, for example, Sahota’s findings from a study in American Indian-Alaska Native Communities is an example showing coordination interests to involve not only scientists, but also involving tribal leaders and legal staff. This has helped to develop a research regulatory agency; as means to help to prepare the tribe to actively participate as research partners with academic research institutions and regulate research that is conducted within the community.⁸⁶²

The case of American Indian-Alaska native communities has made evident the serious situations of vulnerable groups participating. Conflictive situations, such as that in Alaska, have attracted attention in the United States, and some actions have been implemented “in order to minimize the risks of conflict and community harm from genetic research.”⁸⁶³ The National Congress of American Indians has encouraged the participation of indigenous minorities through their representative “tribal governments,” for them “to play a more active role in the regulation of research occurring within the territory of their

⁸⁶¹ R Whitener and others, ‘Engaging American Indian Communities in research through Community Based System Development ’ (ELSI Conference 2011 Academic Ventures, South Carolina, April 2011)

⁸⁶² P Chawla Sahota, ‘Research Regulation in American Indian/Alaska Native Communities:Policy and Practice Considerations ’ NCAI Policy Research Center <http://depts.washington.edu/ccph/pdf_files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf> accessed 27 March 2013

⁸⁶³ Ron Whitener and others, ‘Engaging American Indian Communities in research through Community Based System Development ’ (ELSI Conference 2011 Academic Ventures, South Carolina, April 2011)

sovereign control.”⁸⁶⁴ This example evidences an active proposal to minimise the vulnerability of the group.

Such fundamental points support the rights for minorities to express their basic needs: health and cultural protection. This illustrates the many measures which should be implemented for the legal protection of indigenous communities, regarding their participation in Mexican biobanking research.

Mexican indigenous people have historically suffered from stigmatisation and discrimination. In 2003, the Mexican government passed an anti-discrimination law which made any form of racial discrimination against indigenous people illegal, however Mexico’s indigenous communities still experience marginalization and continue to be disadvantaged and vulnerable.⁸⁶⁵ Even so, passive interest has been expressed towards a more protective legislation for indigenous communities participating in biobanking research. Mexican biobanking requires agreements involving the sharing and exchange of materials between participants from diverse cultural backgrounds.

In this situation, “employment, treaty rights and cultural preservation” are top priorities,⁸⁶⁶ and also within the Mexican experience, cultural preservation is especially prioritised. This involves “access to traditional foods and income sources, and underscores the importance of community engagement when setting research agendas.”⁸⁶⁷ Avoiding legal failure in Mexican practice requires a cultural element to be

⁸⁶⁴ Ibid

⁸⁶⁵ C Underwood, ‘72% of the Indigenous Population in Mexico live in Extreme Poverty Conditions’ *The Yucatan Times* (Merida, Mexico, Sat Aug 16th 2014)

⁸⁶⁶ Puneet Chawla Sahota, ‘Research Regulation in American Indian/Alaska Native Communities:Policy and Practice Considerations ’ NCAI Policy Research Center <http://depts.washington.edu/ccph/pdf_files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf> accessed 27 March 2013

⁸⁶⁷ Whitener and others

incorporated to the law. Vulnerable populations require special legal protection.

8.2.1.4 Given the great inequalities in Mexico, can we expect solidarity?

The idea that social solidarity can be used to justify biobanking in a society as unequal as Mexico's is open to criticism. However, if the most vulnerable person can be afforded the same protection as the most privileged, then this criticism can be mitigated.

The application of social solidarity in Mexico could be directed to society in general (as well as indigenous populations) as long as some boundaries are established. Under traditionally altruistic approaches, even indigenous donors are expected to donate samples with nothing in return. It is not acceptable to influence sample donation by benefits, such as access to knowledge on health conditions revealed through the sample, however, this is not explicitly guaranteed. Modern solidarity supports that researchers at least have to come back to the community and explain potential benefits and their extent. Ideally, as previously suggested, biobanking in indigenous communities should involve not only more participation of the scientific community, but specific benefits for the community under an exceptional protective approach.

8.3 From research to health benefits

In terms of social compensation, reciprocity should be expected from biobank databases. In health research, the transformation of bioscience into societal benefit is known as translation. Social expectations of science are significant, as science expects to benefit society in return for public investment. Biobanks are "the appropriate next step in translating recent advances, such as the mapping of the human genome, into knowledge of direct clinical and public health relevance."⁸⁶⁸

⁸⁶⁸ Salter and Jones 715

Biobanks aim to provide a platform for generating new scientific knowledge to support the development of new policies, systems and interventions for enhancing the public's health.

The demand for studies confirming the usefulness of new genomic devices, with definitive and measurable clinical endpoints, such as sense of well-being and established medical outcomes, is constantly growing.

8.3.1 Knowledge translation and social values

The roles of medicine, science and the law are expected to be balancing elements in forthcoming regulatory processes between scientific and social values. "Translation of biobanking science demands the active involvement and intersection of perspectives of the full range of stakeholders: that is, co-evolution of translational research."⁸⁶⁹ It has also been argued that bioethics has acquired a considerable political value and an ability to incorporate the different interests of citizens, science and industry within an apparently neutral discursive domain.⁸⁷⁰ Benefits should be widely shared, since these databases were created from samples and data originating from public funds. According to Murtagh and others, innovative theories, tools and methods for analysing data in order to maintain privacy and confidentiality are examples of social demands. Their absence affects current models of translation, where biobanking research leads to potential benefits.⁸⁷¹

Whilst biobanking is thought to primarily develop healthcare, "particularly, translation into population level public health,"⁸⁷² the development of science depends on the development of a social context where ethics and law really matter. New laws for the long term need to be directed specifically towards promises of health, since approaches which

⁸⁶⁹ Murtagh and others 340

⁸⁷⁰ Salter and Jones 728

⁸⁷¹ Murtagh and others 339

⁸⁷² Ibid 338

are too diverse can create obstacles in practice. A common characteristic of the multifaceted ways of translation is that they express a sense of a complex, dynamic, but desirable social process beyond the science.⁸⁷³

8.3.2 Knowledge translation and its regional boundaries

The extent of benefit from knowledge translation depends on the development level of the country. Nyika has pointed out that “the development of the necessary frameworks for genetic research and use of archived samples is still in the infancy stages in most developing countries.”⁸⁷⁴ An example situation can be found in a study with patients from Mexico and Vietnam, in which whole exomes of 103 breast cancer abnormal growths and normal DNA tissue were sequenced. Furthermore, the entire genomes of 22 breast cancer abnormal growths and matched up normal tissue were also sequenced. However, the 2 types of samples examined⁸⁷⁵ are not yet subjected to specific ethical norms in either of the countries. In addition, it is highly problematic that the majority of developing countries’ populations may not benefit from new technologies due to prevailing socioeconomic factors. Hence, stakeholders should always make concerted efforts to ensure availability and affordability.⁸⁷⁶

Practical expectations of biobanking are wider than the scarce legislation in Latin-America,⁸⁷⁷ as Mendoza and López have recognised. Mexico depends on the National Institute of Genomic Medicine to act as a hub for various human genomic medicine networks, which can be very beneficial as this will enable other Latin-American countries to understand their public health needs and develop genomic therapies without the need

⁸⁷³ Ibid 334

⁸⁷⁴ Nyika S22

⁸⁷⁵ Banerji and others 409

⁸⁷⁶ Ibid

⁸⁷⁷ HA Mendoza Cárdenas and S Lopez Garcia, ‘Inicio y fin de la vida: aspectos biojurídicos (the beginning and end of life: legal aspects)’ (2011) 22 *Revista de Bioética y Derecho* 18

to duplicate the initial investment already made by Mexico.⁸⁷⁸ As “bioscience reflects the disease priorities of contemporary societies,”⁸⁷⁹ in the case of Mexico, most of the current challenges relate to national health priorities.

Despite recent advances, statistics from 2012 show that health conditions in Mexico are still relatively poor. One out of 11 children have low birth weight, compared with 1 out of 17 in Chile. Mortality in children under one is ten times that of Iceland and twice Chile’s. Despite obstacles, Mexico has recognised that “it is not justifiable to say that research is something luxurious that poor countries cannot afford because there are other priorities.”⁸⁸⁰ The social benefit from translation can take place through scientific benefits. These scientific benefits are beginning to develop with the potential for translation in the Mexican context. However, these are difficult to envisage at the present time.

Limitations, if not seen in context, may prevail over ambitious intentions to reform biobanking regulations in parallel with the national health system. Presumably, large-scale databases are not the best choice for those developing, since risks of exploitation and not recovering great investments are high due to the current weak regulations.⁸⁸¹ Rather, direct investments for the provision of primary healthcare and preferential access to public databases would have a more immediate impact on population research of developing countries. Never the less, currently, great investments are taking place in Mexico. Carlos Slim Helú announced a \$74 million dollar contribution into the Slim Initiative for

⁸⁷⁸ B Séguin and others, ‘Genomics, public health and developing countries: the case of the Mexican National Institute of Genomic Medicine (INMEGEN)’ (2008) 9 *Nat Rev Genet* 487

⁸⁷⁹ Murtagh and others 333

⁸⁸⁰ (The-Mexican-Ministry-of-Health)

⁸⁸¹ Bhardwaj 99

Genomic Medicine in the Americas (SIGMA)⁸⁸², which aims to develop diagnostic tools and medicines for diseases, including breast cancer and type 2 diabetes, which are especially prevalent in the Mexican population. Genomics experts recognise the initial efforts but also their challenges, explaining that “translating genomics insights into useful tools and practices will take much longer than the program’s 3-year second phase, especially in an economy like Mexico’s, in which more than half the population lives in poverty.”⁸⁸³ The legal situation of Mexican current rules needs to improve for this kind of investments to be effective.

Democratically led knowledge translation tends to have an impact on the official policies of countries, an impact which Mexican policies should aspire to. Another prerequisite for the development of public understanding is political will; obtaining funds for knowledge dissemination depends on political support. The next attempt for Mexican biobanking legislation will be critical in reinforcing social trust towards genomic institutions (such as INMEGEN). INMEGEN has accurately targeted diabetes, obesity and cancer as the main diseases affecting the health of the Mexican population.⁸⁸⁴ Therefore, Mexican bioscience must coherently prioritise research with these aims in mind. Institutions involved should demonstrate that the efforts made by public institutions to develop personalised medicine in the country can be fruitful both for economic development and public health. There is a co-dependence between biobanks and the public in terms of benefits, such as those promised to the Mexican population and which motivated the creation of INMEGEN.

⁸⁸² Broad Institute, ‘Mexico-US genomics partnership launches second phase’
<https://www.broadinstitute.org/news/5324>

⁸⁸³ Wade 788

⁸⁸⁴ Jimenez-Sanchez and others 1194, 1195

Participants D and E⁸⁸⁵ have remarked that, in their experience, provision of feedback is impossible, not because they do not want to do it, but because of the particular statistical nature of biobanking projects. In some, genetic data becomes anonymised for a purely statistical treatment. This position is supported by Menasco.⁸⁸⁶ Population biobanking may not be so risky in general, since most of the time, even when anonymisation mechanisms have not yet been implemented in Mexico, population data becomes anonymised.

In the case of INMEGEN, social solidarity can be strengthened by showing how the health system can rely on research. This argument may be contra-posed to the social interests of the citizens that may be hopeful of a potential treatment or a vulnerable population with basic health needs. Therefore, the legitimacy of solidarity is linked to a commitment directed to an undetermined group's welfare, and does not mean that individual privacy and confidentiality will not be considered at the individual level. The solidarity approach for biobanks seems ideal but in practice it requires adjustments and exceptions, especially in the case of vulnerable populations.

Health areas are considered key to reflecting the translation into benefits from biobanks towards the population. The main objective of this collaboration should be the integration of genome-based knowledge and technologies into the clinical and public health research agenda, thus forming the scientific basis for developing sound policies and effective interventions. This approach should become essential to fill the gaps in translating research results into population benefits.⁸⁸⁷

⁸⁸⁵ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

⁸⁸⁶ Manasco 23

⁸⁸⁷ Lumbreras, Porta and I Hernández Aguado756

8.3.3 The desired impact of knowledge translation

Practices of knowledge translation include: use of consensus conferences or expert panels, systematic reviews, narrative syntheses, meta-analyses, meta-syntheses and practice guidelines to contextualise and integrate research finding. It also includes dissemination via briefings and educational sessions with stakeholders (patients, practitioners and policy makers), engaging knowledge users in developing and executing dissemination/implementation plans, and media engagement. Knowledge exchange involves interaction between knowledge users and researchers. Consequently, results in mutual learning are expected from the process of planning, producing, disseminating and applying existing or new research in decision making. These need to be consistent with ethical principles and norms, and social values, as well as legal and other regulatory frameworks. Such networks demand the reshaping of some members' normative cultures and beliefs.⁸⁸⁸ .

Actions improving science of future health care are closely related and include “an explicit acknowledgment of the tools and methodologies that underpin translation of basic and applied research.”⁸⁸⁹ Ideally, knowledge could be converted into benefits for the population's health, through the provision of more effective health services and products. Knowledge translation can happen in a number of ways and has historical links with “health promotion, health education and community development of engaging communities, health care providers and policy makers with health care issues, action and change.”⁸⁹⁰ These efforts could contribute to strengthen the Mexican health care system and society.

⁸⁸⁸ Murtagh and others 340

⁸⁸⁹ Ibid 339

⁸⁹⁰ Ibid 340

8.4 The international experience

Current rules need to be updated as biobanking at the international level keeps expanding. Intense legislative work also needs to respond to international demands for standardisation. Community compensation is normally expected when participating in a research project. An international consensus is that, at a minimum, groups participating in research should receive some benefit.⁸⁹¹ One way of such benefit to materialise could be that profit making institutions donate a percentage of their annual income to social healthcare.

- The case of Sweden

European examples, such as in Sweden, have shown that public awareness is linked to notions of benefit sharing, such as payment or return of health information. People from a Swedish study declared they were donating because it could help a relative with an illness in the future. According to Kettis Lindblad and others, there is a relevant component for this kind of social drive to happen: “the willingness is mainly driven by altruism, and depends on the public being well-informed and having trust in experts and institutions.”⁸⁹² Solidarity has been the focus for social attitudes in countries such as Sweden. The solidarity approach is suitable for populations where people consider themselves similar to these others in a relevant aspect, or where shared practices take place in a given group or community. Welfare societies all share arrangements that are enacted and enforced by law, for example, solidaristic health insurance systems with compulsory contributions.⁸⁹³

Even currently effective regulations, such as those from Sweden, faced challenges centred on ethical foundations. The Swedish biobank

⁸⁹¹ HUGO Ethics Committee, *Statement on benefit-sharing* (2000) 1

⁸⁹² A Kettis-Lindblad and others, ‘Genetic research and donation of tissue samples to biobanks. What do potential sample donors in the Swedish general public think?’ (2006) 16 *European Journal of Public Health* 433

⁸⁹³ Prainsack and Buyx, ‘A solidarity-based approach to the governance of research biobanks’ 76

company UmanGenomics failed to meet the IPR requirements of a successful market, despite its vaunted ethical foundations.⁸⁹⁴ However, these types of situations have triggered positive parliamentary attitudes; the Swedish Parliamentary Commission currently works on the basis that first, there should not be any legitimate area of application in the general field for genetic information, apart from the medical field, the judiciary and other areas and secondly, that these should be subject to a special regulation.

- The case of the UK

Interests over the future of samples and the possibility for them to end up being handled by legitimate or illegitimate third parties have caught the interests of a number of citizens who, at least in the UK, feel that “insurance companies are less likely to be sympathetic than employers in the event of illness.”⁸⁹⁵ However, the number of citizens aware of these concerns in Mexico is significantly low. A clear example of natural trust can be found in the operation of UK Biobank, which depends on the active co-operation of citizens.⁸⁹⁶ The approach followed by the UK in biobanking related pharmacogenetics research has encouraged trust by regulating it specifically through the National Health Service (NHS).

British policies have sought to encourage awareness amongst staff by establishing binding rules and encouraging staff to familiarise themselves with them. A primary need of health staff is evidently that of expertise. Two main positive results have been observed:

- 1) The NHS’s capacity and public trust have been reinforced and
- 2) Its research benefits reassured.

⁸⁹⁴ H Rose, ‘An ethical dilemma. The rise and fall of UmanGenomics – the model biotech company?’ (2003) 425 Nature 123-4.

⁸⁹⁵ Trust and Council 52

⁸⁹⁶ Salter and Jones 711

The latter has built public confidence in the public regulation of pharmacogenetics research and development has been critical for the UK, where there has been “an improving understanding of the needs and benefits of translating research, and an engaged venture capital sector.”⁸⁹⁷ The international experience provides examples coming from medical areas, for example, the role of patient representatives in the UK is transcending to research representation areas and “trust can be immensely useful if one is to conduct public policy.”⁸⁹⁸

A good example of the reciprocity relationship is the basis of UK Biobank’s functioning, in which two elements can be clearly identified for “an appropriate articulation of public good”:⁸⁹⁹ patients need to be informed in what terms accessibility will be granted and on the likelihood of those terms to be challenged, and established access limits according to the needs of the biobank. The main principle for biobanks to be accountable, and therefore trustworthy, is transparency. “Accountability makes it clear that the motivations of politicians and law-makers to open up the bank are informed by their own justificatory commitments to the public good.”⁹⁰⁰ In contrast, Icelanders are to be entitled to drug treatments developed as a result of the database, and such drug treatments are to be freely available to the entire Icelandic population.⁹⁰¹

Deliberative democracy, understood as a model in favour of actual interpersonal engagement⁹⁰², has been one of the main aspirations of countries such as Britain and Germany.⁹⁰³ As a consequence, there have been attempts to attenuate the existing barriers between the technical

⁸⁹⁷ T Ling and A Raven, ‘Pharmacogenetics and uncertainty: implications for policy makers’ (2006) 37 *Studies in History and Philosophy of Science* 546

⁸⁹⁸ L Johnsson, ‘Trust in biobank research. Meaning and moral significance’ (PhD Thesis, Uppsala Universitet 2013) 77

⁸⁹⁹ Capps 8

⁹⁰⁰ *Ibid* 7

⁹⁰¹ Wilson 84

⁹⁰² B Ackerman, ‘Why Dialogue’ (1989) 86 *Jof Philosophy*, 5–22.

⁹⁰³ P Sztomka, *Trust: A Sociological Theory* (Cambridge University Press 1999) 140

character of biobanking and the public. This can be achieved by acknowledging the role of trust in gaining transparency and control.⁹⁰⁴

8.5 Education as means to avoid inequalities

Ducournau and Strand have remarked that when “donors are not familiar with the working of science they accordingly have to trust the experts.”⁹⁰⁵ In this context, donors are seen as “the public” and the biobankers as the “experts”. As reviewed in Chapter 6, the CNB has not achieved a full training scheme equivalent to that in the UK in terms of familiarising health staff with the current ethical and legal frameworks, which could be modified at the same time as trying to achieve this familiarisation.

According to participant O, the main problem in Mexico is the poor dissemination of knowledge; it is not an absence of interest, but an absence of knowledge. Citizens’ demands can materialise if citizens are aware of the rights’ or benefits they are entitled. If the public reached an adequate level of knowledge, it would be necessary for biobanks or any biological sample repository to obtain and maintain the donors’ trust. The limited public knowledge of biobanks (particularly genetic and genomic-oriented biobanks) points to “an ongoing need for public and community education and engagement on issues surrounding biobanking.”⁹⁰⁶

The public seems to show a greater propensity to suffer the consequences of disinformation. It is not the only the public affected by poor dissemination of knowledge, “the biobankers may be unaware of ethical aspects that are contested in society in general or in academic discourse, aspects which in that case will be considered neither by biobankers nor by donors.”⁹⁰⁷

⁹⁰⁴ Ibid

⁹⁰⁵ Ducournau and Strand 9

⁹⁰⁶ Simon and others 828

⁹⁰⁷ Ducournau and Strand 10

Additionally, unintentional misconduct may occur when the sample collection managers do not fully understand the issues. Participant B mentioned she has felt the need for training and recognised, in her scientific position, her ignorance of what to do in many cases,⁹⁰⁸ for example, what to do with collections from projects whose initial purpose has been achieved. In this scenario, legal or ethical knowledge may be genuinely ignored by biobanking staff. Ideally, biobanks would never betray the trust of sample donors, intentionally or unintentionally.

8.5.1 Educating the public

Mexico has promoted an evidence based research agenda and any “research agenda with a population perspective should make public education about genomics a priority.⁹⁰⁹” However this has not yet happened. There have been significant investment efforts towards research, but not as much attention as is required towards educating the population. In the opinion of Participants D and E, for the public to become more involved and less dependent on rules in the long term, “wide changes on education and culture are necessary.”⁹¹⁰

A concerning issue within Mexican society is the population’s low level of access to internet. The average percentage of Mexican homes with internet access in 2012, was 25.9%, “an alarming” one in comparison with that of OECD’s average countries (71.6% in 2011).⁹¹¹ According to Lumbreras et al,⁹¹² despite the increased recognition of the importance of genetic and genomic education, the proportion of public funds devoted to research education, is too small compared with that devoted to basic

⁹⁰⁸ Researcher-at-a-public-biobank-Participant:B

⁹⁰⁹ Lumbreras, Porta and I Hernández Aguado 756

⁹¹⁰ Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE

⁹¹¹ Azteca (news), ‘Usan internet 40.9 millones de mexicanos (40.9 million Mexicans use the internet)’ Azteca Noticias

<<http://www.aztecanoticias.com.mx/notas/finanzas/154659/inegi-409-millones-de-mexicanos-usan-internet>> accessed 15 May 2013

⁹¹² Lumbreras, Porta and I Hernández Aguado 756

research. The OECD has accurately pointed out that “appropriate educational and reward structures are a necessary component for promoting data access and sharing practices. These considerations apply to those who fund, produce, manage, and use research data.”⁹¹³ Hence, “it is crucial for biobank managers to understand and position the biobank in relation to macropolitical rationalities that are able to drive, facilitate, and fund biobanks and biobank networks in the decades to come.”⁹¹⁴

8.6 Concluding remarks

This chapter investigated influential social attitudes towards biobanking in Mexico by analysing the concepts of solidarity and social justice and their application.

Public awareness is the basis to legitimise biobanking research regulation. Social attitudes have been shown to have a great impact in the current state of biobanking in Mexico. The sustainability of biobanks in the long term depends on public scrutiny and trustworthy biobanking governance. A real ethical public debate will require broad participation. Repetitive situations are at risk of continuing to occur if consideration is not taken.

The notion of long term participatory arrangements and understanding prevailing cultural views among stakeholders and public interaction, is crucial. Solidarity can work to legitimise social accountability as long as the intervention of the law establishes the extent of commitment among those participating. Hence, disadvantaged participants can help others and receive benefits as long as they are legally protected.

In developing countries, such as Mexico, two of the main issues consist: firstly, the great differences among society, even when sharing

⁹¹³ The Organisation for Economic Cooperation and Development OECD, *Principles and Guidelines for Access to Research Data from Public Funding* (Science and technology policy, 2007) 12

⁹¹⁴ Gotweis and Lauss 68

the same culture; such differences involve potential discrimination; vulnerable populations are exposed to the historic risk of being exploited in the name of research. Secondly, the improvement of biobanking legal rules. Even when scientists tend to expect that biobanks' results will always be useful, it is a matter of concern whether the results will recover the cost of the biobank's foundation.

Ethical guidelines need to be implemented in a responsive way, following socioeconomic and cultural contexts. It is necessary for scientific work to be led coherently towards the real needs of the population. The variety of stakeholders from diverse areas and different levels of participation, need to be equally regarded by the authority in terms of social, political involvement and knowledge provision. A lesson for Mexican government to learn is that the potential utility of population biobanking needs to be optimised through coordination policies initially focused on health benefits for the public. The establishment of legal thresholds required by scientists will make knowledge translation effective for the public and other stakeholders. Social commitment needs to be particularly emphasised in terms of public engagement and explicit acknowledgement of the required tools for research translation. Deliberative forums in connexion with social programmes thus offer a possible solution, as a way for the public to be prepared and accept personalised medicine. Political action can be exercised by programs encouraging public and private involvement towards planned results and promoting interaction with the public. All collaborations among stakeholders must be based on ethical principles of equality, benefit sharing and solidarity.

9. Conclusions

The findings from chapters one to eight indicate that legal reform for biobanking in Mexico is necessary. National Biobanks are numerous and these are likely to increase. However, the cooperation between the private and public sector has been led by economical goals, leaving behind the ethical aspects of research. The ethics of clinical trials performed outside public health institutions are not only inconsistent, but optional to comply. The prevalence of economic interest has weakened the expansion of biobanks. In the absence of guidelines, each biobanking institution decides independently. Fragmented legislation tends to be only partially effective, promoting uncertain self-regulatory choices.

- **What are the best ways forward to alleviate legal weaknesses in Mexican biobanking governance?**

Biobanks, currently seen as disperse health issues, are included in the General Health Law. The latter rules, far from being effective at covering biobanks, are the result of constant amending and legislative saturation. A complete legal reform is preferable to continually amending frameworks, which 'somehow' cover the topic. Even if biobanks were considered to be covered by the general health regulations, a special chapter would need to be created. This is still excessively complicated.

A new law on biobanking and personal data is the only suitable solution. The basis for biobanking regulation must be independent rules regarding samples for research are necessary. These could be contained in a statutory legal framework, starting by the definition of a biobank. The implementation of completely new rules will need to look at legal considerations, taking into account the legal actors and budget required. It will be also necessary to evaluate legal competence for responsibilities.

- **Are biobanks effectively regulated in Mexico?**

The case studies presented in Chapter 3 'HapMap' and the 'Cohort profile study' facilitated the assessment of important issues, which evidenced: tensions between academics and scientists, ambiguity regarding representatives and funding bodies and concerning failures in the protection of research participants. The analysis of biobanking regulation was approached not only through academic literature but also by data obtained through fieldwork. The responses of stakeholders also pointed out that existing rules on biobanks were limited, evidencing unfit for purpose regulations.

- **What risks, harms and values are involved?**

The general population deserve to have their rights protected, including the ethical treatment of their samples. Individual participation, far from being encouraged is being discouraged when participants discover that the scientists exaggerated the health benefits the participant would receive. Vulnerable groups are at even greater risk, so they will require even tighter legislation than the general public.

The regulation of tissue should be based on exceptional cases. The scientific value of the research and the type of tissue to be used is the key to determine risk levels. Explanatory biobanking guidelines are essential.

- **What can we learn from the international experience?**

Even when various genomics projects are developed nationally, many of them are the result of international collaboration. Biobanking in Mexico does not always meet the basic ethical standards practiced internationally. The illustrative analysis of chapter six indicated that enforced strict national rules are essential. The law needs to be supported by academic expertise and the international experience

- **What changes need to be implemented in Mexico?**

The administrative controlling procedures for biobanks should be constrained to specific areas, such as protection of participants' rights, including informed consent and data protection. The first step is updating the law and the second, organising the official registration of samples taken outside of the country. This should be carried out by an administrative monitoring system in order to balance research participants' protection and scientific progress. The centralisation of current LRECs in a single responsible institution is also recommended. This will simplify their operation and administration. Law makers need to be careful about creating an excess of bureaucracy.

However, the current legal framework requires not only specificity, but also strong oversight. Provision for guidance through non-binding codes of ethics is not enough. It is necessary to create new authorities due to the degrees of expertise required. Governance institutions need to encourage ethical guidance free from subjectivity; there are human rights to be protected through compulsory rules. A good law protects people, includes sanctions for misconduct and encourages freedom of research. This is only being partially achieved in Mexico because of the absence of oversight procedures guaranteeing that biomedical research is ethical. Research ethics could be supported through the implementation of audit controls by legislative action led by ethics experts. Biobanking regulation needs to be based not only on legal principles such as transparency, clarity, independence and efficiency; effectiveness will depend on concrete rules and corresponding oversight procedures. It is fundamental to encourage a responsible regulatory body that can deal with the challenges of oversight as soon as possible.

- **What are the main challenges when implementing change in Mexico?**

The efficacy of new laws will also depend on coordination of all involved in biobanking. Academic work has not transcended to legislative forums as scientists continue working individually, apparently for the benefit of a vulnerable minority who are unaware of this. Most coordination activities which have been attempted in Mexico have not transcended dissemination of knowledge among experts. It is also the public who primarily need to be involved. The question on how the operation and development of biobanks can be combined with dignity and human rights' protection of participants remains open. Several proposals, including the organisation of colloquiums has originated a purely academic discourse. No real demands from the public for better human rights' protection in Mexico have emerged as a consequence.

The role of coordination is extremely important and needs to be encouraged. For example, institutional coordination can solve internal problems. Legal and medical experts must be listened to when laws are elaborated; otherwise lawyers can limit scientists' valuable research. Stakeholders need more direct communication with policy makers. Incoherence and inconsistency within biobanking have led not only to the hampering of personalised medicine, but also failing coordination (among policymakers, regulators, and researchers). The development of scientific research depends on a structural framework adequate to the demands of public genomics, designed to promote its benefits. None of these actions can be guaranteed if no valid rules are implemented. However, the implementation of new biobanking governance and policy making is only a part of the solution. The rest relies on elements such as public awareness, solidarity and public trust.

- **What is the role of social involvement in Mexican biobanking regulation?**

Fieldwork encouraged social investigation on why even fit for purpose regulations involve the risk of being ineffective when social awareness is absent. Social issues such as public awareness can be resolved through education. The legal situation needs to be seen in context, and most importantly, based on the the culturally unique circumstances of Mexico. A fit for purpose regulation should combine legal and bioethical expertise and focus on limitations related to the special characteristics of Mexico.

Legitimation can be expressed by ethical behaviour motivated by the public recognition of the reliability of governmental institutions. Public trust is essential, since even the most adequate policy is useless if it does not become legitimised by the trust of citizens. The efficacy of implemented legal rules will rely on ethics, governance and the demands of a public who trust them. The way to achieve this is through solidarity involving access to the benefits produced by biobanking, social justice and education.

This thesis is aimed at inspiring further legislative works in Mexico and other Latin American countries, where situation regarding biobanks is quite similar. Participants in general were very interested in reading the completed work. Indeed, one participant, who has partial responsibility for legislating in the area of biobanking at the national level, said to be “keen organising a forum to discuss the outcomes of this study so a law project could be made and presented.”⁹¹⁵

⁹¹⁵ Interview with participant K

References

Legislation

Mexican legislation

Ley General de Salud (The General Health Law) (Mex)

Reglamento de la Ley General de Salud en Investigación Científica (Rules of the General Health Law on Scientific Research)

Principios generales del derecho Su función en el ordenamiento jurídico (TCC)

Acuerdo mediante el cual se comunica que es obligación de los directores de los establecimientos en donde se efectúen investigaciones biomédicas construir una comisión de investigación (Agreement which communicates it is compulsory for managers, where biomedical research is carried out, to organise a research commission)

Acuerdo Presidencial por lo que se crea con carácter permanente la Comisión Nacional de Bioética (Presidential agreement, which creates with permanent character, the National Commission of Bioethics)

Acuerdo que establece los lineamientos que deberán observarse en los establecimientos públicos que presten servicios de atención médica para regular su relación con los fabricantes y distribuidores de medicamentos y otros insumos para la salud, derivada de la promoción de productos o la realización de actividades académicas, de investigación o científicas. (Agreement which establishes the guidelines for public health establishments to regulate relationships with pharmaceutical distributors and makers, derived from product promotion, academic or research activities)

Norma Oficial Mexicana del Expediente Clínico (Official administrative rule for clinical files)

Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios COFEPRIS (Rules of the Federal Commission for the Protection against Sanitary Risk rules)

Reglamento de la Ley general de Salud en Materia de Investigación para la Salud (The Ministry of Health Rules of the General Health Law on Health Research)

Rules of the General Health Law on Scientific Research (Reglamento de la Ley General de Salud en Investigación Científica)

The Mexican Constitution (Mex)

Proyecto de Decreto que reforma los artículos 1, 4, 28 y 89 de la CPEUM (Proposal for decree to amend the articles 1.4. 28 and 89 of the Mexican Constitution) (2002)

Decreto por el cual se adiciona la fracción V al artículo 100 y 461, 317 bis y 317 bis I de la Ley General de Salud (Decree that amends fraction V of Article 100 and 461, 317 bis and 317 bis I of the General Health Law) (2008)

(Parliamentary-Health-Commission) CPpLS and (Parliamentary-Science-and-Technology-Commission) CPdCyT, *Dictamen con proyecto de decreto que adiciona la fracción ix bis al art. tercero, adiciona un título quinto bis y su capítulo único, y el artículo 421 bis, todo a la ley general de salud (Report on the Project for decree that reforms fraction IX bis to article third, title V bis and article 421 bis of the General Health Law) (2003)*

(The-Mexican-Ministry-of-Health) SdS, *Programa de Acción: Investigación en Salud (The Ministry of Health, Action programme on health research) (The Mexican Ministry of Health, 2001)*

Decreto por el que se adiciona la fracción IX Bis al artículo 3o.; se adiciona un Título Quinto Bis y su Capítulo Unico; y el artículo 421 Ter de la Ley General de Salud. (DECREE which adds section IX Bis to article 3, the title "V bis" and its unique chapter and article "421 Ter" of the General Health Law) (2011)

Decreto por el que se reforman y adicionan diversas disposiciones de la Ley General de Salud (Decree amending various dispositions of the General Health Law)

Decreto que incluye el artículo 41 bis y reforma el artículo 98 de la Ley General de Salud (Decree which includes article 41 bis and amends article 98 of the General health law) (2011)

International treaties are hierarchically over the federal laws and under the federal constitution (Tratados internacionales se ubican jerárquicamente por encima de las leyes federales y en un segundo plano respecto de la constitución federal) 903483 2810 Pleno Novena Época Apéndice 2000 Tomo I, Const, PR SCJN, P 1958 (Suprema Corte de Justicia de la Nación (Supreme Court of Justice of the Nation) SCJN)

Cardona FP, 'Iniciativa de ley sobre la investigación, el fomento, el desarrollo, control y regulación del genoma humano (Law project on research, encouragement, development, control and regulation of the human genome)'

<http://www.diputados.gob.mx/sia/coord/OBRA_LEG_LIX/obraleg_lix/inic/htm/02dic03_3.htm>

Cardona FP, *Iniciativa de ley sobre la investigación, el fomento, el desarrollo, control y regulación del genoma humano (Law project on research, encouragement, development, control and regulation of the human genome) (2001)*

Carroll A, *Constitutional and Administrative law* (5 edn, Longman 2010)

Wistano M, 'Explanatory preamble for reforms to the General Health regarding the human genome (Exposición de motivos que reforma la ley general de salud, en materia de genoma humano)' Partido Acción Nacional National Action Party PAN

<http://sil.gobernacion.gob.mx/Archivos/Documentos/2001/12/asun_1025_20011214_838707.pdf>

International legislation

The Belgium Law regarding the procurement and use of human body material destined for human medical applications or for scientific research purposes

Código Sanitario de los Estados Unidos Mexicanos (The Health Code of Mexico)

'Federal Regulations for the Control of Organs, Tissues and Cadavers of Human Beings' ('Reglamento Federal para la Disposición de Órganos, Tejidos y Cadáveres de Seres Humanos')

Hungarian Parliamentary, Act No XXI on the protection of human genetic data and the regulation of human genetic studies, research and biobanks

The International Covenant on Economic, Social and Cultural Rights

Ley Federal de Protección de Datos Personales en Posesión de Particulares (Federal Law on Protection of Personal Data Held by Individuals)

Ley reguladora de la base de datos genéticos para el estado de Chihuahua (Rules for genetic databases for the state of Chihuahua) (Mex)

Lithuanian Law on Ethics of Biomedical Research

Council & Parliament Directive 95/46/EC, 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

The Universal Declaration on the Human Genome and Human Rights

German Criminal Code 'Strafgesetzbuch', StGB.

Estonian Human Genes Research Act RT I 2000

Icelandic Act on Biobanks no 110/2000

The Swedish Biobank Act

Essentially Yours: The Protection of Human Genetic Information in Australia (ALRC Report 96, 2003)

Swiss Federal Law Involving Human Subject Bundesgesetz über die Forschung am Menschenv (Humanforschungsgesetz, HFG)

UNESCO International Declaration on Human Genetic Data

Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

The French Public Health Code

UK Human Tissue Act

Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products

Recommendation of the Committee of Ministers to member states on research on biological materials of human origin

Spanish Act 14/2007, on Biomedical Research

Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

Hungarian Parliamentary, Act No XXI on the protection of human genetic data and the regulation of human genetic studies, research and biobanks

UK Regulatory Enforcement and Sanctions Act

Council Recommendation on Human Biobanks and Genetic Research Databases

French Law N° 2011-814 on Bioethics, JORF n°0157

Principios generales del derecho Su funcion en el ordenamiento juridico (TCC)

Acuerdo mediante el cual se comunica que es obligación de los directores de los establecimientos en donde se efectúen investigaciones biomédicas construir una comisión de investigación (Agreement which communicates it is compulsory for managers, where biomedical research is carried out, to organise a research commission)

Acuerdo Presidencial por lo que se crea con carácter permanente la Comisión Nacional de Bioética (Presidential agreement, which creates with permanent character, the National Commission of Bioethics)

Acuerdo que establece los lineamientos que deberán observarse en los establecimientos públicos que presten servicios de atención médica para regular su relación con los fabricantes y distribuidores de medicamentos y otros insumos para la salud, derivada de la promoción de productos o la realización de actividades académicas, de investigación o científicas. (Agreement which establishes the guidelines for public health establishments to regulate relationships with pharmaceutical distributors and makers, derived from product promotion, academic or research activities)

Association for Molecular Pathology v. Myriad Genetics Association for Molecular Pathology Association for Molecular Pathology, et al v Myriad Genetics, Inc, et al (The United States Court of Appeals for the Federal Circuit No. 12–398.)

The Belgium Law regarding the procurement and use of human body material destined for human medical applications or for scientific research purposes

Código Sanitario de los Estados Unidos Mexicanos (The Health Code of Mexico)

'Federal Regulations for the Control of Organs, Tissues and Cadavers of Human Beings' ('Reglamento Federal para la Disposición de Órganos, Tejidos y Cadáveres de Seres Humanos')

Hungarian Parliamentary, Act No XXI on the protection of human genetic data and the regulation of human genetic studies, research and biobanks

The International Covenant on Economic, Social and Cultural Rights

Ley Federal de Protección de Datos Personales en Posesión de Particulares (Federal Law on Protection of Personal Data Held by Individuals)

Ley reguladora de la base de datos genéticos para el estado de Chihuahua (Rules for genetic databases for the state of Chihuahua) (Mex)

Lithuanian Law on Ethics of Biomedical Research

The Mexican Constitution (Mex)

Norma Oficial Mexicana del Expediente Clínico (Official administrative rule for clinical files)

Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitarios COFEPRIS (Rules of the Federal Commission for the Protection against Sanitary Risk rules)

Reglamento de la Ley general de Salud en Materia de Investigación para la Salud (The Ministry of Health Rules of the General Health Law on Health Research)

Rules of the General Health Law on Scientific Research (Reglamento de la Ley General de Salud en Investigación Científica)

The Universal Declaration on Bioethics and Human Rights

The Mexican Constitution

Ley General de Salud (The General Health Law) (Mex)

Reglamento de la Ley General de Salud en Investigación Científica (Rules of the General Health Law on Scientific Research)

The German federal data protection law ('Bundesdatenschutzgesetz', BDSG)

Moore v. Regents of the University of California John Moore, Plaintiff and Appellant, v The Regents of the University of California et al, Defendants and Respondents (Supreme Court of California)

Council & Parliament Directive 95/46/EC, 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data

The Universal Declaration on the Human Genome and Human Rights

German Criminal Code 'Strafgesetzbuch', StGB.

Estonian Human Genes Research Act RT I 2000

Icelandic Act on Biobanks no 110/2000

International treaties are hierarchically over the federal laws and under the federal constitution (Tratados internacionales se ubican jerárquicamente por encima de las leyes federales y en un segundo plano respecto de la constitución federal) 903483

2810 Pleno Novena Época Apéndice 2000 Tomo I, Const, PR SCJN, P 1958 (Suprema Corte de Justicia de la Nación (Supreme Court of Justice of the Nation) SCJN)

Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member

States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
Proyecto de Decreto que reforma los artículos 1, 4, 28 y 89 de la CPEUM (Proposal for decree to amend the articles 1.4. 28 and 89 of the Mexican Constitution) (2002)
 The Swedish Biobank Act
Essentially Yours: The Protection of Human Genetic Information in Australia (ALRC Report 96, 2003)
 Swiss Federal Law Involving Human Subject Bundesgesetz über die Forschung am Menschenv (Humanforschungsgesetz, HFG)
 UNESCO International Declaration on Human Genetic Data
 Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
 The French Public Health Code
 UK Human Tissue Act
 Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products
 Recommendation of the Committee of Ministers to member states on research on biological materials of human origin
 Spanish Act 14/2007, on Biomedical Research
 Hungarian Parliamentary, Act No XXI on the protection of human genetic data and the regulation of human genetic studies, research and biobanks
 UK Regulatory Enforcement and Sanctions Act
 Council Recommendation on Human Biobanks and Genetic Research Databases
Decreto por el que se adiciona la fracción IX Bis al artículo 3o.; se adiciona un Título Quinto Bis y su Capítulo Unico; y el artículo 421 Ter de la Ley General de Salud. (DECREE which adds section IX Bis to article 3, the title "V bis" and its unique chapter and article "421 Ter" of the General Health Law) (2011)
 Decreto por el que se reforman y adicionan diversas disposiciones de la Ley General de Salud (Decree amending various dispositions of the General Health Law)
Decreto que incluye el artículo 41 bis y reforma el artículo 98 de la Ley General de Salud (Decree which includes article 41 bis and amends article 98 of the General health law) (2011)
 French Law N° 2011-814 on Bioethics, JORF n°0157
 ‘Crean Banco Nacional de Cerebros’ *El Universal* (Mexico City, 21 September 2012) <<http://www.eluniversal.com.mx/articulos/73647.html>> accessed 20 October 2012
 (ISBER) ISfBaER, ‘Best practices for repositories: collection, storage, retrieval and distribution of biological materials for research’ (2012) 10 Biopreservation and biobanking
 (news) A, ‘Usan internet 40.9 millones de mexicanos (40.9 million Mexicans use the internet)’ *Azteca Noticias* <<http://www.aztecanoticias.com.mx/notas/finanzas/154659/inegi-409-millones-de-mexicanos-usan-internet>> accessed 15 May 2013
 (Parliamentary-Health-Commission) CPpLS and (Parliamentary-Science-and-Technology-Commission) CPdCyT, *Dictamen con proyecto de decreto que adiciona la fracción ix bis al art. tercero, adiciona un título quinto bis y su capítulo unico, y el artículo 421 bis, todo a la ley general de salud (Report on the Project for decree that reforms fraction IX bis to article third, title V bis and article 421 bis of the General Health Law)* (2003)

- (The-Mexican-Ministry-of-Health) SdS, *Programa de Acción: Investigación en Salud* (*The Ministry of Health, Action programme on health research*) (The Mexican Ministry of Health, 2001)
- Ackerman B, 'Why Dialogue' (1989) 86 *Jof Philosophy*,
- Alexy R, 'On Necessary Relations Between Law and Morality' (2007) 2 *Ratio Juris*
- Aluja M and Birke A (eds), *El papel de la Ética en la investigación científica y la educación superior. (The role of ethics in Scientific research ethics and high education)* (Fondo de Cultura Económica 2004)
- Andorno R, 'Population bio-banks: a juridical analysis based on Icelandic and Estonian experience' (2006) 25 *Rev Derecho Genoma Hum*
- Aréchiga H and others, 'El proyecto del genoma humano: perspectivas de la medicina genómica (The human genome project, perspectives from genomic medicine)' (2000) 43 *Rev Fac Med UNAM*
- Arellano-Mendez A, 'La regulacion juridica de la informacion genetica (the legal regulation of genetic information)' *Derecho comparado de la informacion* <<http://www.juridicas.unam.mx/publica/rev/decoinc/cont/6/art/art2.htm>> accessed 12 February 2013
- Austin M, Harding S and McElroy C, 'Monitoring ethical, legal, and social issues in developing population genetic databases' (2003) 5 *Genet Med*
- Banerji S and others, 'Sequence analysis of mutations and translocations across breast cancer subtypes' (2012) 486 *Nature*
- Barahona A and Ayala F, 'The emergence and development of genetics in Mexico' (2005) 6 *Perspective Nature Reviews Genetics*
- Baudouin L, 'The influence of the Code Napoleon' (1958) 33 *Tul L Rev*
- Beauchamp T and Childress J, *Principles of Biomedical Ethics* (Seventh edn, Oxford University Press 2012)
- Becerril A, 'Aprueba el Senado sanciones a quienes trasladen tejido humano fuera de México' *La Jornada* <<http://www.jornada.unam.mx/2008/03/28/index.php?section=sociedad&article=046n1soc>> accessed 28 March 2008
- Beck U, *Risk society: towards a new modernity* (SAGE Publications 2004)
- Beltrán CL (ed), *Genes (&) Mestizos: Genómica y Raza en la biomedicina Mexicana* (Ficticia Editorial / UNAM 2011)
- Beyleveld D, Townend D and Wright J (eds), *Research Ethics Committees, Data Protection and Medical Research in European Countries* (Aldershot Ashgate 2005)
- Bhardwaj M, 'Rich databases and poor people: Opportunities for developing countries' (2004) 8 *TRAMES*
- Bioethics-expert-at-a-public-legal-research-institution-Participant:N, *PhD Thesis fieldwork* (2012)
- Bioética Cnd, 'Comités Hospitalarios de Bioética (Bioethics Hospital Committees)' (*Comisión Nacional de Bioética (National Bioethics Commission)*, 2 August 2013) <<http://www.conbioetica-mexico.salud.gob.mx/interior/registrocomites/chb.html>> accessed 3 September 2013
- Birmontiene T, 'Changes in the Lithuanian health law and the influence of the Netherlands Civil Code' (2002) 9 *European Journal of Health Law*
- Bister M, 'Discovering informed consent: a case study on the practices of informed consent to tissue donation in Austria' in Lenk C and others (eds), *Human tissue research, a European perspective on the ethical and legal challenges* (Oxford University Press 2011)

Boggio A and others, *Comparing guidelines on biobanks: emerging consensus and unresolved controversies* (The Réseau universitaire international de Genève—Geneva International Academic Network (RUIG-GIAN))

Human Genetic Databases: Towards a Global Ethical Framework, 2005)

Brazier M and Cave E, *Medicine, patients and the law* (Penguin Books 2011)

Brena I, 'Biobanks, a subject pending upon legislation' (2010) 129 *Boletín Mexicano de Derecho Comparado*

Brena I, 'Biobanks in Mexico, legal aspects (Biobancos en Mexico, Aspectos Juridicos)' Coloquio Internacional Muestras Biologicas y Biobancos para la Investigacion Biomedica (International Colloquium Biological Samples and Biobanks for Biomedical Research), Mexico City, 4 July 2008

<<http://juridicas.unam.mx/viv/activ.htm?e=122&t=14&m=884&p=384&mx=1>>

—, 'Privacidad y confidencialidad de los datos genéticos (privacy and confidentiality within genetic data)' *Boletín Mexicano de Derecho comparado*

<<http://biblio.juridicas.unam.mx/revista/pdf/DerechoComparado/123.5/cnt/cnt7.pdf>

> accessed 06 May 2013

—, 'El negocio de los genes (The business of genes)' *Guía internacional de la Bioética* <<http://www.bioeticas.org/bio.php?articulo260>> accessed 20 December 2011

—, 'La perspectiva latinoamericana en la Declaración Universal de Bioética y Derechos Humanos (The Latin American perspective in the Universal Bioethics and human rights declaration)' in Brena I and Teboul G (eds), *Hacia un instrumento regional interamericano sobre la bioética, experiencias y expectativas (Towards an inter-American regional instrument on bioethics, experiences and expectations)*, vol 501 (UNAM IJ 2009) <<http://biblio.juridicas.unam.mx/libros/6/2673/2.pdf>>

—, 'Biobanks, a subject pending upon legislation' (2010) 129 *Boletín Mexicano de Derecho Comparado*

BRTF, *Principles of good regulation* (Better Regulation Task Force 2003)

Buchanan A and others, 'Pharmacogenetics: ethical issues and policy options' (2002) 12 *Kennedy Inst Ethics J*

Budin-Ljøsne I and others, 'ELSI challenges and strategies of national biobank infrastructures' (2012) 21 *Norsk Epidemiologi*

Bunton R and Peterson A (eds), *Genetic governance: health, risk and ethics in the biotech era* (Routledge 2005)

Burgess M, 'Public consultation in ethics, an experiment in representative ethics' (2004) 1 *Journal of Bioethical Enquiry*

Butler S, 'A dialectic of cooperation and competition: solidarity and universal health care provision' (2012) 26 *Bioethics*

Camacho E, 'Proteger datos atraerá capital foráneo: IFAI (Data protection will attract foreign capital: IFAI)' *El Universal*

<<http://www.eluniversal.com.mx/finanzas/93225.html>> accessed 22 February 2012

Cambon-Thomsen A, Rial-Sebbag E and Knoppers B, 'Trends in ethical and legal frameworks for the use of human biobanks' (2007) 30 *Eur Respir J*

CANIFARMA NCotPICNdIIF, *Códigos de la industria farmacéutica establecida en México (Codes of the Pharmaceutical Industry Established in Mexico)* (Consejo de Ética y Transparencia de la Industria Farmacéutica 2009)

Capps B, 'The public interest, public goods and third party access to UK biobank' (2012) 5 *Public Health Ethics*

- Carbonell M, 'El desafío de la salud (The health challenge)' *El Universal* (Mexico City, 17 May 2012) Opinión
<<http://www.eluniversalmas.com.mx/editoriales/2012/05/58536.php>>
- Cárdenas HM and Garcia SL, 'Inicio y fin de la vida: aspectos biojurídicos (the beginning and end of life: legal aspects)' (2011) 22 *Revista de Bioética y Derecho*
- Cardona FP, 'Iniciativa de ley sobre la investigación, el fomento, el desarrollo, control y regulación del genoma humano (Law project on research, encouragement, development, control and regulation of the human genome)'
<http://www.diputados.gob.mx/sia/coord/OBRA_LEG_LIX/obraleg_lix/inic/htm/02dic03_3.htm>
- Cardona FP, *Iniciativa de ley sobre la investigación, el fomento, el desarrollo, control y regulación del genoma humano (Law project on research, encouragement, development, control and regulation of the human genome)* (2001)
- Carroll A, *Constitutional and Administrative law* (5 edn, Longman 2010)
- Casabona CR and Simons J (eds), *Latin banks, study on the legal and social implications of creating banks of biological material for biomedical research*, vol 3 (Bruylant 2011)
- Casassa M, Sharma V and Pearson S, *EnCoRe: Dynamic Consent, Policy Enforcement and Accountable Information Sharing within and across Organisations* (HP Laboratories 2012)
- Castellanos M, 'Clinical Research in Mexico: An Overview. The conduct of clinical trials in developing countries has received increased attention recently. The outlook in Mexico' *Estern Medical, Clinical Research Organization and Consulting Company for Global Biotech's Pharmaceutical and Medical Device Companies*
<<http://www.esternmedical.com/information/article06.php>>
- Caulfield T and Kaye J, 'Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas' (2009) 10 *Medical Law International*
- CETIFARMA, 'XXV Sesión Grupo Compliance CANIFARMA ' (XXV Sesión Grupo Compliance, Mexico City, July 23 2012)
- , 'Consejo de ética y transparencia de la industria farmacéutica (CETIFARMA)' (CETIFARMA, 2013) <<http://www.cetifarma.org.mx/>> accessed 12 May 2013
- Chadwick R and Berg K, 'Solidarity and equity: new ethical frameworks for genetic databases' (2001) 2 *Nature Reviews Genetics*
- Charlesworth A, 'Implementing the European Data Protection Directive 1995 in UK Law: The Data Protection Act 1998 ' (1999) 16 *Government Information Quarterly*
- , 'Implementing the European Data Protection Directive 1995 in UK Law: The Data Protection Act 1998' (16) 1999 *Government Information Quarterly*
- Cho M, 'Understanding Incidental Findings in the Context of Genetics and Genomics' (2008) 36 *J Law Med Ethics*
- CIHR CifHR, 'About knowledge translation and commercialisation ' *Canadian Institutes of Health Research* <<http://www.cihr-irsc.gc.ca/e/29418.html>> accessed 15 April 2013
- CIOMS CfIOOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS, 2002)
- CNB CNdBNBC, 'Consentimiento informado ' <http://www.conbioetica-mexicosaludgobmx/> <http://www.conbioetica-mexico.salud.gob.mx/interior/temasgeneral/consentimiento_informado.html> accessed 2 October 2012
- CNB) TNBCCNdB, *National guidelines for the integracion and operation of the research ethics committees (Guía Nacional para la integración y el funcionamiento de los comités de ética en investigación)* (The Ministry of Health (Secretaría de Salud), 2010)

- COFEPRIS CFpIPcRSFctpahr, 'Registro de comités (Committees' registration)' (COFEPRIS, 4 December 2013) <<http://www.cofepris.gob.mx/AS/Paginas/Servicios%20de%20Salud/Comit%C3%A9-de-%C3%A9tica.aspx>> accessed 15 August 2012
- Comisión Mexicana de Defensa y Promoción de los Derechos Humanos, 'Estudio sobre la actual legislación en vigor (Study on the currently enforced legislation)' El Marco Legal Internacional de los Derechos Humanos y la Normatividad Interna, Mexico City, 2001 <<http://cmdpdh.org/publicaciones-pdf/cmdpdh-incorporacion-del-derecho-internacional-de-los-derechos-humanos-al-sistema-juridico-mexicano.pdf>> accessed 13 April 2014
- Comisión Nacional de Bioética (The National Commission of Bioethics), *Reporte para el proyecto "Sistemas de regulación ética de la investigación biomédica en América Latina y Europa: Análisis comparativo de su pertinencia y aplicación para la protección de los sujetos de investigación - EULABOR"* (Report for the Project EULABOR Latin American and European Ethical Regulation Systems of Biomedical Research: Comparative Analysis of their Pertinence and Application for Human Subjects Protection (CNB, 2006)
- Commin V, 'Legal issues surrounding French research-focused biobanks' in Lenk C and others (eds), *Human Tissue Research A European Perspective on the Ethical and Legal Challenges* (Oxford University Press 2011)
- Committee HE, *Statement on benefit-sharing* (2000)
- CONAPO MPNC, 'Consejo Nacional de Poblacion CONAPO' (SEGOB (Mexican Ministry of Governance), 2009) <<http://www.conapo.gob.mx/>> accessed 28 May 2011
- Consultation OLR, *Summary of the UK Biobank Consultation on the Ethics & Governance Framework* (UK Biobank Ethics & Governance Framework, 2003)
- Council MR, *Principles for access to, and use of, MRC funded research data* (MRC policy on research data-sharing, 2011)
- CR Sunstein, *Laws of fear, beyond the precautionary principle* (Cambridge University Press 2005)
- Crespi R, 'Biotechnology patents and morality' (1997) 15 Trends in Biotechnology
- Dalton R, 'Tribe blasts 'exploitation' of blood samples' (2002) 420 Nature
- Datap-protection-expert-at-a-public-research-institute-Participant:J, *PhD Thesis fieldwork* (2012)
- Dörr B, 'Research with human biological material and personal data in biobanks: legal and regulatory framework in Switzerland' in Lenk C and others (eds), *Human Tissue Research A European Perspective on the Ethical and Legal Challenges* (Oxford University Press 2011)
- Dubey A and others, 'Understanding the Essentials of Pharmacogenomics- The Potential Implications for the Future Pharmacotherapy' (2008) 2 Journal of Clinical and Diagnostic
- Ducournau P and Strand R, 'Trust, Distrust and Co-Production: The Relationship between Research Biobanks and Donors ' in Solbakk JH, Holm S and Hofmann. B (eds), *The Ethics of research biobanking* (Springer-Verlag Solbakk. 2009)
- Ducournau P and Strand R, 'Trust, Distrust and Co-Production: The Relationship between Research Biobanks and Donors ' in Solbakk J, Holm S and Hofmann B (eds), *The Ethics of research biobanking* (Springer-Verlag Solbakk 2009)
- Dulitzky A, 'Aplicación de las Normas Internacionales en Derecho Interno (Application of the international norms in the internal law)' (Memoria del Foro: El marco legal internacional de derechos humanos y la normatividad interna, Mexico City, August 2000)

- Eiseman E and Haga S, *Handbook of Human Tissue Sources A National Resource of Human Tissue Samples* (RAND Monograph Report, 1999)
- Elger B and Caplan A, 'Consent and anonymization in research involving biobanks: Differing terms and norms present serious barriers to an international framework' (2006) 7 EMBO Rep
- Eriksson S and Helgesson G, 'Potential harms, anonymization, and the right to withdraw consent to biobank research' (2005) 13 Eur J Hum Genet
- Escudero D, *Encephalic death in Ibero-America, preliminar inform (Muerte Encefálica en Iberoamérica, informe preliminar)* (Coordinación de Transplantes, Hospital Universitario Central de Asturias, 2007)
- Ethical-adviser-at-an-ethics-public-advisory-institution-Participant:L, *PhD Thesis fieldwork* (2012)
- European Commission D-GfRal, *Biobanks for Europe, A challenge for governance* (2012)
- Expert-on-Bioethics-Philosophy-and-Law-at-a-Public-university-Participant:O, *PhD Thesis Fieldwork* (2012)
- Galán J, 'Condiciona PAN su respaldo a legislación sobre el genoma humano (PAN political party conditions support to human genome legislation)' *La Jornada* (Mexico City, 18 May 2002)
<<http://www.jornada.unam.mx/2002/05/18/041n2soc.php?origen=soc-jus.html>>
- Garduño-Espinosa J and others, 'Local research ethics committees of the Mexican Institute of Social Security: results of a national survey' (2004) 118 Public Health
- Gibbons S, 'Regulating biobanks: A twelve point typological tool' (2009) 17 MLR
- Gibbons S and Kaye J, 'Governing genetic databases: collection, storage and use' (2007) 18 Kings Law J
- Godoy E, 'El negocio de los genes. Ante la proliferación de biobancos, surge el interrogante de cómo se maneja la información de los donantes (The bussiness of genes. Towards biobanks' proliferation, the question of how donors' data is managed has emerged)' *Poder 360° Electronic magazine* <<http://www.degerencia.com/>> accessed 30 March 2010
- González M, *Nuevo Diccionario Jurídico Mexicano (The new Mexican legal dictionary)* (IIJ, Porrúa-UNAM 2009)
- González M, 'Ethnic minorities in Mexico, United States and Canada: a comparative study of coexistence' (2002) 5 Diálogos Latinoamericanos
- Gorodesky C, 'Biobanks and Umbilical Cord Banks: Common and Specific Aspects Related to Research. Social, Ethical and Legal Implications. Biobancos y bancos de celulas de cordon umbilical: aspectos comunes y especificos relativos a la investigacion en las implicaciones sociales, eticas y de regulacion.' (International Colloquium Biological Samples and Biobanks for Biomedical Research Current State and Future Challenges (Coloquio Internacional Muestras Biologicas y Biobancos para Investigacion Biomedica Estado actual y retos de futuro), Mexico City, 4 July 2008)
- Gottweis H and Zatloukal K, 'Biobank governance: trends and perspectives' (2007) 74 Pathobiology
- Gotweis H and Lauss G, 'Biobank governance: heterogeneous modes of ordering and democratization' (2012) 3 J Community Genet
- Governance) SMO, 'Sistema de infomación legislativa SIL (System of legislative data SIL)'
<<http://sil.gobernacion.gob.mx/Numeralia/Iniciativas/resultadosNumeraliaIniciativas.php?SID=&Serial=a0202d11e1b71fd95dbc40d37ad3c2ae&Reg=19&Origen=IL>>

- Guadarrama MM and others, 'Bancos de tumores (tumour banks)' (2011) 49 *Patologia*
- Haga S, Khoury M and Burke W, 'Genomic profiling to promote a healthy lifestyle: not ready for prime time' (2003) 34 *Nat Genet*
- Hamlett P, 'Technology theory and deliberative democracy' (2003) 28 *Science Technology and Human Values*
- Hansson M, *The Use of Human Biobanks – Ethical, Social, Economical and Legal Aspects* (Research Program Ethics in Biomedicine, Uppsala University, 2001)
- Hansson M, 'Building on relationships of trust in biobank research' (2005) 31 *J Med Ethics*
- Hansson M and others, 'Should donors be allowed to give broad consent to future biobank research?' [2006] 7 *Lancet Oncol*
- HapMap-Project I, 'The International HapMap Project: Ethical, Social, and Cultural Issues' (*International HapMap Project*)
<<http://hapmap.ncbi.nlm.nih.gov/downloads/presentations/HapMapELSI.en.ppt>>
- Hardy B-J and others, 'The next steps for genomic medicine: challenges and opportunities for the developing world' (2008) 9 *Nature Reviews Genetics*
- Hardy B and others (eds), *The Next Steps for Genomic Medicine: Challenges and Opportunities for the Developing World*, vol 9 (Nature Reviews Genetics 2012)
- Harmon A, 'Havasupai Case Highlights Risks in DNA Research' *The New York Times* (New York, 21 April 2010)
<http://www.nytimes.com/2010/04/22/us/22dnaside.html?_r=0> accessed 21 April 2010
- , 'Indian Tribe Wins Fight to Limit Research of Its DNA' *New York Times* (New York, 21 April 2010)
<http://www.nytimes.com/2010/04/22/us/22dna.html?pagewanted=all&_r=0>
- Hawkins AK and O'Doherty K, 'Biobank governance: a lesson in trust' (2010) 29 *New genetics and Society*
- Helgesson G and Johnsson L, 'The right to withdraw consent to research on biobank samples' (2005) 8 *Medicine, Health Care and Philosophy*
- Henderson M, *50 genetics ideas you really need to know* (Quercus Publishing Plc 2008)
- Hewitt R, 'Biobanking: the foundation of personalized medicine' (2011) 23 *Current Opinion in Oncology*
- Heyd D, 'Justice and solidarity: The contractarian case against global justice' (2007) 38 *Journal of Social Philosophy*
- HGC HGC, *Inside Information: Balancing Interests in the Use of Personal Genetic Data*. (A report by the Human Genetics Commission, 2002)
- Hidalgo A and others, 'Proyecto Mapa Genómico de los Mexicanos (Project Genomic Map of the Mexicans)' *Ciencia y Desarrollo (Science and Development)* (Mexico, January, 2006)
- Hunt J and Wallace C, 'Governing the body: Examining EU regulatory developments in Relation to substances of human origin' (2005) 27 *Journal of social welfare and family law*
- IBMT, 'Innovative Technologien für die Biomedizin' (*Fraunhofer-Institut für Biomedizinische Technik*, , 2006) <<http://www.ibmt.fraunhofer.de/>> accessed 13 March 2012
- IGC TIGC, 'The International Genomics Consortium' (*IGC*, 2009)
<<http://www.intgen.org/>> accessed 19 December 2009

- IMSS MIOSS, 'Coordinación de investigación en salud (National Council for Health Research)' (IMSS) <<http://www.imss.gob.mx/profesionales-salud/investigacion/etica>> accessed 10 October 2013
- , *Manual de Investigación Médica en el IMSS (IMSS Medical Research Handbook)* (IMSS Internal handbook, 1999)
- INMEGEN, *Reglas Internas de Operación del Comité de Información del Instituto Nacional de Medicina Genómica* (INMEGEN 2006)
- INMEGEN TNOGM, *Consortio Promotor del Instituto de Medicina Genómica, Un paso más hacia el establecimiento del INMEGEN (One more step towards the establishment of INMEGEN)* (INMEGEN Inform of activities, 2003-2004 2004)
- Institute B, 'Mexico-US genomics partnership launches second phase' <https://www.broadinstitute.org/news/5324>
- Institute NHGR, 'International HapMap Project' (2012) <<https://www.genome.gov/>>
- J B, *Doing your research project. A guide for first time researchers in education, health and social science* (Open University Press 2009)
- Jaff H, 'The Right to Health in Mexico: Seguro Popular' (*World Poverty and Human Rights Online: Supporting the Right to Life, Liberty, and Development*, 2010) <<http://wphr.org/blog/2010/03/27/the-right-to-health-in-mexico-seguro-popular>> accessed 19 March 2012
- Jasanoff S, *Designs on nature. Science and democracy in Europe and the United States* (Princeton University Press 2005)
- Jennings B and Dawson A, 'Solidarity in the moral imagination of bioethics' [2015] Hastings Center report
- Jimenez-Sanchez G, 'Developing a Platform for Genomic Medicine in Mexico' (2003) 300 Science
- Jiménez-Sánchez G, Frenk J and Soberón G, 'El poder transformador de la genómica en la economía global (The transforming power of genomics in the global economy)' Este país, tendencias y opiniones <<http://estepais.com/site/?p=34614>> accessed 3 November 2011
- Jimenez-Sanchez G and others, 'Genomic medicine in Mexico: Initial steps and the road ahead' (2008) 18 Genome Research
- Johnsson L, 'Trust in biobank research. Meaning and moral significance' (PhD Thesis, Uppsala Universitet 2013)
- Jonsson L and Landegreb U, *Storing and using biobanks for research* (Report I from the Research Project The Use of Human Biobanks Ethical, Social, Economical and Legal Aspects, Uppsala University, 2003)
- Kahn J, 'Human Genes and Human Rights' (2006) 96 American Journal of Public Health
- Kant I, *Groundwork of the Metaphysics of Morals* (Gregor M and J Timmermann eds, Gregor M tr, Cambridge University Press 2012)
- Katsanis S, Javitt G and Hudson K, 'A Case Study of Personalized Medicine' (2008) 320 Science
- Kaufman D and others, 'Public opinion about the importance of privacy in biobank research' (2009) 85 The American Journal of Human Genetics
- Kaye J, 'Embedding biobanks as tools for personalised medicine' (2012) 21 Norsk Epidemiologi
- Kaye J and others, *Governing Biobanks, Understanding the Interplay between Law and Practice* (Hart Publishing 2012)
- Keiger D, 'Immortal Cells, Enduring Issues' Johns Hopkins Magazine <<http://archive.magazine.jhu.edu/2010/06/immortal-cells-enduring-issues/>> accessed 2 June 2012

- Kettis-Lindblad A and others, 'Genetic research and donation of tissue samples to biobanks. What do potential sample donors in the Swedish general public think?' (2006) 16 *European Journal of Public Health*
- Khoury M and others, 'Challenges in communicating genetics: a public health approach' (2000) 2 *Genet Med*
- Knoppers B and others, 'Children and incompetent adults: consent and safeguards' (2002) 3 *Nature Reviews Genetics*
- Kosseim P, Letendre M and Knoppers B, 'Protection genetic information: A comparison of normative approaches' [2004] *GenEdit*
- Kuri-Morales P and others, 'The prevalence of chronic diseases and major disease risk factors at different ages among 150 000 men and women living in Mexico City: cross-sectional analyses of a prospective study' (2009) 9 *BMC Public Health*
- Lamas E and others, 'A comparative analysis of biomedical research ethics regulation systems in Europe and Latin America with regard to the protection of human subjects' (2010) 36 *J Med Ethics*
- Lara C and Arellano A, 'Farmacogenómica: Un cambio para el sistema de salud (Pharmacogenomics: a change for the health system)' *Forbes, Mexico* <<http://www.forbes.com.mx/sites/farmacogenomica-un-cambio-para-el-sistema-de-salud/>> accessed 3 November 2013
- Laurie G, 'Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of the law' (2011) 130 *Hum Genet*
- Laurie G and T Caulfield, *Biobanks Information Paper* (National Health and Medical Research Council, 2010)
- Legal-adviser-at-an-ethics-public-advisory-institution-Participant:H, *PhD Thesis fieldwork* (2012)
- Legal-researcher-at-a-public-research-institution-Participant:C, *PhD Thesis fieldwork* (2012)
- Legal-researcher-at-a-public-research-institution-Participant:F, *PhD Thesis Fieldwork*
- Ling T and Raven A, 'Pharmacogenetics and uncertainty: implications for policy makers' (2006) 37 *Studies in History and Philosophy of Science*
- Lipset S, *Political man, the social basis of politics* (Doubleday NY ed, 1960)
- Lockart N, 'Ethical and Legal Implications of Return of Research Results to Participants in Biospecimen Studies' (ELSI Congress, South Carolina, April 2011)
- Luengas I, Feinholz D and G Soberón, 'The National Bioethics Commission, understanding and remit (Comisión Nacional de Bioética. Su entender, su quéhacer)' (2007) 1 *Debate bioético*
- Lumbreras B, Porta M and I Hernández Aguado, 'Assessing the social meaning, value and implications of research in genomics' (2007) 61 *Research in Genomics*
- Luna-Zaragoza D and Reyes-Frías ML, 'Donation transplants and tissue banking in Mexico' (2001) 2 *Kluwer Academic Publishers*
- Lyll C, Papaioannou T and Smith J (eds), *The Limits to Governance: The Challenge of Policy-Making for the New Life* (Ashgate 2009)
- M Carbonell, 'La reforma constitucional en materia de derechos humanos: principales novedades (The constitutional reform on the subject of human rights: main novelties)' [miguelcarbonellcom](http://www.miguelcarbonell.com/articulos/novedades.shtml) <<http://www.miguelcarbonell.com/articulos/novedades.shtml>>
- M Muñoz de Alba Medrano, 'La Ley General de Salud: La Biotecnología en la normatividad Mexicana ¿Podemos estar tranquilos? (The General Health Law: Biotechnology in the Mexican normativity, can we stay calm?)' (1998) 96 *Anuario Juridico Nueva Serie, IJ UNAM*

- Mac-Gregor EF, *Interpretación Jurisprudencial a la Jerarquía de los Tratados Internacionales en el Derecho Interno (Jurisprudential interpretation on the hierarchy of the international treaties in internal law)* (UNAM-III 1999)
- Macklin R, 'Splitting Embryos on the slippery slope: Ethics and public policy' (1994) 4 Kennedy Institute of Ethics Journal
- , 'Dignity is a useless concept, it means no more than respect for persons or their autonomy' (2003) 327 BMJ
- Manasco P, 'Ethical and legal aspects of applied genomic technologies: practical solutions' (2005) 5 Current Molecular Medicine
- Manson N and O'Neill O, *Rethink informed consent bioethics* (Cambridge University Press 2007)
- Marcella Favale and Aurora Plomer, 'Fundamental disjunctions in the EU legal order on human tissue, cells and advanced regenerative therapies' (2009) 16 Maastricht journal of European and comparative law
- Marodin G and others, 'Biobanking for health research in Brazil: present challenges and future directions' (2012) 31 Rev Panam Salud Publica
- Martin C, Rodriguez D and Guevara J (eds), *Derecho Internacional de los derechos humanos (International Law on Human Rights)* (Fontamara 2004)
- Martin P and Kaye J, 'The Use of Biological Sample Collections and Personal Medical Information in Human Genetics Research, Issues for Social Science Research and Public Policy' (Background paper for Wellcome Trust workshop on 'The Collection of Human Biological Samples for DNA and Other Analysis')
- Martínez AC, 'Cárcel a quien conserve embriones, pide plan de reforma a la ley de salud (Prison to those who keep embryos, asked by planned reform to the General Health Law)' *La Jornada* (Mexico City, 1 September 2011) Sociedad y justicia (Society and justice) <<http://www.jornada.unam.mx/2011/09/01/sociedad/036n1soc>> accessed 30 September 2011
- Maschke J and TH Murray, 'Ethical Issues in Tissue Banking for Research: The Prospects and Pitfalls of Setting International' (2004) 25 Theor Med Bioeth
- Mayrhofer M and Prainsack B, 'Being a member of the club: the transnational (self-) governance of networks of biobanks' (2009) 12 International Journal of risk assessment and management
- McGuire A and Beskow L, 'Informed consent in genomics and genetic research' (2010) 17 Annu Rev Genomics Hum Genet 15
- McGuire A and Gibbs R, 'Currents in contemporary ethics' (2006) 34 Journal of Law, Medicine and Ethics
- McSmith A, 'Relatives of soldiers killed in Afghanistan receive public apology over body parts stored without permission' *The Independent* (9 August 2012) <<http://www.independent.co.uk/news/uk/home-news/relatives-of-soldiers-killed-in-afghanistan-receive-public-apology-over-body-parts-stored-without-permission-8026974.html>>
- McWhirter R and others, 'Practical Application of Participatory Governance for Biobanks' (ISBER Annual Meeting & Exhibits Sydney Convention & Exhibition Centre (SCEC), Sidney, 2013)
- Medicina UFd, 'Carta de consentimiento informado para menores de edad e incapaces (Informed consent model for underage persons and those incapable)' <<http://investigacionfacmed.com.mx/wp-content/uploads/2015/03/cartaDeConsentimientoParaMenoresDeEdadEIncapaces.pdf>>

- Medicine) INdMGNioG, *Manual de organización específica del Instituto Nacional de Medicina Genómica (Handbook for the specific organization of the National Institute of Genomic Medicine)* (Secretaría de Salud (The Mexican Ministry of Health), 2011)
- Medicine) INlog, *Reglas de Integración y Funcionamiento del Consejo Técnico de Administración y Programación del INMEGEN (INMEGEN's administrative council's integration and operation rules)* (2007)
- Medicine) ITNioG, *Comisión de Bioseguridad, Reglas Internas de Operación (Biosecurity Commission's internal operation rules)*
- Medicine) ITNioG, 'Reglas internas de la comisión de ética (Ethical Commission's internal rules)'
- Medina-Arellano M, 'Stem cell regulation in Mexico: current debates and future challenges' (2011) 5 *Studies in Ethics, Law, and Technology*
- Mendoza SC, 'Erogación de más recursos a investigación, entre los retos de la siguiente administración federal (More resources for research: amongst the challenges of the following federal administration)' *Cambio de Michoacán* (Michoacán, 24 July 2012)
- <<http://www.cambiodemichoacan.com.mx/vernota.php?id=178974>>
- Meslin E, 'The value of using top-down and bottom-up approaches for building trust and transparency in biobanking' (2010) 13 *Public Health Genomics*
- Morales A, 'A 50% no le preocupa datos personales: encuesta IFAI (50% are not concerned about their personal data)' *El Universal*
- <<http://www.eluniversal.com.mx/notas/899033.html>> accessed 28 January 2013
- Moreno-Estrada A and others, 'The genetics of Mexico recapitulates Native American substructure and affects biomedical traits' (2014) 344 *Science*
- Moreno O, *Genoma humano y derecho, resultados de la investigación y su impacto en la investigación jurídica (Human genome and the law, results of research and its impact in legal research)* (Palibrio 2011)
- Murtagh M and others, 'Realizing the promise of population biobanks: a new model for translation' (2011) 130 *Hum Genet*
- News B, *Organ scandal background* (BBC 2001)
- Nõmper A and Kruuv K, 'The Estonian Genome Project. – Society and Genetic Information' in Sándor J (ed), *Society and Genetic Information: Codes and Laws in the Genetic Era* (CEU Press 2003)
- Notimex, 'Promueven entre empresarios aplicar la genómica a economía' *SDP Noticias* (Mexico City, 17 August 2011)
- <<http://www.sdponoticias.com/notas/2011/08/17/promueven-entre-empresarios-aplicar-la-genomica-a-economia>> accessed 12 March 2013
- Nyika A, 'Ethical and practical challenges surrounding genetic and genomic research in developing countries' (2009) 112 *Acta Tropica*
- O'Neill O, 'Some limits of informed consent' (2003) 29 *J Med Ethics*
- O'Doherty K and Burgess M, 'Engaging the public on biobanks: Outcomes of the BC Biobank Deliberation' (2009) 12 *Public Health Genomics*
- OECD, *Getting it Right OECD Perspectives on Policy Challenges in Mexico* (OECD, 2007)
- OECD TOFeCaD, 'The Bioeconomy to 2030: designing a policy agenda' *International Futures Programme* <<http://www.oecd.org/futures/long-termtechnologicalsocietalchallenges/thebioeconomyto2030designingapolicyagenda.htm>> accessed 11 March 2012
- , *Principles and Guidelines for Access to Research Data from Public Funding* (Science and technology policy, 2007)

- , *Guidelines for Human Biobanks and Genetic Research Databases (HBGRDs)* (OECD Guidelines, 2009)
- , 'Key Outcomes' (The OECD/HUGO Symposium on Genomics and Bioeconomy, Montpellier, 17 May 2010)
- Office) MPdIrTP, 'Plan Nacional de desarrollo (2007-2012) National Plan for Development' (2007) <www.presidencia.gob.mx>
- Office) OdACpINUeMUHC, *Diagnóstico sobre la situación de derechos humanos en México (Diagnostic on the situation of human rights in Mexico)* (SRE (The Mexican Ministry of External Affairs), 2003)
- Organisation HG, 'HUGO' (2016) <<http://www.hugo-international.org/>>
- Organization WH, 'Global applications of genomics in healthcare: Mexico' (*WHO Genomic resource centre*) <<http://www.who.int/genomics/professionals/applications/mexico/en/>> accessed 30 November 2012
- , 'Human genetic databases: towards a global ethical framework' (Experts' Consultation Meeting, Geneva, 8 and 9 May 2006)
- Otlowski M, *Implications of Genetic Testing for Australian Employment Law and Practice*, vol 2 (Centre for Law and Genetics, University of Tasmania ; Faculty of Law, University of Melbourne 2001)
- Otlowski M, Nicol D and Stranger M, 'Biobanks Information Paper' *Journal of Law, Information and Science* <<http://www.austlii.edu.au/au/journals/JLLawInfoSci/2010/5.html>> accessed 5 May 2012
- P3G TPPPiG, 'P3G' <<http://www.p3gobservatory.org/>> accessed 16 March 2011
- PD PJ, 'Regulating health care: from self regulation to self regulation?' (2001) 26 *J Health Polit Policy Law*
- Pessini L, Barchifontaine P and Stepke FL (eds), *Ibero-American Bioethics: History and Perspectives*, vol 106 (Bulcock J tr, Springer 2011)
- Ponchel F and others, 'Gene expression analysis in RA: Towards personalised medicine' [2014] *The Pharmacogenomics Journal*
- Porteri C and Borry P, 'A proposal for a model of informed consent for the collection, storage and use of biological materials for research purposes' (2008) 71 *Patient Education and Counseling*
- Prainsack B and Buyx E, *Reflections on an emerging concept in bioethics* (Nuffield Council of Bioethics and Arts and Humanities Research Council 2011)
- , 'A solidarity-based approach to the governance of research biobanks' (2013) 21 *Medical Law Review*
- Prowda J, 'Moore v. The Regents of the University of California: An Ethical Debate on Informed Consent and Property Rights in a Patient's Cells' (1995) 77 *JPat & Trademark Off Soc*
- Puneet Chawla Sahota, 'Research Regulation in American Indian/Alaska Native Communities: Policy and Practice Considerations' NCAI Policy Research Center <http://depts.washington.edu/ccph/pdf_files/Research%20Regulation%20in%20AI%20AN%20Communities%20-%20Policy%20and%20Practice.pdf> accessed 27 March 2013
- R Andorno, 'The right not to know: an autonomy based approach' (2004) 30 *J Med Ethics*
- Rabasa E, *La dualidad en el derecho constitucional mexicano (The duality within the Mexican Constitutional Law)* (Instituto de Investigaciones Jurídicas UNAM 2012)
- Rawls J, *A Theory of Justice* (Harvard University Press 1971)

- Rawls J, "Justice as Fairness: Political not Metaphysical," ' 14 Philosophy and Public Affairs
- RC RE, Olson J and Palmer L, *Biostatistical Genetics and Genetic Epidemiology*. (John Wiley & Sons 2002)
- Reich W, 'Introduction' in Reich W (ed), *The encyclopedia of bioethics* (Simon Schuster Macmillan 1995)
- Rensselaer PV, 'Bioethics, the Science of Survival ' (1970) 14 Perspectives in Biology and Medicine
- Researcher-at-a-public-biobank-Participant:B, *PhD Thesis Fieldwork* (2012)
- Researcher-at-a-public-biobank-Participant:E, *PhD Thesis Fieldwork* (2012)
- Responsible-for-the-research-department-at-a-public-biobank-Participant:A, *PhD thesis fieldwork* (2012)
- Responsible-of-the-ethics-department-and-researcher-at-a-public-biobank-Participants:DandE, *PhD thesis fieldwork* (2012)
- Responsible-of-the-ethics-department-at-a-public-biobank-Participant:D, *PhD Thesis fieldwork* (2012)
- Responsible-of-the-Genetics-department-at-a-public-ethical-advisory-institution-Participant:I, *PhD Thesis fieldwork* (2012)
- Responsible-of-the-Human-Genome-Department-at-a-public-ethics-advisory-institution-Participant:M, *PhD Thesis fieldwork* (2012)
- Responsible-of-the-legal-department-at-a-public-biobank-Participant:G, *PhD Thesis fieldwork* (2012)
- Rial-Sebbag E and Cambon-Thomsen A, 'The Emergence of Biobanks in the Legal Landscape: Towards a New Model of Governance' (2012) 39 Journal of Law and Society
- Ribeiro S, 'Genómica, biopiratería y pueblos indígenas (Genomics, biopiracy and indigenous towns)' *La Jornada* (Mexico City,, 31 March 2007) Opinion
<<http://www.jornada.unam.mx/2007/03/31/index.php?section=opinion&article=021a1pol>>
- Riegman P and others, 'Biobanking for better healthcare' (2008) 2 Molecular Oncology
- Riegman PHJ, 'TubaFrost 1: uniting local frozen tumour banks into a European network: an overview ' (2006) 42 European Journal of Cancer risks) CFpIPcRSFCftpah, *Atribuciones, funciones y características de la COFEPRIS (COFEPRIS' attributions, functions and characteristics)*
- (Secretaría de Salud (The Mexican Ministry of Health, 2010)
- Rosales HG and Betancourt MS (eds), *Incorporación del derecho internacional de los derechos humanos al sistema jurídico mexicano (Incorporation of international law of human rights to the Mexican Legal System)* (Comisión Mexicana de Defensa y Promoción de los Derechos Humanos (Commission for the defence and promotion of human rights) CMDPDH 2008)
- Rose H, 'An ethical dilemma. The rise and fall of UmanGenomics – the model biotech company?' (2003) 425 Nature
- Ruha B, 'A Lab of Their Own: Genomic sovereignty as postcolonial science policy' 28 Policy and Society
- Sahota PC, 'Research Regulation in American Indian/Alaska Native Communities:Policy and Practice Considerations ' NCAI Policy Research Center
<http://depts.washington.edu/ccph/pdf_files/Research%20Regulation%20in%20AI%2

- [OAN%20Communities%20-%20Policy%20and%20Practice.pdf](#)> accessed 27 March 2013
- Salter B and Jones M, 'Biobanks and bioethics: the politics of legitimation' (2005) 12 *Journal of European Public Policy*
- Sánchez GJ, *Programa de Trabajo para dirigir el Instituto Nacional de Medicina Genómica* (Fundación Mexicana para la Salud, 2004)
- Sánchez M, 'En México, más de 5000 experimentos con seres humanos' *Contralínea* (Mexico City, 19 February 2012) <<http://contralinea.info/archivo-revista/index.php/2012/02/19/en-mexico-mas-de-5-mil-experimentos-clinicos-con-humanos/>> accessed 21 March 2012
- Sánchez M, 'En México, más de 5000 experimentos con seres humanos (more than 5000 experiments with human beings in Mexico)' *Contralínea* (Mexico City, 19 February 2012) <<http://contralinea.info/archivo-revista/index.php/2012/02/19/en-mexico-mas-de-5-mil-experimentos-clinicos-con-humanos/>> accessed 21 March 2012
- Sándor J and Bárd P, *The legal regulation of biobanks National report: Estonia* (GeneBanc 2009)
- Santiago-Rodriguez F, *Facing the Trial of Internationalizing Clinical Trials to Developing Countries: With Some Evidence from Mexico* (UNU-MERIT, Maastricht, The Netherlands, 2008)
- Schmidt M, 'Regulatory aspects of genetic research with residual human tissue: Effective and efficient data coding' (2009) 45 *European journal of cancer*
- Schwartz-Marín E and Silva-Zolezzi I, 'The Map of the Mexican's Genome: overlapping national identity, and population genomics' (2010) 3 *Identity in the Information Society*
- Schwartz E, 'Filosofía para la nueva genética (Philosophy for the new genetics)' (Simposios Filosofía para la Nueva Genética, Mexico City, 25 January 2010)
- Schwartz E, 'Genomic Sovereignty and the "Mexican Genome" an ethnography of postcolonial biopolitics' (DPhil thesis, University of Exeter 2011)
- Schwartz E and Mendez A, 'The law of Genomic Sovereignty and the protection of "Mexican genetic patrimony"' (2012) 2 *Medicine and law*
- Science-and-Technology-Commission-Participant:K M-o-T-M-P-a-T, *PhD Thesis Fieldwork* (2012)
- SCJN, 'Suprema Corte de Justicia de la Nación (The Mexican Supreme Court of Justice)' <<https://www.scjn.gob.mx/Paginas/Inicio.aspx>> accessed 20 May 2011
- Secko D and others, 'Informed consent in biobank research: a deliberative approach to the debate.' (2009) 68 *Soc Sci Med*
- Séguin B and others, 'Genomics, public health and developing countries: the case of the Mexican National Institute of Genomic Medicine (INMEGEN)' (2008) 9 *Nat Rev Genet*
- Séguin B and others, 'Genomic medicine and developing countries: creating a room of their own' (2008) 9 *Nat Rev Genet*
- Serrano-Delgado V, Novello-Garza B and Valdez-Martinez E, 'Ethical issues relating to the banking of umbilical cord blood in Mexico' (2009) 10 *BMC Medical Ethics Services*
- HgUSDoHH, 'Issues to Consider in the Research Use of Stored Data or Tissues' (1997) <<http://www.hhs.gov/ohrp/policy/reposit.html>>
- , 'Guidance on Research Involving Coded Private Information or Biological Specimens' OHRP <<http://www.hhs.gov/ohrp/policy/cdebiol.html>>
- Sforza LC and Feldman M, *Cultural Transmission and Evolution: A Quantitative Approach*. (Princeton University Press 1981)

- Sharp R and Foster M, 'An analysis of research guidelines on the collection and use of human biological materials from American Indian and Alaskan Native communities' (2002) 42 *Jurimetrics*
- Shekelle P and others, *Maintaining Research Integrity: A Systematic Review of the Role of the Institutional (Review Board in Managing Conflict of Interest* (Evidence-based Synthesis Program (ESP) Center, West Los Angeles VA Medical Center, 2012)
- Shickle D, Griffin M and El-Arifi K, 'Inter- and Intra-Biobank Networks: Classification of Biobanks' 77 *Pathobiology*
- Silva-Zolezzi I and others, 'Analysis of genomic diversity in Mexican Mestizo populations to develop genomic medicine in Mexico' (2009) 106 *PNAS*
- Simon C and others, 'Active choice but not too active: public perspectives on biobank consent models.' (2011) 13 *Genet Med*
- Simon J and others, 'A legal framework for biobanking: the German experience' (2007) 15 *Eur J Hum Genet*
- Skloot R, *The Immortal Life of Henrietta Lacks* (Broadway Books 2011)
- Souza YD and Greenspan J, 'Biobanking past, present and future: responsibilities and benefits' (2013) 27 *AIDS*
- Stjerschantz J, 'Changing perspectives in biobanks research: from individual rights to concerns about public health regarding the return of results' (2009) 17 *Eur J Human Genet*
- Sztomka P, *Trust: A Sociological Theory* (Cambridge University Press 1999)
- Tamayo RP, 'La investigación Médica en seres humanos (Medical research in human beings)' (2008) 19 *Medicina Universitaria*
- Tansey J and Burges M, *The foundation, applications and ethical dimensions of biobanks* (Electronic Working Paper Series W Maurice Young Centre for Applied Ethics, University of British Columbia, 2004)
- Taylor M, 'Special Focus: Ethical and Regulatory Concerns Regarding Human Genomic Databases - Perspective' (2007) 4 *Personalized Medicine*
- Technology HoCSCoSa, *The Work of the Medical Research Council* (The House of Commons, 2003)
- Thacker E, *The global genome: biotechnology, politics and culture* (Cambridge MIT Press 2005)
- The-International-HapMap-Consortium, 'Integrating ethics and science in the international HapMap Project' (2004) 5 *Nature Genetics*
- Theilade M, Knudsen L and Renneberg J, 'Regulatory requirements for inclusion of pharmacogenetic testing in applications for clinical trials' (2001) 12 *The Regulatory Affairs Journal*
- Tinoco JC, *La aplicación Judicial de los Tratados Internacionales de Derechos Humanos (The judicial application of human rights international treaties)* (IIJ-UNAM, 2002)
- Tridimas T, *The General Principles of Law in the European Union Legal Order* (2 edn, Oxford European Union Law Library 2007)
- Trusheim M, Berndt E and Douglas F, 'Stratified medicine: strategic and economic implications of combining drugs and clinical biomarkers' (2007) 6 *Nature Reviews Drug Discovery*
- Trust TW and Council MR, *Public Perceptions of the Collection of Human Biological Samples* (Qualitative research to explore public perceptions of human biological samples, 2000)
- Tsuru Morales Isla Abogados SC, 'Publicación de la Reforma a la Ley General de Salud en materia de Medicina Genómica' Tsuru Morales Isla Abogados SC,

- <<http://www.tmtlaw.com.mx/reformas-medicina-genomica.php>> accessed 19 January 2012
- UK G, 'Genetic discrimination by insurers and employers: still looming on the horizon An update on the use of genetic test results by employers and insurers' www.genewatch.org <http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Genetic_TestingUpdate2006.pdf>
- UNAM, 'Código Ético para el personal académico del Instituto de Investigaciones Biomédicas (Code of Ethics for the academic staff of the Institute of biomedical research)' (2005) <https://www.biomedicas.unam.mx/_administracion/reglamentos_formatos/archivos_pdf/CodigolIBO.pdf>
- Underwood C, '72% of the Indigenous Population in Mexico live in Extreme Poverty Conditions' *The Yucatan Times* (Merida, Mexico, Sat Aug 16th 2014)
- UNESCO, 'Social and Human Sciences' (UNESCO) <<http://www.unesco.org/new/en/social-and-human-%20sciences/themes/bioethics>> accessed 11 October 2012
- Valadés ASaD (ed), *Panorama sobre la legislación en materia de genoma humano en America Latina y el Caribe (Legal panorama on the human genome in Latin America and the Caribbean)* (National Autonomous University of Mexico, Latin American and Caribbean bioethics network of UNESCO 2006)
- Valdez-Martinez E and others, 'Understanding the structure and practices of research ethics committees through research and audit: a study from Mexico' (2005) 74 *Health Policy*
- Valdez-Martinez E and others, 'Descriptive ethics: A qualitative study of local research ethics committees in Mexico' (2006) 6 *Developing World Bioethics*
- Vargas J, 'An Introductory Lesson to Mexican Law: From Constitutions and Codes to Legal Culture and NAFTA' *San Diego Law Review Association* <<https://litigation-essentials.lexisnexis.com/webcd/app?action=DocumentDisplay&crawlid=1&srctype=smi&srcid=3B15&doctype=cite&docid=41+San+Diego+L.+Rev.+1337&key=d6072d42f4e12efe3c30337714413506>> accessed 18 of January 2012
- , 'Mexico and its Legal System' Law and Technology resources for legal professionals (llrxcom) <<http://www.llrx.com/mexicolegalsystem.htm>> accessed 18 January 2012
- , 'Features - The Federal Civil Code of Mexico' Law and technology resources for legal professions <<http://www.llrx.com/features/mexcc.htm>> accessed 27 February 2012
- Vaught J and Lockhart N, 'The Evolution of Biobanking Best Practices' (2009) 413 *Clin Chim Acta*
- Vayena E, Ganguli-Mitra A and Andorno NB, 'Guidelines on biobanks: emerging consensus and unresolved controversies' in Elger B and others (eds), *Ethical Issues in Governing Biobanks* (Ashgate 2013)
- Vázquez-Elizarrarás J, 'El Derecho Internacional ante los desafíos del genoma humano y la bioética, en el marco de la organización y las declaraciones internacionales. Su proyección al derecho mexicano' (2008) 8 *Anuario mexicano de derecho internacional*
- Veen EV, 'Tubafrost 3: Regulatory and ethical issues on the exchange of residual tissue for research across Europe' (2006) 42 *Eur J Cancer*
- , 'Obstacles to European research projects with data and tissue: Solutions and further challenges' (2008) 44 *European Journal of Cancer*

- Virk K, 'Trials in Mexico: Addressing the challenges. Clinical trials outsourcing Mexico' (2009) 21 *Biotech and pharmaceutical research language connections*
- Wade L, 'Initiative Aims to Minister to Mexico's Unique Genetic Heritage' (2013) 342 *Science*
- Wallace E and BM Knoopers, 'Harmonised consent in international research consortia: an impossible dream?' (2011) 7 *Genomics, society and policy*
- Watson P and Barnes R, 'A Proposed Schema for Classifying Human Research Biobanks' (2011) 9 *Biopreservation and Biobanking*
- Weber S, Wilson-Kovacs D and Hauskeller C, 'The regulation of autologous stem cells in heart repair: comparing the UK and Germany' in Lenk C and others (eds), *Human Tissue research A European Perspective on the Ethical and Legal Challenges* (Oxford University Press 2011)
- Whitener R and others, 'Engaging American Indian Communities in research through Community Based System Development' (ELSI Conference 2011 Academic Ventures, South Carolina, April 2011)
- Whitener R and others, 'Engaging American Indian Communities in research through Community Based System Development' (ELSI Conference 2011 Academic Ventures, South Carolina, April 2011)
- Wilson S, 'Population biobanks and social justice: Commercial or communitarian models? A comparative analysis of benefit sharing, ownership and access arrangements' (2004) 8 *TRAMES*
- Wistano M, 'Explanatory preamble for reforms to the General Health regarding the human genome (Exposición de motivos que reforma la ley general de salud, en materia de genoma humano)' Partido Acción Nacional National Action Party PAN <http://sil.gobernacion.gob.mx/Archivos/Documentos/2001/12/asun_1025_20011214_838707.pdf>
- Zielinski S, 'Henrietta Lacks' 'Immortal' Cells' SMITHSONIANCOM <<http://www.smithsonianmag.com/science-nature/henrietta-lacks-immortal-cells-6421299/>> accessed 20 January 2012

10. Annex

Table 1

A	<p>Biobanks are not regulated effectively. I don't know whether there is really legislation to modify regarding confidentiality. I know that there were many gaps based on joint analysis on data confidentiality and privacy. There is much on privacy, but not on genetic privacy, which only a few times is included. The General Health Law provides with general articles, but if you do not have rules which detail due procedures, a general law is helpless.</p>
B	<p>In my opinion, biobanks are not regulated effectively. In my point of view, the legal side is fundamental and the main problem is the definition of questions to know the competence of the authorities in the institutes, the competence of the researcher, that of the sponsor or to determine if there is a limit of the pharmaceutical industry to support us. The law is not ambiguous but inexistent. In my view a legal framework, which could help us (researchers, in these areas of biomedicine), is being required; how to manage samples within biobanks.</p>
C	<p>The regulation of biobanks in Mexico is inexistent. There is no rule whatsoever to regulate biobanks in general. We can find that each biobank has a 'self regulation'. This can be elaborated by governance actors or even by individuals. For example, there are private blood banks and they are covered by general norms on the use of blood. Then, they have internal rules. There are minimum standards, but these do not apply to these concrete cases. We have no concrete security measures.</p>
D, E	<p>Biobanks are not regulated effectively in Mexico. There is a far way to go, this is a very easy question to answer. We have the general Health Law, obviously the rules on health research, the NOM regarding specific matters on blood banks. But, not something for established biobanks, to enable preservation and sharing of samples within research projects, there is nothing.</p>

F	Regarding biobanks, there is a health legislation that is applicable. Not in every aspect, but most of them. Instead, we need manuals or guidance so the user knows what laws are applicable for their biobanks.
G	The legislation for biobanks in Mexico is not clear.
H	I consider that biobanks are not regulated effectively. This and other novelty health topics are outside the legislation. We may try to make the topic fit into the framework forcefully through general principles. But that is not the case; there is not an explicit ad-hoc regulation for biobanks. It would be risky to give a determinant answer. I think it is necessary to analyse what parts of the legislation need to be reinforced. Some parts may be applicable. Initially I would say that it is necessary to enforce a new specific chapter on biobanks within the general Health Law, not outside this instrument. It could be also a NOM or another secondary instrument to explain additions to the General Health Law on biobanks. Mixing topics generates just confusion in applicability, we must avoid that. It has happened before, only because there is an article the topic we say it is regulated. We need a substantial proposal.
I	I believe that the topic of biobanks, as many other bioethics topics, is included by a particular form, divided into various instruments of different types (civil, health, penal). They are unfocussed in the legal framework. My understanding is that there is no policy or specific section for the regulation of biobanks. I know that they are understood as sensitive data, such as health data contained in biological samples.
J	The current Mexican legislation allows that regulation through the Federal Law of Transparency and Access to Federal Public Data (LFTAIPF) on personal data.
M	Biobanks are not legally regulated as such specifically. They may be regulated somehow, but they are immersed in the Mexican legal framework.
N	I know there is legislation, but I do not know until what point they are effective. I also know work is being done in that respect.

0	<p>If effectiveness is understood in terms of complying with the legislation, biobank legislation is effective. If effectiveness is understood in terms of covering the main theoretical and practical biobanking topics, the answer is no. The law is very vague, ambiguous, lacks of clarity, no definitions, little consolidation, little study, little results from debate. We are very backwards in comparison with international advances.</p>

Table 2

A	It is probably COFEPRIS, dependant on the Ministry of Health, which authorises many things. We have had authorisation from COFEPRIS for samples which have been transported outside the country, justifying the research project. COFEPRIS has a lot of legal force.
D,E	I believe that COFEPRIS has too much work. It is the authority on drugs, food and publicity. I do not think it will manage to do this other role. A lot of people has complained that applications for lab authorisations, for example, do not have a response after months. I think that the commission will not have the time for the careful oversight of samples.
G	COFEPRIS must extend an authorisation in order to transport organs, tissue and blood outside the country. This is in the law. However, this is obsolete in terms of DNA. COFEPRIS is in charge of biobanks' oversight. INMEGEN is granted licenses and authorisations by COFEPRIS, similarly to other health institutes. These authorisations include permissions for the operation of labs, correct handling of biological materials. A granted license involved that inspections can be carried out without notice to the institute.
H	I believe that the authority in charge is COFEPRIS. That is the sanitary and sanitary care authority in general.
I	In my opinion the maximum authority for biobanks is still the ethics committee.
M	My understanding is that COFEPRIS is the main authority. One of the ways the commission can collaborate with COFEPRIS is through the analysis of ethical implications. Joint collaboration is highly recommendable.

Table 3

D	<p>I believe that the CNB could play an important role beyond the organisation of research ethics committees. The CNB should have a more active role in terms of regulation. The CNB is going across a new stage. On the 31st of October a new reform came up regarding the organisation of the ethics research and health committees. It is about an authorisation for those committees to keep operating, once the authorisation from COFEPRIS has been obtained. They are at a very early stage and I hope this more active role involves protocol revision.</p>
F	<p>The CNB is not an authority, but it has officially been established that the commission will be consulted for bioethical matters. The commission can recommend following specific national instruments.</p>
H	<p>The CNB organises studies for consultancy purposes and provides training for ethics committee members (so members understand their role within the committee). The recent changes on compulsory committees for health and research within the General Health Law give more faculties to the commission. It is on the way to be more like a governance institution. I think we are in a transition period. In terms of biobanks we have nothing but the organisation of academic seminars. The ethics committees are internal. We anticipate a mechanism to register and follow these committees. This registry originally used to belong to COFEPRIS. Now the CNB is collaborating with them in this registry. COFEPRIS is still the authority. I do not think the CNB will intervene as an authority because it was created with a different nature. The creation decree does not allow the commission to go further than help with the registration of committees. The main points are to strengthen the committees, to make sure that any research project in Mexico is done by an institution, that the institution has an ethics committee to authorise the research project and protect the dignity of the participants.</p>
I	

	<p>The role of the CNB is to be an adviser. It will not say whether something is legal or illegal but can say if it is correct or incorrect. The nature of the commission is not to be an authority of any kind. It would be good that it had more legal strength. However the commission's role is to provide guidance on public policies from a bioethical point of view. The commission will never become a public prosecutor on bioethics, it is an administrative organ. The commission, after the amendments, was involved in the formalisation of ethics committees in health institutions. The commission is elaborating guidelines for the operation and structure of such committees; number of members, resolutions, general requirements.</p>
L	<p>The commission has the challenge of training. It organises plenty of courses. We are looking for strategies to cover the training demands. The commission has records of the committees. They know that at least those registered must comply with the CNB guidance. The intention is to unify the operation of the committees and avoid that some are less strict than others, that they are multi-disciplinary and plural. The commission follows some issues closely and gives an opinion. We have guidance for the integration of the ethics committees at hospitals and research institutions. They are mandatory. The commission sometimes provides opinions on law projects that are sent to us.</p>
M	<p>The CNB is a non centralised institution of the Ministry of Health. It is dedicated to study and disseminate bioethics questions and knowledge.</p>

Table 4

C	A year ago it was established that these committees are compulsory. More progress is necessary and it must be determined in what cases advisory committees are required and when they should be stringent. In my opinion, biomedical research deserves to be looked at by an authority. A way of taking control is authorisation at the project's beginning; no project can be done without approval. Afterwards, projects must be followed up by an ethics committee.
O	The ethics committees are completely unstructured and passive. I perceive that the CNB has a few lawyers (who are very young by the way, just starting), it is not plural. They have understood the commission as a group of medical doctors which will apply purely medical ethics. This is not bioethics. There are no philosophers, no jurists in the committees. It is sad that "The Bioethics College," Mexican NGO, is more organised than the CNB.
L	Committee members are not experts i.e. on data protection. They are intended to protect the research subject by making sure that the research protocol is well founded. There is a tendency, I notice, towards making the committees stronger by training committee members.
I	It is difficult to standardise the committees, it is not the same a committee in Mexico City and a committee in a remote community.
H	The 2011 reform to the General Health Law introduced the committees. Now, the addition to the article 41 bis will be governed by criteria from the CNB. Our guidelines are becoming compulsory in the integration and operation of the committees, so they are plural, multidisciplinary, have clear objectives, clear boundaries and extents. This will impact positively on the protection of the research subject.
M	

In my opinion, ethics committees should definitely be stronger. I see committees as the instruments to make bioethics practical. The idea is to train committee members that can also be trainers in the future. One of the limits of the commission is a reduced number of staff for a great number of committees to train in the country. Ethical guidelines are as important as legal rules. The key point is educating the population so they also consider ethical criteria. However, some stakeholders are over defensive on what will happen to them if they do not comply with some requirements. Research committees have to be registered in both COFEPRIS and the CNB. I attended a health related event in which a bi-national committee was discussed. The two involved countries were participating in the project. According to Mexican legislation, the committee scrutiniser has to be that one from the place where the research takes place. The rules of the place apply in that case.

Table 5

C	I believe both the ethics and the law are complementary. We need to act ethically and generate these principles from inside the community. This can be developed within the community of stakeholders. However the social impact of the topic requires legal rules as well. For example establishing a biobank, the fact of collecting biological samples involves risks regarding the use of the samples.
G	In my opinion, we do not have the culture. I believe that law and ethics must complement each other. The ethics will not always be coherent with the law in practice, especially on subjects where genetics is related. It goes beyond individual rights. Relatives are also involved.
A	Ethical guidance is fine, but you also need sanctions when things are not well done. Not everybody is ethical. Perhaps, both are necessary.
D,E	I think both the law and the ethics are necessary. The legal side is necessary to establish the rules of the game and make people respect those rules. It is also about essential controls, not bureaucratisation. It involves a lot of work. I believe on the ethics as the cultural side of doing science, sharing and collaborating. I believe it is the two pillars, the ethical and the legal one. If people's mentality and culture do not change, we have to be dependent on the stringency of law. If things change, researchers will be familiar with the idea that it is not their samples, but with the idea that there is a lot to gain from sharing. It will take time though.
O	A bioethics code cannot be stringent because that is not its nature; I understand codes of ethics as codes of principles. I do not think that creating new codes is the answer. I think education on bioethics is central at universities. The bioethical principles are not being taught. That does not depend on whether rules should be mandatory or not.
I	I believe there is always a tendency, perhaps due to lack of trust, to believe that there is a separation between law and ethics. They are closely related but not all the ethical principles have to be legal.
F	We are full of ethical guidelines. People feel that ethical codes are not mandatory, so they are not respected.

H	I believe that topics such as biobanks start with ethical guidelines and then these become part of the legal framework. However, first the topics need to be deeply studied, starting by the law makers.
L	Not all of us are ethical. So we need to encourage protective measures beyond just goodwill.

Table 6

C	<p>The role of international principles is to orientate countries, so they can select guidelines and then develop and adapt them to their own legislations. Legislators many times copy other countries' legislations that they believe are more advanced. Approximately 8 years ago, it was being planned to implement a Spanish act by copying it to the Mexican framework. Such an act had been derogated in Spain as it was contradicting European Union principles. Mexico was aiming to copy it identically. In the case of biobanks, the advantage is that there are numerous instruments which can be adapted. Comparative law is always helpful. It allows you to investigate how your country is positioned. The problem is when you try to apply frameworks incoherently with the reality of the country. Comparative law presents advantages, the problem is the implementation. Every topic is related to specific problems of the country. It is also related to cultural and ethical levels.</p>
D,E	<p>Mexico is very different from other countries, yet there is nothing (in terms of biobanking).</p>
I	<p>We do have a human genome law, but we have a chapter on the human genome and we have some sanctions in the penal code. However, we are not like France, for example, they have a bioethics law.</p>
K	<p>Before making the law, we need information on pioneer countries' public policies, authorities. We need to determine the frequency of abuse and recurrence on this topic.</p>
O	<p>I have seen that the academia becomes desperate to participate in the encouragement of new laws without serious analysis. They do not look at comparative law. I do not mean that we need to implement other countries' legislation, but we can reference the experiences and failures from other countries. It may work.</p>

Table 7

C	I believe that the informed consent depends on each biobank's purpose and extent. The utility of the sample must be defined in advance, which involves the destruction of samples once such a purpose is reached.
D,E	Informed consent varies to a great extent. If it is for individuals, we aim to protect their autonomy, if it is for indigenous communities; we aim to protect the group.
F	I am against general informed consents and general explanations on benefits, benefits have to be clear as well as the damage caused. That is another important point I have seen in informed consent. I believe that there must be a general regulation of informed consent, but each case needs a specific consent according to the participant's age. However, I consider that there needs to be a general context for informed consent. This would provide the rationale (unknown by many) of any informed consent. Something very important is the determination of benefits for the individual and the group, how it will impact on the group permanently. In genomic population studies it is not clear how the community is benefited, how the individual and the group are protected. We need to define specific informed consents for each situation. Some can include extension of periods to study the samples and some of them are project limited or time limited.
G	Informed consent within the INMEGEN is a form sent by our labs. Our area revises them to verify they comply with the General Health Law requirements. This informed is general as it aims to cover the majority of consent points by different areas.
L	Sometimes researchers do not understand what is being protected through some administrative measures that seem just bureaucratic. I learned that in my Masters degree. At some point in the past I was doing research in child obesity. One day I became very frustrated that a mother refused to participate in the project. I thought it was a waste, since the benefits were for her children, who suffered obesity, because she was obese. I could not understand that she had the right to refuse to participate and I only saw the researcher's perspective and thought it as for their benefit. Now I see the value of respecting persons' decision on their participation, beyond research benefits.
M	Our main concern regarding informed consent is that autonomy is respected at all times, depending on the participant's understanding of the consent. We look for clearness on the implications for the participant and concise language and that the informed consent is seen as a process, not a document. I think it would be risky if the commission elaborated a consent form as each situation requiring IC is different. The commission disseminates the importance of informed consent. We have worked on informed but not exhaustively, there is still a lot to do.

O	The problem about informed consent is that it is known only by some lawyers and the health institutions. However, other public servants do not know it.
N	I believe that informed consent presents gaps to really be considered effective.
H	The commission has aimed to promote the informed consent not as a document, but as a process so the patient understands the procedures in which he is participating freely, within a clinical treatment. We aim that people stop looking at the IC as a document who protects the doctor. The main problem with IC in my opinion is that it has been strongly encouraged as a legal document, not as a process.
L	I think that IC is one of the greatest challenges will be understanding informed consent for research. The role of the IC in Mexico has been misunderstood. It started in health areas. The research consent does exist in Mexico and so do the research committees. They will not approve a protocol without consent. It is recent and unfortunately a signed IC does not guarantee that the person understood the IC. Legally the hospitals use informed consent to protect themselves. This should not happen within research. I understand informed consent for research in more general sense. I have participated in a research project from the National Institute of Nutrition. It was about women's hormonal cycles. It consisted of the donation of a samples and a hormonal profile in exchange. I remember signing something but never knew what use was given to my sample. I think that is a serious institution so they might have used it for a single purpose and destroyed it afterwards.

Table 8

	PARTICIPATION	OBJECT	CHRONOLOGY	SAMPLE COLLECTION	SAMPLE LOCATION	DATA PROTECTION	RESULTS	RESULT AVAILABILITY	RESPONSIBILITY	INTERVENING INSTITUTIONS
'Cohort Profile': The Mexico City Prospective Study	150 000 adults	To assess reliably the associations of established risk factors and possible new ones, with common causes of death in Mexico. To seek information on the incidence of cancer, non-fatal vascular events, and diseases.	1995 – 1997 Sample collection: 1995-1997 Lasting: undefined Future: Undefined, depending on participants' mortality rates	10 ml venous blood samples into a single EDTA tube labelled with a barcode unique to the participant.	Mexico City, The Mexican Ministry of Health "Secretaría de Salud", Oxford United Kingdom. CTSU Lab.	Participants followed up indefinitely for cause-specific mortality through Mexican death registries. At 5 year intervals, a reasonably representative sample of at least a few thousand surviving participants will be invited for re-assessment, including initial questions, measurements, and blood collection procedures. The underlying and contributing causes of death were coded according to the 10th International Classification of Diseases. This information, together with personal identifying information was recorded in a Ministry of Health database that was established as a consequence of this study and in other official databases.	Chronic diseases often associated with affluence tend to be most prevalent in the north of the country; whereas chronic diseases normally associated with poverty tend to be most prevalent in the south.	Publishing in the International Journal of Epidemiology Language: English	The study has been funded by the Mexican Ministry of Health, the National Council for Science and Technology and the UK Wellcome Trust. Indirect funds came from the Medical Research Council, the British Heart Foundation and Cancer Research UK, and additional support for international studies of smoking from the US NIH Fogarty International Centre.	Ministry of Health General ministry of epidemiology, Mexico Ministry of health's promotion and prevention. Clinical Trial Service Unit, University of Oxford, UK. Conacyt authorised the study
Genomic diversity of the Mexican Population: The 'HapMap' Project	300 people, including adults and children.	Population study. Ancestry analysis by the inclusion of one Mexican Amerindian group and data from the HapMap. Providing evidence of genetic differences between Mexican subpopulations that	2005 - 2009 Lasting: 4 years. Future: No re-contact purposes	Anonymous blood samples from 300 nonrelated and self-defined <i>Mestizos</i> and 30 <i>Amerindian Zapotecos</i> were collected in 7 states in Mexico: Guanajuato, Guerrero, Sonora, Veracruz, Yucatan, Zacatecas, and Oaxaca. Samples were labelled to know where they came from and the sex of the donor.	National Institute of Genomic Medicine INMEGEN, Mexico City	Open forums organised in the participating communities, which were approached 3 weeks before the study to explain its purposes and implications. Translators came from the participating communities. Anonymisation with no withdraw possibilities was initially intended and further exceptional recontact was not discarded. Two witnesses intervened to ensure that participation (including that of children) was self willing.	Genetic differences among Mexican <i>Mestizos</i> from different regions in Mexico are mainly because of differences in Amerindian and European contributions. Outliers with an African proportion 15% and intraregional variability in this component were observed in Veracruz and Guerrero. When Mexican	INMEGEN webpage Languages: English/Spanish	INMEGEN This work was supported by funds from the Federal Government of Mexico to the National Institute of Genomic Medicine and by infrastructure donated by the Mexican Health Foundation (FUNSALUD) and the Gonzalo Río Arronte Foundation. The study was approved by the Ethics, research	The study was approved by both the scientific and ethics committees of the National Council of Technology 'Conacyt' and the Ministry of Health. The study was conducted following the current legal framework by the General Legislation of Health. Experts from the National Commission of Bioethics and the

		<p>should be considered for association studies of complex diseases. The first genome wide genotyping efforts of a recently admixed population in Latin America. Contributions to the development of genomic medicine in Mexico and Latin America.</p>					<p>subpopulations were compared to Hap- Map populations, most showed decreased diversity, and only Sonora had a similar pattern to that of Asians.</p>		<p>and biosecurity internal Commissions of the Institute.</p>	<p>President of the Human Genome World Organisation participated and CIOMS guidelines were followed. Institutional local agreements were signed.</p>
--	--	--	--	--	--	--	--	--	---	--

