

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)

Developing a writing intervention for patients with seizures

1. Is your project research?

Yes No

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Basic science study involving procedures with human participants
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
- Study limited to working with data (specific project only)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

Yes No

2b. Please answer the following question(s):

- a) Does the study involve the use of any ionising radiation? Yes No
- b) Will you be taking new human tissue samples (or other human biological samples)? Yes No
- c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

3. In which countries of the UK will the research sites be located?(Tick all that apply)

- England
 Scotland
 Wales
 Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
 Scotland
 Wales
 Northern Ireland
 This study does not involve the NHS

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
 Social Care Research Ethics Committee
 Research Ethics Committee
 Confidentiality Advisory Group (CAG)
 National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

- Yes No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

- Yes No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

- Yes No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

- Yes No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

- Yes No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of

identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

Yes No

9. Is the study or any part of it being undertaken as an educational project?

Yes No

Please describe briefly the involvement of the student(s):

PhD student managing all aspects of study under the supervision of Prof. Markus Reuber and Prof. Brendan Stone

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

Yes No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

Yes No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

Yes No

Integrated Research Application System
Application Form for Other clinical trial or investigation

NHS/HSC R&D Form (project information)

Please refer to the *Submission and Checklist* tabs for instructions on submitting R&D applications.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting [Help](#).

Please define any terms or acronyms that might not be familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
 Developing a writing intervention for patients with seizures

PART A: Core study information
1. ADMINISTRATIVE DETAILS
A1. Full title of the research:

Developing a writing intervention for patients with epilepsy and nonepileptic attack disorder

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Mr	Gregg	Rawlings
Address	Academic Neurology Unit, Royal Hallamshire Hospital		
	Glossop Road		
	Sheffield		
Post Code	S10 2JF		
E-mail	ghrawlings1@sheffield.ac.uk		
Telephone			
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
 PhD in Neuroscience

Name of educational establishment:
 The University of Sheffield, Medical School, Department of Neuroscience

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Professor	Markus	Reuber
Address	Academic Neurology Unit, Royal Hallamshire Hospital		
	Glossop Road		
	Sheffield		
Post Code	S10 2JF		
E-mail	m.reuber@sheffield.ac.uk		
Telephone	01142268763		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
 Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Mr Gregg Rawlings	<input checked="" type="checkbox"/> Professor Markus Reuber

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- Student
- Academic supervisor
- Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	Markus	Reuber
Post	Reader and Honorary Consultant		
Qualifications	MD, PhD, FRCP		
Employer	Sheffield Teaching Hospitals NHS Foundation Trust		
Work Address	Academic Neurology Unit, Royal Hallamshire Hospital		
	Glossop Road		
	Sheffield		
Post Code	S10 2JF		
Work E-mail	m.reuber@sheffield.ac.uk		
* Personal E-mail			
Work Telephone	01142268763		
* Personal Telephone/Mobile			
Fax			

* This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.

A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?

This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title Forename/Initials Surname Mrs Samantha Lewis
Address	Sheffield Teaching Hospital NHS Foundation Trust D49, D Floor, Clinical Research Office, Royal Hallamshire Hospital Glossop Road Sheffield
Post Code	S10 2JF
E-mail	samantha.lewis@sth.nhs.uk
Telephone	01142265942
Fax	01142265937

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available): STH18910

Sponsor's/protocol number:

Protocol Version: 1

Protocol Date: 15/07/2015

Funder's reference number:

Project website:

Registry reference number(s):
The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):

ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

Yes No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

This study will investigate the health effects of a brief and time-limited writing intervention in patients with epilepsy and non-epileptic attack disorder (NEAD). Previous research in other chronic conditions has suggested that writing can be effective in symptom management and improve physical, and psychological health. Although writing is an inexpensive,

easy to administer form of therapy, there is no work investigating its effects on patients with seizures. The study will also explore patients' writing with the view to generate deeper insight and understanding of living with the individual conditions.

Patients will be recruited from the outpatient Neurology Clinic at the Royal Hallamshire Hospital, by responding to an advertisement on Social media webpages and by responding to information passed on from self-help organisations for epilepsy and NEAD. Patients must be over the age of 18 years old, diagnosed with epilepsy or NEAD and currently experience seizures.

This study is part of a PhD project at the University of Sheffield funded by the School of Medical Humanities and will be carried out between August 2015 and August 2017 at the Royal Hallamshire Hospital in Sheffield

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

The study should not raise any major ethical issues

Completion of the Neurological Disorders Depression Inventory for Epilepsy (NDDIE) and the Generalised Anxiety Disorder (GAD) questionnaire may suggest an existing psychiatric disorder. The patients' consultant (if known) and General Practitioner will be informed of any self-reported evidence of relevant mood or anxiety disorder.

Individuals with seizures have rated the topics patients will be writing about in the treatment writing condition as acceptable. Patients will be encouraged to contact the research team if they experience any difficulties and reminded they have the right to withdraw without giving a reason. This will not affect any health care services provided to them.

Whilst feedback on the writing tasks we are going to use in this study from patients with seizures has suggested that the tasks are acceptable, participants could write about upsetting material. We will provide patients agreeing to take part in this study telephone advice during office hours if they have any concerns and we will provide them with information about helplines for patients with seizures and individuals with personal or mental health problems.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- Case series/ case note review
- Case control
- Cohort observation
- Controlled trial without randomisation
- Cross-sectional study
- Database analysis
- Epidemiology
- Feasibility/ pilot study
- Laboratory study
- Metanalysis
- Qualitative research
- Questionnaire, interview or observation study
- Randomised controlled trial
- Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The study will evaluate the effects of a writing intervention on: the frequency of seizures and health-related quality of life in patients diagnosed with epilepsy or NEAD.

A11. What are the secondary research questions/objectives if applicable? Please put this in language comprehensible to a lay person.

Secondary aims are:

- 1) to investigate the effect on healthcare usage, levels of anxiety and depression, illness perception and seizure severity
- 2) to investigate the illness narrative i.e. the patient's writings, using qualitative techniques with the view to generate a better understanding of what it is like to live with epileptic or nonepileptic seizures.

A12. What is the scientific justification for the research? Please put this in language comprehensible to a lay person.

Epilepsy and nonepileptic attack disorder (NEAD) are chronic conditions characterised by recurrent seizures and impaired consciousness. Both disorders are further associated with an increased risk of developing other psychiatric symptoms and reduced quality of life. Previous research has demonstrated in patients with other chronic illnesses (such as, cancer, HIV and fibromyalgia) that writing about thoughts and emotions, compared to writing about emotional devoid topics, can be effective in symptom management and improve physical and psychological health. Although writing is an inexpensive, easy to administer form of therapy there is no work investigating its effects on patients with seizures.

This study will help to evaluate the health effects of a writing intervention, which could later be used as a supplement to therapy or as a stand-alone self-help tool for patients with seizures. We will also use qualitative methods to explore patients' writings to gain a deeper understanding of the subjective experience of living with seizures. This knowledge is currently lacking from the literature.

A13. Please summarise your design and methodology. It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.

Hypothesis: We hypothesize that patients randomised to the treatment writing condition will show greater improvements in psychological and physical health compared to patients in the control-writing group.

Design: The study will be a randomised controlled trial. Patients will be randomised into two groups, a therapeutic writing intervention and a controlled writing intervention. A controlled group is necessary to control for any effects of the writing process itself, such as the allocation of time to reflect. Patients will be assessed at baseline, one- and three-month follow-up following the last writing session. Although patients who have consented to this may later be contacted for future studies. To reduce research and participant bias, the study will be single blinded, patients will not be aware of whether they were given the writing tasks designed to have therapeutic effects of the tasks not likely to be associated with therapeutic benefit. The student researcher will be blinded to the diagnosis (epilepsy or NEAD) whilst carrying out the narrative analysis. Patients will be allocated a unique ID. Only the principle investigator will have this key.

Procedure for outpatient clinic recruitment: Patients attending the neurology outpatient clinic with a confirmed diagnosis of either epilepsy or NEAD will be invited to take part in the study. The diagnosis will be based on the clinical judgment of a consultant neurologist. Patients will receive via post an invitation letter and patient consent form including study purposes and procedure at least 48 hours in advance of their appointment in the neurology outpatient clinic.

In addition to recruitment from the outpatient clinic, we will approach patients with seizures under the current care of a Consultant Neurologist at Sheffield Teaching Hospitals NHS Foundation Trust about this study by letter. We will send information about the study and a return slip. Patients will be encouraged to contact the research team if they want to take part or find out more about the study.

Procedure for social media recruitment / recruitment via self-help groups: An invitation letter and patient consent form including study purposes and procedure will be placed on social media or self-help group webpages. Patients must have a diagnosis of either epilepsy or NEAD. Potential participants will be asked to provide consent for the research team to contact their doctor and seek confirmation of their diagnoses. .

All potential participants will be screened for their suitability to take part in the study. This will be based on the

exclusion/inclusion criteria. Suitable participants will have an opportunity to discuss any questions that may have arisen from reading the information sheet with a member of the research team (when they come to the outpatient clinic in Sheffield or by telephone or email). Patients willing to take part in the project will sign a consent form and complete a set of baseline questionnaires (at the time of their hospital appointment with the neurologist if recruited from outpatient clinic), assessing their demographic characteristics, quality of life, physical and mental health, anxiety, depression, seizure frequency and severity, illness perception and healthcare usage.

Intervention: Patients who have provided baseline data will receive the writing intervention according to the random allocation to treatment or control group. Patients can complete the intervention by either using pen and paper and sending us their writings by free post, or by typing their writing and submitting it to us using a specific website address. This is a home-based study, as the writing intervention will be completed at the patients' home. All communication between the research team and patient will be achieved through email, telephone or post (except for patients recruited from the outpatient clinic as the initial meeting will take place at the Royal Hallamshire Hospital).

The writing intervention is time limited. Patients are asked to complete four writing sessions over two weeks, ideally on consecutive days. Patients are asked to write for a minimum of 20 minutes per writing session. Each writing session has a clearly defined set of instructions that the patients should write about. After each writing session patients are asked to record the time and date they started and finished writing. They are also required to complete a questionnaire asking them to reflect on their writing experience. This will monitor progress and adherence.

Patients are given a writing intention document asking when and where they intend to complete each writing session. Patients are provided contact details of the researchers and organisations should they experience any difficulties with the intervention.

During the study patients may be contacted a maximum of up to two times by phone, two times by email and one letter to monitor progress and adherence. Follow up will be arranged for both groups one and three -month following the last writing session. Patients will be contacted by post, telephone or email depending on consent and preference. The follow up assessment will involve completing the same outcome measures as the baseline measures.

Timetable:

July 2015 – October 2015 – Internal review and ethics approval
 October 2015 – November 2016 –Data collection
 December 2016 – March 2017 – Data analysis and interpretation
 April 2017 – August 2017 – Write up and dissemination of findings

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- Design of the research
- Management of the research
- Undertaking the research
- Analysis of results
- Dissemination of findings
- None of the above

Give details of involvement, or if none please justify the absence of involvement.

Advice has been taken from patients who experience seizures. We asked patients to rate the acceptability of seven possible topics that participants could write about for each of the four writing session. The final four was selected based on their responses. Patients were also asked about acceptability of the intervention protocol i.e. length of writing periods, setting of the intervention.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- Blood
- Cancer
- Cardiovascular
- Congenital Disorders
- Dementias and Neurodegenerative Diseases
- Diabetes
- Ear
- Eye
- Generic Health Relevance
- Infection
- Inflammatory and Immune System
- Injuries and Accidents
- Mental Health
- Metabolic and Endocrine
- Musculoskeletal
- Neurological
- Oral and Gastrointestinal
- Paediatrics
- Renal and Urogenital
- Reproductive Health and Childbirth
- Respiratory
- Skin
- Stroke

Gender: Male and female participants

Lower age limit: 18 Years

Upper age limit: No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

1. Diagnosis of epilepsy (and no additional NEAD) or NEAD (and no additional epilepsy)
2. Over the age of 18 years
3. Able to complete the self-report questionnaires without any help and literate in English.
4. Able to give informed consent

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

1. Patients likely to have mixed seizure disorders (epilepsy and NEAD)
2. People who are unable to give informed consent
3. People who are unable to complete the self-report questionnaires and illiterate in English
4. People who have not experienced a seizure within the last 12 months
5. People whose diagnosis remains uncertain

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. These include seeking consent, interviews, non-clinical observations and use of questionnaires.

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Screening and seeking informed consent	1	0	10 minutes	A member of the research team will go through the screening questions and ask the participant to sign the consent form. Depending on recruitment this will either be completed during the patient's outpatient appointment or the documents will be emailed to patients.
Self-report questionnaires	3	0	25-35 minutes	Patients will complete the baseline set of self-report questionnaires. The patient will further complete the same set of self-report questionnaires at one and at three months after the last writing session. This will take place at the patient's home without a member of the research team present.
Self report questionnaire - monitor progress	4	0	5 minutes	Questionnaire after each individual writing session to monitor progress. This will take place at the patient's home without a member of the research team present.
Writing session prompt	4	0	5 minutes	A member of the research team will contact the patient a maximum of two phone calls, two emails, 1 letter to monitor progress and adherence.

A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol. *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Writing intervention	4	0	at least 20 minutes	This will take place at the patient's home without a member of the research team present. Ideally the four sessions will be completed on consecutive days, although completed within two weeks

A20. Will you withhold an intervention or procedure, which would normally be considered a part of routine care?

Yes No

A21. How long do you expect each participant to be in the study in total?

Each patient will be involved in the study for a maximum of 15 weeks in total (maximum of 2 weeks to complete the writing intervention plus 13 week for follow-up). However patients maybe contacted in the future for longer term follow up.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes

to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Although the writing topics have been found to be acceptable, some patients may choose to write about upsetting or embarrassing events that may result in distress or discomfort. To minimise this risk we have taken several measures.

- (1) We ask patients to write about events or situations they can handle right now
- (2) We ask patients to complete the writing sessions in their own homes; a safe, comfortable and familiar environment
- (3) A monitoring aid will be used, as patients are asked to complete a questionnaire after every writing session.
- (4) Patients can stop writing at any time and withdraw from the study, which will not affect the quality of care they receive.
- (5) Patients will be encouraged to contact the research team if they experience any difficulties with the study measures or the intervention.
- (6) We will provide patients with details of services and organisations they can contact for further support.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

Yes No

If Yes, please give details of procedures in place to deal with these issues:

Yes. Although the writing topics have been found to be acceptable, some patients may choose to write about upsetting or embarrassing events that may result in distress or discomfort. To minimise this risk we have taken several measures.

- (1) We ask patients to write about events or situations they can handle right now
- (2) We ask patients to complete the writing sessions in their own homes; a safe, comfortable and familiar environment
- (3) A monitoring aid will be used, as patients are asked to complete a questionnaire after every writing session.
- (4) Patients can stop writing at any time and withdraw from the study, which will not affect the quality of care they receive.
- (5) Patients will be encouraged to contact the research team if they experience any difficulties with the study measures or the intervention.
- (6) We will provide patients with details of services and organisations they can contact for further support.

A24. What is the potential for benefit to research participants?

Patients will contribute to the evaluation of a brief and time-limited writing intervention for reduction of symptoms associated with seizure disorders. If the study provides evidence that the writing intervention is effective, it may be used as a supplement to therapy or as a stand-alone self-help tool for patients with seizures. Similarly, it could be further applied to patients with other neurological- and functional neurological- disorders.

Insights from patients' illness narrative will further contribute to a better understanding of what it is like to live with the individual condition, which may highlight differences between the conditions.

A25. What arrangements are being made for continued provision of the intervention for participants, if appropriate, once the research has finished? May apply to any clinical intervention, including a drug, medical device, mental health intervention, complementary therapy, physiotherapy, dietary manipulation, lifestyle change, etc.

If patients request they will be sent a newsletter of the study outcome.

A26. What are the potential risks for the researchers themselves? (if any)

This study is not associated with any potential risks to the researchers.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

For patients recruited from the outpatient clinic: Their consultant neurologist will identify patients. Suitable patients who have been invited for an appointment at the neurology outpatient clinic will be sent an invitation letter with an information sheet about the study via post at least 48 hours prior to their appointment at the clinic.

For patients recruited from social media / self-help group websites: Patients will volunteer.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

Yes No

Please give details below:

For patients recruited from the outpatient clinic: This will be done by the patients' neurologist, not the researcher. The researcher will have no access to identifiable personal information until participants have consented to take part in the research study.

For participants recruited from social media websites: researchers talk to potential participants over the telephone to assess that they meet inclusion and exclusion criteria.

A27-3. Describe what measures will be taken to ensure there is no breach of any duty of confidentiality owed to patients, service users or any other person in the process of identifying potential participants. *Indicate what steps have been or will be taken to inform patients and service users of the potential use of their records for this purpose. Describe the arrangements to ensure that the wishes of patients and service users regarding access to their records are respected. Please consult the guidance notes on this topic.*

Any screening and reviewing of personal information will be done by the patients' neurologist (a member of the patients existing clinical care team) and not the researcher. The researcher will have no access to identifiable personal information until participants have consented to take part in the research study. Self-report questionnaire data will be stored in anonymised form, patients will only be identified by their study number. Any extracts from narratives used in publications or reports will be pseudonymised.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

Yes No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

Yes No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

An invitation letter will be posted on the website (please see attached document). Social media websites will be used including Facebook and websites of Epilepsy Action, the Epilepsy Society and NEAD self-help groups.

A29. How and by whom will potential participants first be approached?

For patients recruited from the outpatient clinic: Patients will initially be sent an information sheet for the study at least 48 hours prior to their appointment in the neurology outpatient clinic. A member of the research team will approach the patient when they arrive for their appointment in the outpatient clinic, once the patient's consultant neurologist has confirmed that the patient may be suitable for participation in the study.

For patients recruited from social media / self-help websites: An invitation letter and patient consent form including study purposes and procedure will be placed on social media websites for epilepsy and NEAD.

A30-1. Will you obtain informed consent from or on behalf of research participants?

Yes No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

At the beginning of the study a member of the research team will go through the information sheet and the consent form with the patient, answer any questions and address any concerns they may have. If they wish to take part in the study, the patient will be asked to sign the consent form. The consent form outlines the fact that the data will be anonymised and kept confidential, that patient can withdraw from the study at any time. Potential participants who have learned about the study on websites will be encouraged to ring the researcher to find out more about the study and to allow the researcher to ensure they meet inclusion and exclusion criteria. A patient information sheet and consent form would be sent out to individuals wanting to go ahead. The writing task leaflet would be sent out when consent and baseline self-report questionnaires have been returned.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

Yes No

A31. How long will you allow potential participants to decide whether or not to take part?

For patients recruited from the outpatient clinic: Information sheet detailing the purposes and procedures of the study will be sent to patients at least 48 hours in advance of their appointment in the neurology outpatient clinic. This will allow potential participants at least 48 hours to decide whether or not they wish to take part in the study.

For patients recruited from social media/ self-help websites: The advertisement for the study will remain on the research forum webpage for the duration of patient recruitment.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

Yes
 No
 Not Known

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?(e.g. translation, use of interpreters)

The inclusion criterion specifies that only participants capable of completing the self-report questionnaires without help and are literate in English can take part in the study. The research team does not have sufficient resources to provide validated translations or interpreters and patients who do not adequately understand written English will therefore be excluded from the study.

A34. What arrangements will you make to ensure participants receive any information that becomes available during the course of the research that may be relevant to their continued participation?

For patients recruited from the outpatient clinic: Completion of the self-report questionnaires assessing psychopathology (namely anxiety and depression) may reveal existing psychiatric disorder. We will seek consent from participants to inform their General Practitioner (and if relevant, their Neurologist) about such findings. The participants' GP (and if possible their Neurologist) would be informed of any self-reported evidence of affective disorder.

All patients: Patients will be provided with details of services and organisations that can offer further support and encouraged to contact them, if necessary. Patients will be made aware that they are free to withdraw from the study at any time, without giving a reason and without their medical care being affected.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? Tick one option only.

- The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- The participant would continue to be included in the study.
- Not applicable – informed consent will not be sought from any participants in this research.
- Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? (Tick as appropriate)

- Access to medical records by those outside the direct healthcare team
- Electronic transfer by magnetic or optical media, email or computer networks
- Sharing of personal data with other organisations
- Export of personal data outside the EEA
- Use of personal addresses, postcodes, faxes, emails or telephone numbers
- Publication of direct quotations from respondents
- Publication of data that might allow identification of individuals
- Use of audio/visual recording devices
- Storage of personal data on any of the following:

- Manual files including X-rays
- NHS computers
- Home or other personal computers
- University computers
- Private company computers
- Laptop computers

Further details:

For patients recruited from the outpatient clinic: If a participant has consented to the researcher accessing their medical records, the researcher may access these to clarify details that may be needed for the study.

All patients: As qualitative research methods will be used, any direct quotes from patient's writings including names and locations will be pseudonymised. Storage of electronic files will be on NHS, Sheffield university computers and private laptop.

A37. Please describe the physical security arrangements for storage of personal data during the study?

Any paper records and patients' writings will be kept in a lockable cabinet, which can only be accessed by the chief investigator and the student researcher. Patients name will not appear on these records as patients will only be identified by patient ID. The key for patient ID will be locked in another location, which the chief investigator will only be able to access.

Any anonymised electronic files will be stored on a private laptop (enabled with filevault for encryption and password protected), NHS or Sheffield University computer. The data will be saved on the University of Sheffield network with is password protected and encrypted using 128-bit Advanced Encryption Standard (AES).

The dedicated website patients can use and send their writings (as a pose to hand writing) will be password protected and encrypted on University of Sheffield network.

A38. How will you ensure the confidentiality of personal data? Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.

All data will be anonymised by coding the names of the patients by the researchers

A40. Who will have access to participants' personal data during the study? Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.

For patients recruited from the outpatient clinic: The chief investigator and the student researcher will have access to participants' personal data during the study, after consent has been obtained from the participant.

For patients recruited from social media/self help websites: researchers will only have access to personal information patients send us and information from their doctor (provided with the participant's consent).

Storage and use of data after the end of the study**A41. Where will the data generated by the study be analysed and by whom?**

The data will be analysed only by members of the research team on the Royal Hallamshire Hospital NHS and University of Sheffield site.

A42. Who will have control of and act as the custodian for the data generated by the study?

Title Forename/Initials Surname
Professor Markus Reuber

Post	Reader and Honorary Consultant
Qualifications	MD, PhD, FRCP
Work Address	Academic Neurology Unit, Royal Hallamshire Hospital Glossop Road Sheffield
Post Code	S10 2JF
Work Email	m.reuber@sheffield.ac.uk
Work Telephone	01142268763
Fax	

A43. How long will personal data be stored or accessed after the study has ended?

- Less than 3 months
- 3 – 6 months
- 6 – 12 months
- 12 months – 3 years
- Over 3 years

If longer than 12 months, please justify:

The data will be stored for 15 years to allow the researchers to answer questions about publications related to this research and to perform possible additional analyses on the data

A44. For how long will you store research data generated by the study?

Years: 15

Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. Say where data will be stored, who will have access and the arrangements to ensure security.

All data will be stored on Sheffield University archive corporate system. This can only be accessed by members of the research team.

INCENTIVES AND PAYMENTS**A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?**

- Yes No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

- Yes No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

- Yes No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

Yes No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

Yes No

Please give details, or justify if not registering the research.

This project will be registered on the STH R&D research database.

Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? Tick as appropriate:

- Peer reviewed scientific journals
- Internal report
- Conference presentation
- Publication on website
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- No plans to report or disseminate the results
- Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Any direct quotes from patient's writings will be pseudonymised.

A53. Will you inform participants of the results?

Yes No

Please give details of how you will inform participants or justify if not doing so.

Participants will be asked whether they wish to be informed of the results of the study. A record of those participants who wish to be informed about the results will be kept and they will be sent a summary of the findings once the study is completed.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? Tick as appropriate:

- Independent external review
- Review within a company
- Review within a multi-centre research group
- Review within the Chief Investigator's institution or host organisation
- Review within the research team
- Review by educational supervisor
- Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:

This study was independently scientifically reviewed by several members of staff of the University of Sheffield. The reviewers' reports are enclosed.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? Tick as appropriate:

- Review by independent statistician commissioned by funder or sponsor
- Other review by independent statistician
- Review by company statistician
- Review by a statistician within the Chief Investigator's institution
- Review by a statistician within the research team or multi-centre group
- Review by educational supervisor
- Other review by individual with relevant statistical expertise
- No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

Title	Professor
Forename/Initials	Markus
Surname	Reuber
Department	Neurosciences
Institution	Sheffield Teaching Hospitals NHS FT
Work Address	Academic Neurology Unit, Royal Hallamshire Hospital
	Glossop Road
	Sheffield
Post Code	S10 2JF
Telephone	01142268763
Fax	
Mobile	
E-mail	m.reuber@sheffield.ac.uk

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

The primary outcome measure is self-reported physical and psychological health

A58. What are the secondary outcome measures? (if any)

NA

A59. What is the sample size for the research? How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.

Total UK sample size: 180
 Total international sample size (including UK): 180
 Total in European Economic Area: 180

Further details:

Given the time frame of the study and the number of patients attending the clinic and number of registered patients on the Epilepsy Action forum, the researchers anticipate recruiting approximately 90 patients with seizures in each group (control and therapy writing conditions) (180 in total). Based on attrition from previous studies using writing therapy the expected drop out rate is about 20%. This will result in a final sample size of approximately 75 participants in each group, i.e. 150 in total.

A60. How was the sample size decided upon? If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.

A power analysis based on Cohen's (1988) recommendation was used. The power calculation was based on meta-analyses investigating health benefits of expressive writing. One review used data from 9 clinical samples reporting an effect size of $d = 0.19$ the other looked at 13 studies of healthy participants reporting an effect size of $d = 0.47$. In order to achieve 80% power with a sample size of 75 (same subjects) and the significant level of $\alpha = 0.05$, the required effect size will be 0.33. Based on the findings of previous studies, the researchers anticipate that this is realistic.

A61. Will participants be allocated to groups at random?

Yes No

If yes, please give details of the intended method of randomisation:

Patients will be allocated to either the treatment or control intervention group by their unique identification number prepared by the researcher. Randomisation will be achieved using an online randomisation tool.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

1. To test randomisation: Any differences in demographics between conditions (control and therapy writing) and seizure disorders (NEAD and epilepsy) will be verified by a series of t-tests for continuous data and chi-square tests for categorical data

2. Primary aim: Evaluate the effects of a writing intervention on frequency of seizures and quality of life.

Data will be obtained from patients at three time points, T0 (at baseline), T1 (one month following the last writing session) and T2 (three months following the last writing session). A repeated measures analysis of variance (ANOVA) will be conducted in relation to primary and secondary outcome measures with time of assessment (T0 versus T1, T0 versus T2) being the within subjects factors and group (control versus therapy) being the between subjects factor. This will be analysed as patients all patients with seizures, and for individual conditions (epilepsy and NEAD).

Analyses will be controlled for by intention-to-treat carrying the last measurement (T0, T1, T2) forward.

3. Secondary aim: Investigate the patient's writings using narrative analysis, a qualitative technique with the view to generate understanding of what it is like to live with seizures. This approach focuses the diegetic levels of the texts; use of tense; lexis; pronouns; the construction and presentation of identity; the negotiation of temporality; and the relationship between memory, history, and the present.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Ian	Brown
Post	Clinical Psychologist and Honorary Researcher		
Qualifications	CPsychol AFBPsS		
Employer	University of Sheffield		
Work Address	Clinical Psychology Unit Department of Psychology, University of Sheffield, Western Bank, Sheffield		
Post Code	S10 2TN		
Telephone			
Fax			
Mobile			
Work Email	ian.brown@sheffield.ac.uk		

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status: <input checked="" type="radio"/> NHS or HSC care organisation <input type="radio"/> Academic <input type="radio"/> Pharmaceutical industry <input type="radio"/> Medical device industry <input type="radio"/> Local Authority <input type="radio"/> Other social care provider (including voluntary sector or private organisation) <input type="radio"/> Other	Commercial status: <input type="radio"/> Non-Commercial <input type="radio"/> Commercial
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If Other, please specify:

Contact person

Name of organisation	Sheffield Teaching Hospital NHS Foundation Trust
Given name	Simon
Family name	Heller
Address	Clinical Research Office, Sheffield Teaching Hospital NHS Foundation Trust, Glossop Road
Town/city	Sheffield
Post code	S10 2JF
Country	UNITED KINGDOM
Telephone	
Fax	
E-mail	s.heller@sheffield.ac.uk

Is the sponsor based outside the UK?

Yes No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- Funding secured from one or more funders
 External funding application to one or more funders in progress
 No application for external funding will be made

What type of research project is this?

- Standalone project
 Project that is part of a programme grant
 Project that is part of a Centre grant
 Project that is part of a fellowship/ personal award/ research training award
 Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? Please give details of subcontractors if applicable.

Yes No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

Yes No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title Forename/Initials Surname
	Mrs Samantha Lewis
Organisation	Sheffield Teaching Hospitals NHS Foundation Trust, Research Department
Address	D49, D Floor, Clinical Research Office, Royal Hallamshire Glossop Road Sheffield
Post Code	S10 2JF
Work Email	samantha.lewis@sth.nhs.uk
Telephone	01142265942
Fax	01142265937
Mobile	

Details can be obtained from the NHS R&D Forum website: <http://www.rdforum.nhs.uk>

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/10/2015

Planned end date: 30/11/2016

Total duration:

Years: 1 Months: 1 Days: 30

A71-1. Is this study?

- Single centre
 Multicentre

A71-2. Where will the research take place? (Tick as appropriate)

- England
 Scotland
 Wales
 Northern Ireland
 Other countries in European Economic Area

Total UK sites in study 1

Does this trial involve countries outside the EU?

- Yes No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:

- NHS organisations in England 1
 NHS organisations in Wales
 NHS organisations in Scotland
 HSC organisations in Northern Ireland
 GP practices in England
 GP practices in Wales
 GP practices in Scotland
 GP practices in Northern Ireland
 Social care organisations
 Phase 1 trial units
 Prison establishments
 Probation areas
 Independent hospitals
 Educational establishments
 Independent research units
 Other (give details)

Total UK sites in study: 1

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

Yes No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The study will be monitored and audited as per STH SOPs

A75-1. What arrangements will be made to review interim safety and efficacy data from the trial? Will a formal data monitoring committee or equivalent body be convened?

There will be no interim analysis.

If a formal DMC is to be convened, please forward details of the membership and standard operating procedures to the Research Ethics Committee when available. The REC should also be notified of DMC recommendations and receive summary reports of interim analyses.

A75-2. What are the criteria for electively stopping the trial or other research prematurely?

N/A

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? Please tick box(es) as applicable.

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (NHS sponsors only)
 Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? Please tick box(es) as applicable.

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

- NHS indemnity scheme will apply (protocol authors with NHS contracts only)
 Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

- NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
 Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A77. Has the sponsor(s) made arrangements for payment of compensation in the event of harm to the research participants where no legal liability arises?

- Yes No

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

- Yes No Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

Research site		Investigator/ Collaborator/ Contact	
Institution name	NHS Sheffield Teaching Hospitals Foundation Trust	Title	Professor
Department name	Department of Neurology, Royal Hallamshire Hospital	First name/ Initials	Markus
Street address	Glossop Road	Surname	Reuber
Town/city	Sheffield		
Post Code	S10 2JF		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
 - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
 - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
 - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
 - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
 - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. I understand that the main REC or its operational managers may share information in this application or supporting documentation with the Medicines and Healthcare products Regulatory Agency (MHRA) where it is relevant to the Agency's statutory responsibilities.
12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- Chief Investigator
- Sponsor
- Study co-ordinator
- Student
- Other – please give details
- None

Access to application for training purposes (Not applicable for R&D Forms)

Optional – please tick as appropriate:

I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature:

Print Name:

Date: (dd/mm/yyyy)

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

Please note: The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

Signature:

Print Name:

Post:

Organisation:

Date: (dd/mm/yyyy)

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

Signature:

Print Name:

Post:

Organisation:

Date: (dd/mm/yyyy)

