

BRAIN UK

Application Form

Version 2.0

Date: 01/04/2019

Please complete all sections of this form and send a signed electronic copy (with supporting documents) to brainuk@soton.ac.uk

Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
-	1.01	03/05/2016	C. Mitchell	Previously approved version under ethics ref: 14/SC/0098
-	2.0	01/04/2019	C. Mitchell	Simplified and clarified.

Contact Details:

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Name of Research Study:

Principal Investigator (PI) Contact Information

Name:	
Name of Organisation:	
Division or Department:	
Contact email:	Contact telephone:
Full Postal Address:	

Contact Person (if different from PI named above)

Name:	
Name of Organisation:	
Division or Department:	
Contact email:	Contact telephone:
Full Postal Address:	

Name of Research Governance Sponsor *:

**This is usually the institution where the research is taking place (not BRAIN UK). It is to ensure compliance with and support from the sponsoring local institute and needs to be done before the study becomes active.*

Has the study received a favourable opinion from a UK Research Ethics Committee? Yes/No

If 'yes' please provide a copy of the approval letter from the Ethics Committee.

Does the study intend to perform genetic analysis? Yes/No

If yes please provide details and include a consideration of the potential ethical implications and how these might be handled:

Has the study secured funding? Yes/No

If yes please provide the source and period of funding:

1. Details of tissue and/or data requirements

Please summarise the cases you require and include all of the following information:

- Number of cases
- Diagnosis
- Data relating to the cases that you require
- If you have identified potential cases, please provide the details

Number of cases: Either a specific number or range of the minimum to an “ideal” number

Diagnosis: describe in as much detail as possible, for example, using the diagnosis, historic or alternate names, any useful terms relatable to a neuropathological diagnosis or report, SNOMED number or other coding

Data: Information relating to the cases, if an important variable in your research

Cases identified: Potential candidates for the cases, please provide the details you have, such as, Participating Centre, contact name, laboratory numbers (if available).

Type of tissue required **Please highlight those that apply*

Post-mortem

Biopsy (from living patients)

Formalin Fixed Paraffin Embedded (FFPE)

Frozen

None (Data Only)

Other **Please specify*

2. Study Protocol

Please complete the sections below thoroughly and concisely. Omissions and incomplete sections will result in a delayed review process. If available, please also attach a copy of local or external peer review of the study. Please feel free to contact us for advice.

- **Study Title**
- **Contacts And Co-Investigators (If Applicable)**

Names, titles and contact information for:

- Investigators not already listed
- Addresses and contact information for all study sites

- **Lay Summary**

Please provide a brief summary (around 200 words) of the application in a form suitable for publication on the BRAIN UK website, using language easily understood by the public. The BRAIN UK website¹ provides guidance about writing a good lay summary.

- **Abbreviations**

- **Background**

- Literature review
- Clear explanation of research
- Potential benefits
- Feasibility/time scale

- **Aims**

Purpose of study

- **Study Design And Methods**

- Inclusion and exclusion criteria
- Methodology - use of tissue
- Justification for sample size

- **Analysis**

Statistical methods

- **Publication**

How will the findings be disseminated?

- **Further Work**

Highlight any proposed follow on work

- **References**

¹ [How to Write a Good Lay Summary](#)

3. BRAIN UK Terms and Conditions

I agree to the following:

1. I have read, understood and agree to the generic ethical approval conditions in Appendix 1.
2. The favourable ethical opinion from BRAIN UK is only applicable to the study detailed in the approved application and is only valid if these conditions and those outlined in Appendix 1 are met.
3. Tissue or data will be used solely for the purposes of the research study outlined in this protocol and only by those named in this application (or local researchers working under the direction of named individuals).
4. I will not pass on tissue or data to third parties unless it is part this study protocol or has the written permission of the supplying centre.
5. I will meet all costs relating to my request, such as retrieval of data, processing and transport of samples.
6. I will not exhaust material supplied as tissue blocks.
7. I assume all responsibility and risk for the receipt, storage, handling and use of all tissues received. BRAIN UK does not accept any responsibility for any injury, damages or loss incurred as a direct or indirect result of their use, or for the transportation of human tissues from the supplying centre to the Applicant (or any other recipient). BRAIN UK will not physically handle or transport any tissue on behalf of either a Participating Centre or a researcher.
8. Tissues are provided with no guarantee of their fitness for a particular application or purpose. BRAIN UK makes no guarantees as to the accuracy of any diagnosis or to the safety or integrity of any tissues released by any Participating Centre. BRAIN UK cannot guarantee that tissues are devoid of infectious agents, including prion disease.
9. Researchers will ensure that they comply with the Human Tissue Act², the Human Tissue Authority Codes of Practice and any other appropriate legislation dealing with the use of human tissue in research. Recipients outside of the UK will ensure that they comply with local laws and regulations.
10. I will ensure that staff are appropriately trained in and adhere to the dangers and procedures in handling human tissues, local conditions and Health and Safety regulations.
11. I will provide BRAIN UK with an annual report of research on this study.
12. On completion of the study, I will dispense with any remaining tissue as agreed in the Materials Transfer Agreement (MTA). If not specified in the MTA, I will contact the supplying centre to ask their requirements. I understand that the options will be to either: transfer the tissue back to the originating centre or to an alternative HTA-licensed establishment; apply for a HTA licence; apply for specific project approval from a Research Ethics Committee (REC); or to dispose of the human tissue. I will appropriately document the agreement.
13. Co-authorship of any resultant papers can be negotiated between the custodians of the originating archive(s), members of BRAIN UK and the Principal Investigator on a case-by-case basis.

² Either Human Tissue Act 2004 <http://www.legislation.gov.uk/ukpga/2004/30/contents> or Human Tissue (Scotland) Act 2006 <http://www.legislation.gov.uk/asp/2006/4/contents>

14. I will acknowledge BRAIN UK and each NHS Trust that provided tissue in any publication arising from its use, with the suggested wording:

'Tissue samples were obtained from [name(s) of NHS Trust(s)] as part of BRAIN UK, which is funded by the Medical Research Council and Brain Tumour Research.'

Signature of Principal Investigator*	
Date	

For completion by the Head of Department where research primarily takes place.

I confirm that I am aware of this study and that the necessary resources are available for its completion.

Name of Head of Department	
Signature of Head of Department*	
Date	

*Scanned signatures are acceptable

BRAIN UK and the network of Participating Centres aim to exercise responsible stewardship of archived neurological tissues and to maximize their benefits to research. The information requested is to enable all applications to be considered fairly and consistently and to fulfil our ethical obligations. All information is treated in the strictest confidence and is processed in accordance with the Data Protection policies of the University of Southampton.

4. Appendix 1 - NHS Health Research Authority Conditions of Ethical Approval

Studies fulfilling the approval criteria will be able to study tissue derived through BRAIN UK without the requirement for their own ethical approval. Below is an extract of the NHS Health Research Authority Conditions of Ethical Approval for BRAIN UK that are also applicable to Applicants. For the purposes of this application the term “Bank” is interpreted to mean BRAIN UK and “Committee” is the BRAIN UK Committee.

4. “Generic ethical approval for projects receiving tissue

- 4.1. Samples of human tissue or other biological material may be supplied and used in research projects to be by researchers and research institutions external to the Bank within the UK and in other countries in accordance with the following conditions.
 - 4.1.1. The research project should be within the fields of medical or biomedical research described in the approved application form.
 - 4.1.2. The Bank should be satisfied that the research has been subject to scientific critique, is appropriately designed in relation to its objectives and (with the exception of student research below doctoral level) is likely to add something useful to existing knowledge.
 - 4.1.3. Where tissue samples have been donated with informed consent for use in future research (“broad consent”), the Bank should be satisfied that the use of the samples complies with the terms of the donor consent.
 - 4.1.4. All samples and any associated clinical information must be non-identifiable to the researcher at the point of release (i.e. anonymised or linked anonymised).
 - 4.1.5. Samples will not be released to any project requiring further data or tissue from donors or involving any other research procedures. Any contact with donors must be confined to ethically approved arrangements for the feedback of clinically significant information.
 - 4.1.6. A supply agreement must be in place with the researcher to ensure storage, use and disposal of the samples in accordance with the HTA Codes of Practice, the terms of the ethical approval and any other conditions required by the Bank.
- 1.1. A research project in the UK using tissue provided by a Bank in accordance with these conditions will be considered to have ethical approval from the Committee under the terms of this approval. In England, Wales and Northern Ireland this means that the researcher will not require a licence from the Human Tissue Authority for storage of the tissue for use in relation to this project.
- 1.2. The Bank may require any researcher to seek specific ethical approval for their project. Such applications should normally be made to the Committee and booked via the NRES Central Allocation System.
- 1.3. A Notice of Amendment form should be submitted to seek the Committee’s agreement to change the conditions of generic approval. “

1.