

**BRAIN UK**  
**UK Brain Archive Information Network**

**TISSUE REQUEST FORM**

***Version 1.4***

***Date: 11 February 2011***

## **GUIDANCE NOTES**

Please complete all sections of this form and send an electronic and a signed printed copy (with supporting documents) to:

Mr Neil Bailey  
Division of Clinical Neurosciences  
School of Medicine  
University of Southampton  
South Academic Block, Mailpoint 806  
Southampton General Hospital  
Tremona Road  
Southampton  
SO16 6YD

Telephone: 07917 185 017  
Fax: 023 8079 4542  
e-mail: [N.E.Bailey@southampton.ac.uk](mailto:N.E.Bailey@southampton.ac.uk)  
Website: <http://www.brain-uk.org>

If you would like further information or clarification then please do not hesitate in contacting us.

### **Check list of supporting documents which should accompany application:**

	<b>Yes</b>	<b>N/A</b>
Study protocol (see Appendix 3)	<input type="checkbox"/>	
Copy of independent peer review (if available)	<input type="checkbox"/>	<input type="checkbox"/>
Copy of ethical approval letter (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>
List of co-investigators (if applicable)	<input type="checkbox"/>	<input type="checkbox"/>

**1. Principal Investigator contact information**

*Name of Organisation*

*Division or Department*

*Title*  *Surname*

*Forename(s)*

*Contact Telephone*

*Contact e-mail*

*Full Postal Address*

Contact Person (if different from PI named above)

*Name of Organisation*

*Division or Department*

*Title*  *Surname*

*Forename(s)*

*Contact Telephone*

*Contact e-mail*

*Full Postal Address*

**2. Study Details**

*Name of Research Study*

*Name of Study Sponsor\**

*\*Please note that BRAIN UK does not act as sponsor for research*

**Please attach the study protocol (as outlined in Appendix 3) and, if available, a copy of local or external peer review of the study.**

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**

Is it intended to use supplied material for the purposes of genetic analysis? Yes  No

If yes please provide details including potential ethical implications:

Is the Research Study to take place solely at the Institution named above? Yes  No

**If 'no' please provide the names, contact details and locations of all co-investigators on a separate sheet**

Has the proposed study secured funding? Yes  No

Source of Funding

Period of Funding

#### 4. Details of tissue requirements

Please summarise the cases you require (diagnosis, SNOMED number or equivalent if known, preferred format and quantity). Please also include information relating to patient sex and/or age at death if this is likely to be an important variable in your research:

Paraffin embedded tissue blocks will only be provided on the understanding that they are not to be exhausted. They must be returned in accordance with the material transfer agreement with the provider, and at the latest within three months of completion of the study. Unstained mounted sections may be provided with the agreement with each participating centre, but may incur an additional cost.

## DECLARATION BY PRINCIPAL INVESTIGATOR

I agree the following:

1. The tissue will be used solely for the purposes of the research study outlined in the protocol and only by those named in the application (or researchers working under the direction of named individuals).
2. I will not to pass on tissue to another user without the written permission of the participating centre from which such material originated.
3. I undertake to meet the transport and retrieval costs relating to my request.
4. I will not exhaust material supplied as tissue blocks, and will return unused tissue material to the supplying centre as agreed in the Materials Transfer Agreement (or earlier if requested by the centre).
5. I have read, understood and agree to the Terms and Conditions in Appendix 1.
6. I agree to provide *BRAIN UK* with an annual report of research on this study.
7. I understand that *BRAIN UK* ethical approval is only valid for this study if these conditions and those outlined in Appendix 2 are met.
8. I will acknowledge *BRAIN UK* and each participating centre from which tissue has been provided, in any publication arising from its use with the following wording:

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

Signature of Principal Investigator

Date

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### FOR COMPLETION BY HEAD OF DEPARTMENT WHERE RESEARCH WILL PRIMARILY TAKE 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

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*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 has been asked for to enable all requests to be considered fairly and consistently and to ensure best practice. All information is treated in the strictest confidence and will be processed in accordance with the Data Protection policies of the University of Southampton.*

## APPENDIX 1 - TERMS AND CONDITIONS

*Version 1.6 11 February 2011*

### Applications

1. Applicants must ensure that their applications to *BRAIN UK* for human tissue (and related clinical information) provide the following information:
  - details of their proposed study in the fields of medical or biomedical research (see Appendix 3 for details)
  - a copy of any local or external scientific review that has been undertaken on the the research proposal
  - a completed tissue request form
  - where the Applicant proposed activities outside of England, Wales and Northern Ireland, confirmation that tissues supplied to the Applicant will be used in accordance with local laws and regulations.
2. Researchers should satisfy *BRAIN UK* and participating centres that the project they submit is both ethically and scientifically justified. Those researchers already in receipt of Ethical Approval from a UK Research Ethics Committee should submit copies of their ethical application and approval together with their *BRAIN UK* application. The generic ethical approval granted to *BRAIN UK* will only be applicable to the study as detailed in the approved application.
3. Any human tissue or data released under the *BRAIN UK* programme are for the sole use of the Applicant's study as described in the application, under the supervision of a Principal Investigator approved by *BRAIN UK*. Work, outside the remit of the Applicant's original study protocol will require a new application or study amendment to be submitted to *BRAIN UK*.
4. Human tissue or data must not be passed onto third parties unless it is part of a study protocol approved by *BRAIN UK* and with the express permission of the custodians of the originating archive.
5. It is the responsibility of researchers to ensure that they comply with the Human Tissue Act and the Human Tissue Authority Codes of Practice or any other appropriate legislation dealing with the use of human tissue in research. HTA licences are not normally required to store tissue for use in a project approved by an NHS Research Ethics Committee, in accordance with and for the duration of the ethical approval.
6. The Applicant will ensure that any human tissue that remains after the completion of a project should be returned to the originating archive in the first instance and appropriately documented. Where this is not possible, or it has been agreed with the originating archive, tissues, and derivatives thereof (e.g. stained sections) must be stored in premises with an appropriate licence from the Human Tissue Authority or disposed of in accordance with Human Tissue Authority Codes of Practice. Recipients will also ensure that, where they lie outside of England, Wales and Northern Ireland, tissues supplied will be used in accordance with local laws and regulations.
7. The Applicant must ensure that any human tissue and any associated clinical information provided under the *BRAIN UK* programme will be unidentifiable to individuals handling the tissue.
8. Tissue will not be released to any project requiring further data or tissue from donors. Any contact with donors or their next of kin must be confined to ethically approved arrangements for the feedback of clinically significant information. Under such circumstances, additional ethical approval must be sought from the Southampton and

South West Hampshire Research Ethics Committee B using the Central Allocation System.

9. Any human tissue released to the Applicant under the *BRAIN UK* programme must be subject to a written supply agreement between the Applicant and the original holder of archived tissue to ensure storage, use, disposal and/or return of the samples in accordance with the HTA Codes of Practice and subject to any applicable terms of the ethical approval and any other conditions as required by *BRAIN UK* or the local custodians of the tissue. Notification will be required if tissue is to be exported outside of the UK.
10. All costs incurred due to the retrieval, processing and transportation of tissue and any other costs associated with the study will be met by the investigator's grant fund.
11. The Applicant must acknowledge the contribution of *BRAIN UK* and the NHS Trust(s) from which such tissues originate in all publications resulting from the use of such human tissue using the following recommended wording:

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

Co-authorship of any resultant papers will be negotiated between the custodians of the originating archive, members of *BRAIN UK* and the Principal Investigator of that particular research study on a case-by-case basis.

12. *BRAIN UK* takes no responsibility for the transportation of human tissues from the originating archive 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.
13. *BRAIN UK* makes no guarantees or representations as to the accuracy or validity of any diagnosis attached to any particular tissue provided by a participating centre, or as to the safety or integrity of any human tissues released by any participating centre. *BRAIN UK* can offer no guarantee that formalin-fixed tissues are devoid of infectious agents such as those associated with prion disease.
14. It is the responsibility of the Applicant to ensure that staff are appropriately informed and trained in relation to the dangers and procedures in the handling of human tissues and that they are trained in, and adhere to, local conditions and Health and Safety regulations.
15. Tissues are provided with no guarantee of their fitness for a particular application or purpose. No responsibility will be taken by *BRAIN UK* for any injury, damages or loss that may as a direct or indirect result of their use.
16. The Applicant agrees to assume all responsibility and risks for the receipt, storage, handling and use of all tissues obtained from those centres participating in the *BRAIN UK* network programme.

## APPENDIX 2 - GENERIC ETHICAL APPROVAL

Studies fulfilling the following core criteria will be able to proceed with tissue(s) derived through the *BRAIN UK* network of participating centres without the requirement for your own ethical approval:

1. The research project should be within the fields of medical or biomedical research as described in the Tissue Request Form and supporting Study Protocol
2. *BRAIN UK* will need to be satisfied that the research has been subjected 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
3. 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. Samples will not be released to any project requiring any further data or tissue from donors or their relatives or involving any other research procedures not detailed in the Tissue Request Form or supporting Study Protocol
5. Any contact with donors or their relatives **must be** confined to ethically approved arrangements for the feedback of clinically significant information
6. A supply agreement must be in place between the researcher and the centre providing tissue(s) to ensure use, storage and disposal of samples in accordance with the HTA Codes of Practice, the terms of the Ethical Approval or any other conditions required by *BRAIN UK*

A research project in the UK using tissue provided through the *BRAIN UK* network of participating centres will be deemed to have Ethical Approval from the Southampton and South West Hampshire Research Ethics Committee 'B' under the terms of their approval for *BRAIN UK*. In England, Wales and Northern Ireland this means that the researcher will not require a licence from the Human Tissue Authority for storage of tissue in relation to this project for its stated duration.

***BRAIN UK* may require any researcher to seek specific Ethical Approval for their project. Such applications should normally be made to the Southampton and South West Hampshire Research Ethics Committee 'B' and booked via the NRES Central Allocation System.**

For further information and guidance in relation to the granting of Generic Ethical approval for your project please contact *BRAIN UK* using the above points of contact.

## **APPENDIX 3 - STUDY PROTOCOL**

The research study protocol should contain the following headings/information:

### ***STUDY TITLE***

### ***CONTACTS***

Names, titles and contact information for:

- Principal Investigator
- Other investigators
- Addresses and contact information for study site(s)

### ***ABBREVIATIONS***

### ***BACKGROUND***

Literature review  
Clear explanation of research area  
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***

### ***PROTOCOL VERSION NUMBER AND DATE***