

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.