
Newcastle Brain Tissue Resource Access Policy

1. Background

- 1.1 The Newcastle Brain Tissue Resource (NBTR) includes fresh frozen, formalin fixed and formalin fixed paraffin embedded, tissue blocks from human brain, spinal cord and other tissue samples and derivatives collected post mortem. In addition there are some blood samples collected from potential donors during life. Further details (including details of sample availability) can be obtained from the NBTR Manager (nbtr@ncl.ac.uk).
- 1.2 The NBTR is funded, in part, by a grant from the UK Medical Research Council, by NIHR Newcastle Biomedical Research Centre and Unit awarded to the Newcastle upon Tyne NHS Foundation Trust and Newcastle University, and as part of the Brains for Dementia Research Programme jointly funded by Alzheimer's Research UK and Alzheimer's Society.
- 1.3 The NBTR is hosted by Newcastle University at the Campus for Ageing and Vitality.

2. Outline access process

- 2.1 Access to the collection is available to research groups based in the UK and elsewhere. The access policy has been formulated in line with the guidelines and using the template set out by the National Cancer Research Institute¹.
- 2.2 The application process consists of four stages, which must be completed before samples are provided:
 1. Determination of the availability of samples in the collection and the eligibility of the proposed study for access
 2. Completion of an application form and provision of any supporting information required
 3. Consideration by the NBTR custodians (Manager/Director/Committee and scientific group) of the application for approval

¹ <http://www.ncri.org.uk/wp-content/uploads/2013/09/Initiatives-Biobanking-2-Access-template.pdf>

4. Where access is approved a User Agreement (internal to Newcastle University) or a Material Transfer Agreement (MTA) will be put in place.

Further details of the application process are given below.

3. Eligibility for access

- 3.1 The collection has approval from the National Research Ethics Service to provide consent for use in research when required into the functioning of the human body and the causes and improved treatment of human diseases particularly dementia and neurodegenerative disease.
- 3.2 The collection is made available as a community resource in line with the UK Research Clinical Research Collaboration “Funder’s Vision for Human Tissue Resources”².
- 3.3 Requestors should be employees of a recognised academic institution or NHS organisation, a hospital with research or diagnostic capacity, or a commercial research organisation working directly on healthcare related products or services.
- 3.4 Requestors working in academic or medical organisations should be able to demonstrate, through their peer reviewed publications in the relevant research area, their ability to carry out the proposed study.
- 3.5 Requestors working in commercial organisations should be able to supply sufficient information from their respective research and development department to allow an evaluation of capacity to undertake relevant research and have undergone internal review.
- 3.6 Requestors will be asked to ensure that they have suitable facilities to undertake the planned research safely and successfully.
- 3.7 Where demand for material exceeds its availability, access will be prioritised based on scientific merit (as judged by the access committee)

4. Application submission

- 4.1 Researchers who wish to access the collection should initially contact the NBTR Manager (nbtr@ncl.ac.uk) directly giving a brief outline of the proposed study, the methodology to be followed and the number and type of samples required. The Manager will assess the suitability of the application and respond to the applicant.
- 4.2 Applications may be submitted at any time and will be considered in the order in which they are received.

² (<http://www.ukcrc.org/infrastructure/expmed/fundersvisionforhumantissuesresources/>)

- 4.3 The NBTR aims to acknowledge all applications within two weeks of receipt and to provide a decision *in principle* within 6 weeks of receiving a full application.
- 4.4 Applications to the collection can be made before funding and ethical approvals are obtained. In these cases, if required, a letter stating the intent to grant access subject to the appropriate conditions will be issued to the requestor.
- 4.5 Any 'letter of intent' will be valid for 6 months from the date of issue but does not guarantee access to particular samples. If the requested samples are no longer available when funding and other approvals are secured, the Manager will attempt to provide similar samples although this will not always be possible and cannot be guaranteed.
- 4.6 On receipt of the full application, the Manager will check to ensure that the requested samples are available, surplus to any which have been set aside for other available the requestor will be notified with details of possible alternatives. If any information is missing from the application the requestor will be asked to supply this before the application is considered further.
- 4.7 The proposed study protocol will be reviewed by the Manager for suitability. If the protocol is not considered appropriate the Manager will contact the requestor to explain why this is the case and may suggest improvements
- 4.8 All applications for samples will be circulated for review electronically to both a scientific committee (the Dementia and Neurodegenerative Diseases group at Newcastle University) and the NBTR Committee.
- 4.9 Where applications meet agreed criteria, and in the absence of objections from the scientific group and Committee, conditional approval may given by the NBTR Manager/Director. All other applications will be tabled for discussion by the NBTR Committee.
- 4.10 Where the amount of material available is limited, requestors who propose similar studies may be put in touch with a suggestion that they collaborate. If the requestors are not willing to collaborate then both applications will be considered as usual. However, it is very unlikely that access to the collection will be granted for two very similar studies and the applications treated in chronological order.
- 4.11 Once the conditions for access specified in any 'letter of intent' are met, evidence of this (for example letters from funding bodies or RECs) should be submitted to the Manager. If gaining funding or the required approvals will require significant changes to the study, the Manager should be informed as soon as possible together with details of the changes. Depending on the nature of these changes, a new application may be required.

5. Conditions of access

- 5.1 Before access to the collection is granted, requestors must agree to the conditions of access set out below and return a signed Materials Transfer Agreement or Local User Agreement to the Manager.
- 5.2 *Fees*
The recipient will be required to cover the costs of retrieving, processing and dispatching samples as per MRC brain banking strategy. Applicants unable to meet the associated costs of dealing with a tissue application will be considered on a case by case basis.
- 5.3 *Usage limitation*
Samples supplied from the collection must only be used for the purposes stipulated in the application and described in the Materials Transfer Agreement/Local User Agreement. Use outside the purpose for which the application was approved is strictly prohibited and any additional use must be approved by the NBTR.
- 5.4 *Onward transfer to collaborators*
Samples supplied from the collection may only be transferred to collaborators named at the time of the original application or in subsequent applications and specified in the Materials Transfer Agreement or later amendments.
- 5.5 *Protection of anonymity*
Recipients must agree not to link the anonymised samples provided with any other data set without the permission of the Manager/Director. Recipients must not attempt to identify any individual from the data or samples provided. Should recipients believe that they have inadvertently identified any individual, they must not record this or share the identification with any other person and should report this to the NBTR immediately.
- 5.6 *Protection of Intellectual Property (IP)*
The right to any IP arising from the data or samples provided will be made on a case-by-case basis and will be set out in the Materials Transfer Agreement.
- 5.7 *Publication policy*
Recipients working in academic institutions are expected to submit their results to a peer reviewed journal as soon as possible. Details of any publications resulting from the use of the samples should be forwarded to the Manager immediately after they become accessible.
- Recipients should aim to publish the results of all studies, including negative results, unless this is not possible because of the need to protect intellectual property. If it is not possible to publish negative findings, the manuscript should be submitted to the Manager for inclusion in the collection.
- In the instance of a recipient undertaking intellectual property protection, the Manager should be informed of this at the earliest opportunity.

Any publication or presentation using data or samples from the collection should include an acknowledgement using the text below:

“Tissue for this study was provided by the Newcastle Brain Tissue Resource which is funded in part by a grant from the UK Medical Research Council (G0400074), by NIHR Newcastle Biomedical Research Centre and Unit awarded to the Newcastle upon Tyne NHS Foundation Trust and Newcastle University, and as part of the Brains for Dementia Research Programme jointly funded by Alzheimer’s Research UK and Alzheimer’s Society .”

Details of any such publication or presentation should be forwarded to the Manager at the earliest opportunity.

6. Enrichment of the collection

- 6.1 On completion of their study, recipients should provide a means of accessing their data to the Manager in order to enrich the data available for the collection.
- 6.2 Submission of results to the collection does not affect the requirement for recipients to maintain their own research records.
- 6.3 Derived data or materials submitted to the collection may only be made available to other research groups with the permission of the originator.

7. Withdrawal of consent

- 7.1 Where consent for use of samples is withdrawn all samples remaining in the NBTR will be disposed of according to NBTR policy (NBTR SOP 04 Disposal v 3) .
- 7.2 Where samples have already been issued for research, such samples and results obtained from them need not be destroyed.

8. Destruction of samples on completion of the study

- 8.1 Once the approved study is complete, any remaining samples must be destroyed by the recipient, or returned to the NBTR as agreed with the Manager. In line with the HTA policy on making the best use of samples, efforts should be made to avoid sample disposal wherever possible and NBTR would be happy to consider applications for reuse of excess samples.

9. Compliance policy

- 9.1 Recipients are required to submit an annual progress report until publication of their results and to acknowledge the NBTR in the correct format in all such resulting publications. Failure to do so will be considered a breach of the Material Transfer Agreement. Progress reports will be treated as confidential.
- 9.2 Recipients found to be in breach of the Materials Transfer Agreement will be denied future access to the collection and their institutions and funders informed. All remaining samples must be returned to the bank.