

## NIH Neurobiobank Tissue Access Policy

**Purpose:** This document describes the policy governing access to human tissues by qualified investigators through the NIH Neurobiobank, a federated infrastructure of brain and tissue repositories.

**Background:** The NIH Neurobiobank is a national federated infrastructure for brain tissue collection, analysis, and distribution for research purposes that is supported by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the National Institute of Mental Health (NIMH), and the National Institute of Neurological Disorders and Stroke (NINDS). The goal is to increase the availability of, and access to, high quality tissues for research to understand the neurological basis of disease, while also increasing efficiency and economy of scale. Beginning in fiscal year 2013, NIH-supported Brain and Tissue Repositories (BTRs) will be managed through contracts rather than grants to better coordinate brain banking efforts and to increase tissue quality and availability through the implementation of more rigorous standards and an emphasis on quality management (see [NOT-MH-12-020](#)).

### Principles & Applicability:

The Neurobiobank will serve as a gateway and single point of access for two related resources: tissues and associated clinical data. The tissues will be stored at the individual BTRs. Standardized clinical data will be submitted to and stored at the Neurobiobank by the BTRs. The clinical data submitted to the Neurobiobank will be de-identified and coded by the submitting BTR, and the key code will not be provided to NIH. Access to both the tissues and the data will be granted via the password-protected Neurobiobank web portal, and will be limited to qualified researchers—that is, researchers associated with an institution that holds an active Federal-wide assurance (FWA). Federal-wide assurances may not be necessary, but are desirable to protect the donor's family. Approved qualified researchers will be able to query the Neurobiobank and upload requests for tissues and data.

- Types of tissues available: brain tissue, spinal cord, peripheral nerves and muscles, blood samples, and possibly other tissues (i.e., CSF, hair samples)
- Types of clinical data available: associated clinical information about deceased tissue donors, including, but not limited to, when available:
  - medical history (including medication at time of death), cause of death
  - demographic information
  - imaging data if available from participation in studies prior to death
  - psychological autopsy
- Individual-level coded clinical data collected will be provided to researchers who are approved to receive associated tissues. Data can be downloaded from the portal.

- Families will have the right to withdraw donated tissues (and associated clinical information) that can be traced to a given individual donor from the Neurobiobank at any time; however, the Neurobiobank cannot stop ongoing research with previously distributed tissues from already distributed requests.

Broad informed consent will be used at all BTRs associated with the Neurobiobank, in order to ensure the highest ethical standards, and the broadest possible availability of tissues and data to the research community. For retrospectively collected tissues and data, the Neurobiobank will grant access in accordance with the terms of the informed consent process used at the time of collection.

### **Tissue & Data Access**

Requests for tissue and associated clinical data will be made through the Neurobiobank website (<http://nih.neurobiobank.gov>) and will be processed by the Tissue Access Committee (TAC), consisting of NIH program staff and the Contracting Officer's Representative (COR). The NIH COR will serve as the chair of the TAC. The process for approving requests is as follows:

1. Requestor applies for a Neurobiobank account via the Neurobiobank website. The account will require a User ID and password, which will enable the Requestor to search for available tissues.
2. Requestor browses the Neurobiobank inventory for available tissues and data, selects what s/he needs and completes a Tissue Request Application, including scientific justification for the request, online.
3. All requests should be submitted by researchers and co-signed by the Institution's business official.
4. The request is routed automatically to the NIH tissue access committee for approval. Decisions or requests for additional information will be made within 7 business days.
5. The TAC is encouraged to suggest modifications to requests when appropriate to conserve limited resources (e.g., smaller quantities or alternate brain regions). The TAC and COR will utilize appropriate NIH staff for programmatic expertise as needed.
6. Final approval by the NIH COR will initiate a notification to the requestor that the tissue request has been approved as is, or with any modifications.
7. Approved requests will be fulfilled (tissue distributed and associated clinical data provided) within 21 working days of approval.

### Tissue Access Committee Membership

The TAC comprises NIH Neurobiobank working group staff members and the NIH COR, with the NIH COR serving as the chair. Ad hoc participation by NIH program officers from participating Institutes will occur as needed to provide appropriate disease and technical expertise. Contact information is available on the Neurobiobank website.

### **Publication**

NIH expects all investigators who obtain Neurobiobank tissues and data to acknowledge the NIH Neurobiobank in all resulting oral or written presentations, disclosures, or publications of the analyses.

### **Inquiries**

Additional information and detailed implementation guidance related to the Neurobiobank can be found at <https://neurobiobank.nih.gov>  
Specific questions about this policy should be directed to:

National Institute of Mental Health, National Institutes of Health  
Phone: (301) 443-3563  
[Neurobiobank@mail.nih.gov](mailto:Neurobiobank@mail.nih.gov)