

Supporting Statement A for

The National Institutes of Health (NIH) Neurobiobank  
Tissue Access Request, National Institute of Mental Health  
(NIMH)

Date

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- Attachment 1 : Neurobiobank Tissue Access Policy (pdf)
- Attachment 2: Pre-Mortem Donor Recruitment Form (pdf)
- Attachment 3: NIH Neurobiobank Tissue Access Request Form (pdf)

## **A. Justification**

The National Institute of Mental Health (NIMH), National Institute of Neurological Diseases and Stroke (NINDS) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), components of the National Institutes of Health (NIH), created the NIH Neurobiobank (Neurobiobank), a centralized program to coordinate the acquisition, receipt, storage and dissemination of human brains, related biospecimens, and associated clinical data, via a federation of several contracted brain and tissue repository sites. The goal of this project is to increase the availability of, and access to, high quality specimens for research in order to understand the neurological bases of diseases and mental disorders. NIMH is seeking a three-year OMB approval for two existing Neurobiobank data collections currently without OMB clearance: 1) Pre-Mortem Donor Recruitment Form, and 2) Tissue Access Request Form

### **A.1 Circumstances Making the Collection of Information Necessary**

The National Institute of Mental Health (NIMH), National Institute of Neurological Diseases and Stroke (NINDS) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), components of the National Institutes of Health (NIH), created the NIH Neurobiobank (Neurobiobank), a centralized program to coordinate the acquisition, receipt, storage and dissemination of human brains, related biospecimens, and associated clinical data, via a federation of several contracted brain and tissue repository sites. The goal of this project is to increase the availability of, and access to, high quality specimens for research in order to understand the neurological bases of diseases and mental disorders.

The potential for public benefit to be achieved through sharing brain tissue and related biospecimens is significant. However, such precious resources are by nature scarce and expensive to obtain, maintain, and distribute. The scarcity and expense necessitate fair and accountable procedures for determining who can obtain access to them. As per the Tissue Access Policy (Attachment 1), an NIH Tissue Access Committee will review and approve requests for tissues. Ad hoc members will be utilized as appropriate based on disease/technology-specific expertise. Membership will change every two years, and the NIMH contracting officer's representative (COR) will serve as the chairperson.

Information obtained by the contracted sites from prospective donors or next-of-kin—i.e., the pre-mortem consent to donate and a medical history—will be stripped of identifiers and coded. Personally identifiable information will not be shared with or by the Neurobiobank. Information requested from investigators seeking access to the tissue stored in the repository, as part of an NIH Neurobiobank Tissue Access Request, may be made public in part or in whole for tracking and reporting purposes.

At this time, NIMH is seeking OMB approval for two Neurobiobank data collections: 1) Pre-Mortem Donor Recruitment Form, and 2) Tissue Access Request Form. The pre-mortem consent and medical history form and the Tissue Access Request form will both provide a Privacy Act Notification pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. The legal authority to collect this information is granted under 42

U.S.C. Sections 232, 281 and 285g of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0036, (<http://oma.od.nih.gov/public/ms/privacy/pafiles/0036.htm>) covering “Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH.” The NIH System of Record Notice was previously published in the Federal Register on September 26, 2002, Volume 67, No 187, page 60742.

Evaluation of the program will be done using criteria such as the number of tissues distributed, number of researchers provided tissues, the number and type of publications generated, impact of the findings upon the field, etc.

## **A.2 Purpose and Use of the Information Collection**

The Neurobiobank will collect pre-mortem information from potential donors and information from researchers who wish to gain access to the tissue stored throughout the Neurobiobank network (Attachment 2). The primary use of donor information is to ensure and enable appropriate research use of the tissues and biospecimens. Knowledge about the health history surrounding a particular tissue or biospecimen is essential to ethical scientific research conducted upon it. The primary use of the tissue access information is to verify that the researcher applying to use the tissue is qualified to conduct human tissue research, to maintain appropriate ethical standards, and to document, track, monitor, and evaluate the appropriate use of the Neurobiobank tissue and biospecimens resources, to notify recipients of updates, and to meet all legal obligations.

The Neurobiobank Tissue Access Request Form asks researchers who are seeking access to tissues and biospecimens to provide information documenting their identity, place of employment, grant support, description of tissue requests, and to provide a description of the research project they are proposing to perform with Neurobiobank resources. This valuable information will help NIH understand and evaluate the use of the Neurobiobank in the neuroscience research community.

## **A.3 Use of Information Technology and Burden Reduction**

A donor’s medical history is conducted in person or over the phone by a trained professional at one of the federated sites with either the prospective donor or next-of-kin, as appropriate. As this is an extremely stressful time for the prospective donor or next of kin, the interaction with an experienced and trained professional is necessary both to minimize stress to the person providing the information, and to ensure that the information obtained is as accurate as possible.

To gain access to the Neurobiobank tissue, a researcher must complete the web-based Neurobiobank Tissue Access Request form on the Neurobiobank website (<https://neurobiobank.nih.gov/>). The form requests the following pieces of information (Attachment 3):

- Contact and shipping information for the investigator seeking access (the Neurobiobank Tissue Recipient);
- Funding support information;
- Description of the tissue requested, to be selected from a series of drop-down menus for: tissue type; number of specimens; brain region; specimen/subject specifics; minimum/optimum tissue volume;
- Brief summary/abstract and scientific rationale of the Research Project for which Neurobiobank tissues/biospecimens are sought;
- Description of assays to be used in analyses;
- Rationale for tissues requested;
- Intended use of results (e.g., commercial or non-commercial purposes); and,
- Additional comments—Recipients will have the opportunity to upload supporting attachments as necessary.

Once completed, the request package is then sent for adjudication to the Neurobiobank Tissue Access Committee (TAC) established to oversee access to the Neurobiobank specimens. When the investigator's request is approved, the investigator is notified by e-mail and explained the conditions under which the approval is granted.

#### **A.4 Efforts to Identify Duplication and Use of Similar Information**

While information pertaining to a researcher's grants may exist in other NIH databases, the Neurobiobank Tissue Access Policy requires the researcher to identify which specific portions of which specific grant, are the bases for the tissue request. Recipients will not need to replicate their information in the Neurobiobank Tissue Request system for subsequent requests. Only new project information or updated institution/address would be required.

#### **A.5 Impact on Small Businesses or Other Small Entities**

The NIH Neurobiobank adheres to established biobanking best practices and standards. As this is a limited resource, we have both legal and ethical requirements which make it impossible to modify the requested tissue recipient information based on business type/size. The same information is collected from large and small businesses. To minimize burden on investigators, including those at small businesses and other small entities, the information requested is the minimum required for the purpose of tissue access request.

#### **A.6 Consequences of Collecting the Information Less Frequently**

The information requested in the Neurobiobank Tissue Access Request does not ask investigators to generate any new information, because the type of information being requested is fundamental to conducting any research study. The data are collected on an as-needed basis.

As stated before, brain tissue and biospecimens are a valuable and scarce resource, and ensuring appropriate use of these resources through the validation of requests is critically important.

#### **A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

Not applicable.

#### **A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency**

A Federal Register Notice was published on February 13, 2014, Vol 79 FR 8723 (<https://www.federalregister.gov/articles/2014/02/13/2014-03204/proposed-collection-comment-request-nih-neurobiobank-tissue-access-request>). No public comments were received. NIH Neurobiobank Tissue Access Request has been reviewed and approved by the Neurobiobank Tissue Access Committee (TAC) that shall consist of NIH program officers. 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.

#### **A.9 Explanation of Any Payment of Gift to Respondents**

No gifts or payment will be provided.

#### **A.10 Assurance of Confidentiality Provided to Respondents**

As per applicable NIH and NIMH policies and clearance by the NIMH Privacy Officer, donor identities will be stored at the individual federated brain bank that holds the donated specimens. No personally identifiable information will be shared. The data will be stripped of identifiers and a code number will be assigned. The key will reside at the individual brain bank in a secure office with no direct web connection, and it will not be shared with NIH or with the other federated brain banks. In addition, data security, privacy, and integrity will be maintained through a layered approach: firewall, log-in ID and strong password, encryption, and VeriSign.

The Federal Privacy Act ensures that no sensitive or personally identifiable information, located in federal systems of records (e.g., Recipient NIH records), is being shared. A system of records is any group of records under the control of a federal agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The NIH and any sites that are provided access to the datasets will have access to the data collected from the Recipient for the purposes described above. In addition, the Privacy Act allows the release of some information in the Recipient's records without his/her permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for obtaining access to data. Information requested from investigators seeking access to the tissue stored in the repository, as part of a Tissue Access Request, may be made public in part or in whole

for tracking and reporting purposes. The Tissue Access Request will provide a Privacy Act Notification pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. The legal authority to collect this information is granted under 42 U.S.C. Sections 232, 281 and 285g of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0036, (<http://oma.od.nih.gov/public/ms/privacy/pafiles/0036.htm>) covering “Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH.” The NIH System of Record Notice was previously published in the Federal Register on September 26, 2002, Volume 67, No 187, page 60742.

Each of the brain banks federated with the NIH Neurobiobank has established best practices for protecting donor medical data and the identity of next of kin. In all cases, privacy involves a tiered system and holding records in locations that are locked, with password /secure access that is not connected to the internet. See below for specific descriptions of each brain bank.

#### **A.11 Justification for Sensitive Questions**

For donors, medical histories will be obtained. This is necessary to make the tissues useful for biomedical research. This information may contain sensitive information such as illicit or prescription drug abuse, and medical history. This information is required in order for researchers to be able to conduct research on these specific issues and to control their experimental design so they are effective in answering specific research questions. Personally Identifiable Information will be protected as described in A.10.

The Neurobiobank does not ask Recipients any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; and therefore, does not need to provide a justification for this type of information.

#### **A.12 Estimates of Hour Burden Including Annualized Hourly Costs**

These data were estimated from other NIH programs (Common Fund Genotype-Tissue, Expression Program and Office of Rare Disease Research Biorepositories). For pre-mortem consent/medical history: up to 1 hour, depending on completeness of medical history.

For Tissue Recipients: 15 minutes to complete web-based Tissue Request Form.



<b>A.12 - 1 ESTIMATES OF HOUR BURDEN</b>				
<b>Form</b>	<b>Number of Respondents</b>	<b>Frequency of Response</b>	<b>Average Time per Response (in hours)</b>	<b>Annual Hour Burden</b>
Neurobiobank Tissue Access Request	50	1	30/60	25
Pre-Mortem Donor Recruitment Form	50	1	15/60	13
<b>Totals</b>	100			38

**A.12 - 2 ANNUALIZED COST TO RESPONDENTS**

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondents (in hours)	Hourly Wage Rate	Respondent Cost
Investigators/Tissue Recipients	50	1	30/60	\$30	\$ 750
Brain and Tissue Repository Staff	50	1	15/60	\$25	\$1,250
<b>Total</b>	100				\$2,000

Source: NIMH Contract proposal which detailed employee salaries as part of their budget documents.

Salary/Wage Source: Office of Personnel Management 2014 General Schedule Locality Salary Table for various GS-levels; Bureau of Labor Statistics/Occupational Employment "Life, Physical, and Social Scientist" [http://www.bls.gov/oes/current/oes\\_13644.htm#19-0000](http://www.bls.gov/oes/current/oes_13644.htm#19-0000), occupational code 19-2099.

**A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers**

There are no additional costs to the respondents other than their time.

**A.14 Annualized Cost to the Federal Government**

The annualized cost to the Federal Government is \$91,158.

<b>Staff</b>		<b>Grade/Salary (Percent FTE or Effort)</b>	<b>NIH Neurobiobank Staff Hourly Rate</b>	<b>Neurobiobank Operations Cost*</b>
<b>NIH Neurobiobank Staff</b>				<b>\$50,783/year</b>
Health Scientist Administrator		GS-14 Step 1 (\$106,263) (10% FTE)	\$50.92	\$10,626/year
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Health Scientist Administrator		GS-14 Step 1(\$106,263) (10% FTE)	\$50.92	\$10,626/year
Program Analyst		GS-12 Step 1 (\$75,621) (25% FTE)	\$36.23	\$18,905/year
<b>Principal Investigator</b>		\$75,000 (40% Effort)	\$36.05	<b>\$30,000/year</b>
<b>Total per Donor Submission</b>	400/yr			<b>\$ 10,000</b>
<b>Annual # of Neurobiobank Tissue Access Requests</b>	50/yr			<b>\$ 375</b>
<b>Total Annualized Cost</b>				<b>\$ 91,158</b>

**A.15 Explanation for Program Changes or Adjustments**

This is an existing data collection without OMB clearance.

**A.16 Plans for Tabulation and Publication and Project Time Schedule**

The Neurobiobank has been funded since September 2013. The Neurobiobank has been actively processing tissue requests since September, 2014. There is no specific plan to publish the data collected from this form. These data are for internal monitoring purposes.

**A.17 Reason(s) Display of OMB Expiration Date is Inappropriate**

Not applicable.

**A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

Not applicable.