

Supporting Statement A for

The National Institutes of Health (NIH)  
NeuroBioBank Tissue Access Request Form

OMB Control # 0925-0723 (Expiration: 11/30/21)

Date: September 8, 2021

Check off which applies:

- New
- ✓ Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing

Abigail Adebisi Soyombo-Shoola, Ph.D.  
National Institute of Mental Health  
6001 Executive Blvd, NSC 8157  
Rockville, MD 20852  
301-827-7329  
abigail.soyombo@nih.gov

Table of contents

**A. JUSTIFICATION.....**

A.1 CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY.....

A.2. PURPOSE AND USE OF THE INFORMATION COLLECTION

A.3 USE OF INFORMATION TECHNOLOGY AND BURDEN REDUCTION.....

A.4 EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION.....

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES.....

A.6 CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY.....

A.7 SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5.....

A.8 COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE AGENCY.....

A.9 EXPLANATION OF ANY PAYMENT OF GIFT TO RESPONDENTS.....

A.10 ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS.....

A.11 JUSTIFICATION FOR SENSITIVE QUESTIONS.....

A.12 ESTIMATES OF HOUR BURDEN INCLUDING ANNUALIZED HOURLY COSTS.....

A.13 ESTIMATE OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORD KEEPERS.....

A.14 ANNUALIZED COST TO THE FEDERAL GOVERNMENT.....

A.15 EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS.....

A.16 PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE.....

A.17 REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE.....

A.18 EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS.....

#### **LIST OF ATTACHMENTS:**

- Attachment 1: NIH Neurobiobank Tissue Access Request Form
- Attachment 2: NIH Neurobiobank Tissue Access Guidance
- Attachment 3: HHS Privacy Impact Assessment (NIH NeuroBioBank)

## **A. Justification**

When unraveling the complexities of neurological, neurodevelopmental, and neuropsychiatric disorders, there is no substitute for studying human brain tissue. Brain donation is critically important, now more than ever. The more brain tissue available for research, the faster science can advance toward a better understanding of how to prevent, diagnose, treat, and cure disorders of the human brain. In order to meet this need, three NIH institutes came together to build a network of biorepositories to collect and distribute brain tissue to investigators across the country for research on a variety of brain disorders. With support from the National Institute of Mental Health (NIMH), the National Institute of Neurological Disorders and Stroke (NINDS), and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the NIH NeuroBioBank (NBB) was launched in 2013. The major goals of the NBB are to enhance the distribution of high-quality, well-characterized human post-mortem brain tissue to investigators and to increase awareness of the value of brain donation among the public. Due to its success in achieving this mission, two NIH institutes, the National Institute on Aging and the National Institute on Drug Abuse, have also joined the NBB network. The NBB provides access to the collections of six partner sites, as well as additional resources to facilitate research studies, including donor medical records and clinical data sets (when available) and tissue quality metrics. Each NBB site collects approximately 100 brains per year, offering researchers access to specimens across a broad range of diseases. Each donated brain is a precious resource, with the potential to provide tissue to hundreds of investigators. At the same time, each donated brain is ultimately non-renewable, and more are needed to keep pace with opportunities for novel studies.

With specimens that span neurological, neuropsychiatric, and neurodevelopmental diseases and disorders, the NBB serves as a central point of access to the world-class collections of six biorepositories. By coordinating the dissemination of human brains, related biospecimens, and associated clinical data and thus increasing availability of, and access to, high quality specimens for research purposes, the NBB strives to meet the NIH mission of understanding the neurological bases of diseases and mental disorders.

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

The NBB has catalyzed scientific discovery through the centralization of resources aimed at the collection and distribution of human post-mortem brain tissue through a networked federation of brain tissue repository (BTR) sites. The public benefit achieved through sharing brain tissue and related biospecimens remains significant, as such precious resources continue to be scarce by nature and expensive to obtain, maintain, and distribute. The scarcity and expense continue to necessitate fair and accountable procedures for determining appropriate access to research specimens.

Researchers seeking access to specimens stored in the NBB biorepositories must continue completing the NBB Tissue Access Request Form as part of their application package, therefore NIMH is currently seeking OMB's approval of the revised NBB Tissue Access Request Form (See Attachment 1) for three years. The NBB *Tissue Access Request Form* will continue to 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 remains granted under 42 U.S.C. Sections 232, 281 and 285g of the Public Health Service Act. These records will continue to be maintained in accordance with the Privacy Act System of Record Notice 09-25-0036, 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.

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

The NBB Tissue Access Request Form will continue collecting information from researchers wishing to gain access to specimens stored throughout the NBB network of BTRs (<https://neurobiobank.nih.gov/about/#network>). The primary use of the tissue access request information is to verify that the requester is qualified to conduct human tissue research, maintain appropriate ethical standards, and to document, track, monitor, and evaluate the appropriate use of the NBB tissue and biospecimens resources, to notify recipients of updates, and to meet all legal obligations.

The NBB Tissue Access Request Form asks researchers 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 NBB resources. This valuable information significantly helps NIH understand and evaluate the use of the NBB in the neuroscience research community.

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

A donor's medical history is collected by a trained professional at one of the federated BTRs in person or over the phone 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, interaction with an experienced and trained professional at the repository site 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 NBB tissue, a researcher must continue to complete the web-based NBB Tissue Access Request form on the NBB website (<https://neurobiobank.nih.gov/>) (See Attachment 1). Prior to completing the form, the requestor pre-selects specimens from NIH's inventory. Then, they are taken to a request form that is pre-populated with the specimens they selected. The form requests the following information:

- Contact and shipping information for the requestor seeking access and the name and email address for the Principal Investigator if that individual is not the requestor;
- Whether the requestor has requested tissue from the Neurobiobank in the past
- Funding support information;
  - If the funding is NIH-related, the requestor must provide information on whether the funding is extramural or intramural, which IC it is affiliated with, and the 6-digit project serial number.
  - The requestor is also asked whether the funding is through Congressionally mandated funding opportunities and is provided with a list of options to select from, or None, or Other funding types.
  - If the funding is not related to NIH, the requestor must choose from a drop-down list which type of institution the funding is coming from and provide a short explanation.
- Inclusion and exclusion criteria for any requested specimen replacements;
- Requestors must enter tissue amounts for the list of specimens that were pre-selected by the requestor;
- Research plan to include the summary/abstract and scientific rationale of the Research Project for which NBB tissues/biospecimens are sought (i.e. rationale, main hypothesis, and proposed research aims);
- Description of assays to be used in analyses;
- Whether the investigators used the proposed methods with human post-mortem tissue;
- If it is a pilot study;
- Rationale for biospecimens requested;
- Intended use of results (e.g., commercial or non-commercial purposes);
- Additional comments—Recipients will have the opportunity to upload supporting attachments as necessary; and
- A Curriculum Vitae (CV) for the Principal Investigator.

Once completed, the request form is then reviewed by the Brain and Tissue Repositories (BTRs) to determine availability of requested tissue. The BTRs collaborate to fulfill requests in a manner that best meets the needs of the requestor/researcher and utilizes tissue prudently. Once reviewed by the BTRs, requests are approved or disapproved by NBB program staff. When a tissue access request is approved, the requestor 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 NBB Tissue Request Process 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 NBB 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 NBB will continue to adhere to established biobanking best practices and standards. As this is a limited resource, we have both legal and ethical requirements which prevent the modification of 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 purposes of accessing tissue.

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

The information requested in the NBB Tissue Access Request does not ask investigators to generate additional 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 July 7, 2021, pages 35815-35816 (86 FR 35815). No comments were received.

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

No gifts or payment will be provided to respondents completing the NBB Tissue Access Request form.

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

As per applicable NIH and NIMH policies and clearance by the NIMH Privacy Officer, donor identities are stored at the individual federated brain banks that hold the donated specimens. No personally identifiable information is shared or collected by NIH. The data collected is stripped of identifiers and a code number is 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, 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 federated BTRs 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.

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

Medical histories are obtained from donors by the BTRs and may include sensitive information such as illicit or prescription drug abuse. This information is necessary to make the donated tissue useful for biomedical research and required 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 NBB Tissue Access Request Form does not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, or 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**

The estimated annual burden hours to complete the NBB Tissue Access Request Form are 100 total hours. Based upon a review of the past response rate, NIMH has updated the number of estimated respondents to 400 from 225. Given the further streamlining of the form, NIMH estimates the form will take only 15 minutes to complete.

A.12-1: Estimated Annualized Burden Hours

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Researchers	400	1	15/60	100
<b>Total</b>	<b>400</b>	<b>400</b>		<b>100</b>

A.12-2: Estimated Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
Researchers	100	\$38.15	\$3,815
<b>Total</b>			<b>\$3,815</b>

\*Bureau of Labor Statistics: May 2020 National Occupational Employment and Wage Estimates for Life, Physical and Social Science Occupations (<https://www.bls.gov/oes/current/oes190000.htm>).

**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 **\$58,723**.

Cost Descriptions	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
<b>Federal Oversight Staff</b>					
Health Scientist Administrator (NIMH)	GS-14/1	\$122,530	10%		\$12,253
Health Scientist Administrator (NINDS)	GS-14/1	\$122,530	10%		\$12,253
Health Scientist Administrator (NIDA)	GS-14/1	\$122,530	3%		\$3,676
Health Scientist Administrator (NIA)	GS-14/1	\$122,530	3%		\$3,676
Health Scientist Administrator (NICHD)	GS-14/1	\$122,530	5%		\$6,127
Program Analyst	GS-13/1	\$ 103,690	220		\$20,738
<b>Contractor Cost</b>					
<b>Travel</b>					n/a
<b>Other Cost</b>					n/a
<b>Total</b>					<b>\$58,723</b>

\* <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB.pdf>

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

There have been changes to the information collected by the NBB Tissue Access Request Form (Attachment 1). Based upon a review of the past response rate, NIMH has updated the number of estimated respondents to 400 from 225. Given the further streamlining of the form, NIMH estimates the form will take only 15 minutes to complete.

The “Requestor Information” portion of the request form now asks for the name and email address for the Principal Investigator if that individual is not the requestor.

The “Research Funding Information” portion of the request form has been streamlined for the requestors. Additionally, this portion of the request form now asks if the researched related to the request is supported by funding from the NIH. If the funding is NIH-related, the requestor must provide information on whether the funding is extramural or intramural, which IC it is affiliated with, and the six-digit project serial number. The requester is also asked whether the funding is through Congressionally mandated funding opportunities and is provided with a list of options to select from, or None, or Other funding types. If the funding is not related to NIH, the requestor must choose from a drop-down list which type of institution the funding is coming from and provide a short explanation. This new requested information is to assist with NBB reporting of utilization metrics to contributing programs, in terms of data collection on

tissue utilization by requesters funded through the listed programs. For example, NIH ICs and Special Initiatives that contribute to the NBB often request data on utilization by their grantees.

The “Requested Specimens” portion has been streamlined for the requestors. Additionally, this portion now includes prompts/requests with comment boxes for the requestors’ input and a portion to specify and describe the requested specimen(s). This portion requests for inclusion and exclusion criteria for any requested specimen replacements. This portion provides the requestor with an opportunity to edit the requested specimens including the subject’s ID number, clinical diagnosis, brain region, repository, age, preparation, and amount of tissue requested.

The “Request Details” portion now also requests for the requestors to indicate if they have used the proposed methods with human post-mortem tissue, and if it is a pilot study. This form now additionally requests for the Principal Investigator’s curriculum vitae.

The accompanying NIH Neurobiobank Tissue Access Guidance (Attachment 2) has also been updated. The “Planning Your Tissue Request” and “Completing Your NBB Tissue Request Form” portions have been shortened, and the “Determining Your Tissue Needs” portion has been rearranged to more clearly request information from the Principal Investigator(s).

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

There is no specific plan to publish the information collected. The information is solely for internal monitoring purposes.

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

The OMB expiration date will be appropriately displayed.

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

Not applicable.