

Supporting Statement A for

The National Institutes of Health (NIH)
NeuroBioBank Tissue Access Request and Progress Report Forms

OMB Control # 0925-0723 (Expiration: 10/31/24)

Date: September 2024

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 (NIH-Funded Research)
- Attachment 2: NIH Neurobiobank Tissue Access Request Form (Other US Federal Government-Funded Research)
- Attachment 3: NIH Neurobiobank Tissue Access Request Form (State Government-Funded Research)
- Attachment 4: NIH Neurobiobank Tissue Access Request Form (Foreign Government-Funded Research)
- Attachment 5: NIH Neurobiobank Tissue Access Request Form (Private Industry/Commercial-Funded Research)
- Attachment 6: NIH Neurobiobank Tissue Access Request Form (Other Entity-Funded Research)
- Attachment 7: NIH Neurobiobank Tissue Access Guidance
- Attachment 8: NIH Neurobiobank Progress Report
- Attachment 9: HHS Privacy Impact Assessment (NIH NeuroBioBank)

A. Justification

This application for the National Institutes of Health (NIH) NeuroBioBank Tissue Access Request Form and Progress Report Form is a revision to the Neurobiobank Tissue Access Request (NBB) application, which OMB approved in 2021. 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 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, the National Institute on Aging and the NIH Blueprint for Neuroscience Research, have also joined the NBB network. The NBB provides access to the tissue collections of six contracted 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 its mission of facilitating understanding the neurological bases of neurological diseases and mental health disorders.

A.1 Circumstances Making the Collection of Information Necessary

The NBB has catalyzed scientific discovery through the centralization of resources for 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.

This application is a revision to the approved 2021 OMB application, “Neurobiobank Tissue Access Request (NBB).” 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 1-5) for three years. Additionally, NIMH is currently seeking OMB’s approval of the NBB Progress Report Form (See Attachment 8) for three years. Progress reports are requested every 12 months from tissue shipment date until the researcher indicates that the project is completed. An email is generated from the NBB website asking the researcher to log in to the NBB portal and submit the Progress Report Form. Obtaining such reports allows the NBB to monitor the use of tissue, collect information about findings and publications, and the impact of the program in facilitating scientific discovery.

The NBB *Tissue Access Request Form* and the *NBB Progress Report 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.

Since the 2021 OMB approval, the NBB has processed 900 requests for human specimens from the research community, and has contributed to scientific knowledge by facilitating research that led to publications in high impact journals. During this period, over 180 publications in several scientific journals cited the NBB as the source of human tissue. The current updates to the forms are to obtain information required for programmatic reporting on research funding and to incorporate the NIH data sharing requirements.

The NBB Tissue Access Request Form (Attachments 1-6) asks researchers seeking access to tissues and biospecimens to provide information documenting their identity, place of employment, funding support, description of tissue requests, and to provide a description of the research project they are proposing to perform with NBB resources. Researchers are also notified of NIH Scientific Data Sharing requirement on this form as it pertains to data generated from NBB specimens. This valuable information significantly helps NIH understand and evaluate the use of the NBB by the neuroscience research community.

The NBB Progress Report Form (Attachment 8) requests researchers report information regarding publications and manuscripts resulting from the use of samples obtained from the NBB. The form requests for information regarding background on the tissue samples, results of research, future studies, and changes from the initial application; the presentation and publication of the research that utilized the tissue samples; new scientific question, specific aims, and/or grant applications; new individuals working in this research area as a result of the research using the provided tissues; and utilization of tissue provided from another source, in addition to the NBB-provided tissues, in research.

A.3 Use of Information Technology and Burden Reduction

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 Attachments 1-6). 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 (please note, five versions of the form are included in this application to depict the series of questions that are asked depending on respondent input regarding funding, as described below);
 - 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 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 (e.g., state government, foreign government, private industry, other) 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;
 - The requestor is asked to specify the brain region, **tissue type**, preparation, repository, age, subject ID, clinical brain diagnosis, and amount requested for the specimen.
- 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;
- **NeuroBioBank Data Sharing: recipients are notified of data sharing requirements following the NIH Data Management and Sharing policy, and are strongly requested to deposit genomics data in the NIMH Data Archive;** 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 requester/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.

After the samples from the NBB are utilized by researchers, the NBB Progress Report Form requests researchers report information regarding publications and manuscripts resulting from the use of samples obtained from the NBB. Specifically, the form requests the following information:

- Summary: Background on the tissue samples, results of research, future studies (optional), and changes from the initial application (optional)
- Presentation: Whether the research that utilized the tissue samples was presented at any scientific conference/meeting, and if so, where.
- Manuscripts: Whether any manuscripts that utilized the provided tissues were published, and if so, the PubMed ID, journal, and date of publication information; and if any manuscripts (not yet officially published) that utilized the provided tissues were submitted, and if so, the title and name of the journal to which they were submitted.
- New Scientific Questions/Specific Aims/Grant Applications: Whether the research using the provided tissues lead to any new scientific question, specific aims, and/or grant applications, and if so, with which institution is the aim/grant affiliated.
- Personnel/Hours: Whether there are new individuals in their group working in this research area (who were not previously doing so) as a result of the research using the provided tissues, and if so, how many.
- Project Complete: Whether all planned manuscripts have been officially published.
- Other Tissue Sources: Whether their research also utilized tissue provided from another source, in addition to the NBB-provided tissues, and if so, the type of tissue acquired and its source.
- Sharing Scientific Data: Whether data generated from the tissues have been submitted to a data repository, and if so, the name of the repository.

For reference, please see the HHS Privacy Impact Assessment that was obtained for the NBB (Attachment 9).

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. The NBB Progress Report form requests for information not already reported to the NBB.

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 **and Progress Report Form** do 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 16, 2024, page 57915 (Vol. 89, No. 136). NIMH did not receive any comments.

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 and Progress Report, 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

The NBB Tissue Access Request and NBB Progress Report forms do 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 and NBB Progress Report Form combined are 175 total hours. NIMH estimates each version of the NBB Tissue Access Request Form (Attachments 1-6) and the NBB Progress Report Form (Attachment 8) will each take 15 minutes to complete.

The below table depicts the various instruments, to include the multiple versions of the NBB Tissue Access Request Form (Attachments 1-6) and the NBB Progress Report Form (Attachment 8)

A.12-1: Estimated Annualized Burden Hours

Collection Instrument	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
NBB Tissue Access Request Form (NIH-Funded Research)	Researchers	200	1	15/60	50
NBB Tissue Access Request Form (Other US Federal Government-Funded Research)	Researchers	20	1	15/60	5
NBB Tissue Access Request Form (State Government-Funded Research)	Researchers	20	1	15/60	5
NBB Tissue Access Request Form (Foreign Government-Funded Research)	Researchers	20	1	15/60	5
NBB Tissue Access Request Form (Private Industry/Commercial-Funded Research)	Researchers	20	1	15/60	5
NBB Tissue Access Request Form (Other Entity-Funded Research)	Researchers	20	1	15/60	5
NBB Progress Report	Researchers	400	1	15/60	100
Total			700		175

A.12-2: Estimated Annualized Cost to Respondents

Collection Instrument	Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
NBB Tissue Access Request Form (NIH-Funded Research)	Researchers	50	\$42.24	\$2,112
NBB Tissue Access	Researchers	5	\$42.24	\$211

Request Form (Other US Federal Government-Funded Research)				
NBB Tissue Access Request Form (State Government-Funded Research)	Researchers	5	\$42.24	\$211
NBB Tissue Access Request Form (Foreign Government-Funded Research)	Researchers	5	\$42.24	\$211
NBB Tissue Access Request Form (Private Industry/Commercial-Funded Research)	Researchers	5	\$42.24	\$211
NBB Tissue Access Request Form (Other Entity-Funded Research)	Researchers	5	\$42.24	\$211
NBB Progress Report	Researchers	100	\$42.24	\$4,224
Total				\$7,391

*Bureau of Labor Statistics: May 2023 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 **\$66,824**.

Cost Descriptions	Grade/Step	Salary*	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight Staff					
Health Scientist Administrator (NIMH)	GS-15/1	\$163,964	5%		\$8,198
Health Scientist Administrator (NINDS)	GS-15/1	\$163,964	2%		\$3,279

Health Scientist Administrator (NINDS)	GS-14/1	\$139,395	5%		\$6,970
Health Scientist Administrator (NIA)	GS-15/1	\$163,964	2%		\$3,279
Health Scientist Administrator (NICHD)	GS-15/1	\$163,964	2%		\$3,279
Health Program Analyst (NIMH)	GS-14/1	\$139,395	30%		\$41,819
Contractor Cost					
Travel					n/a
Other Cost					n/a
Total					\$66,824

* <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/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 (Attachments 1-5), and the addition of the NBB Progress Report Form. Based upon the addition of the NBB Progress Report Form, NIMH has updated the total annual burden hours for respondents to 175 (from 100). NIMH estimates the NBB Tissue Access Request Form and the NBB Progress Report Form will each take 15 minutes to complete.

The “Research Funding Information” portion of the request form now includes a link to <https://projectreporter.nih.gov/report.cfm> within the description of the ‘NIH Report Tool’ (that was formerly noted as the ‘NIH RePORTER tool’ in the last application).

The “Requested Specimens” portion has been updated to provide the requestor with an opportunity to edit the tissue type of requested specimens (in addition to the subject’s ID number, clinical diagnosis, brain region, repository, age, preparation, and amount of tissue requested, as was included in the previous application).

Through the NBB Progress Report Form, Program would also like to request researchers report information regarding publications and manuscripts resulting from the use of samples obtained from the NBB. As detailed above, Program would like to request the following information:

- **Summary:** Background on the tissue samples, results of research, future studies (optional), and changes from the initial application (optional)
- **Presentation:** Whether the research that utilized the tissue samples was presented at any scientific conference/meeting, and if so, where.
- **Manuscripts:** Whether any manuscripts that utilized the provided tissues were published, and if so, the PubMed ID, journal, and date of publication information; and if any manuscripts (not yet officially published) that utilized the provided tissues were submitted, and if so, the title and name of the journal to which they were submitted.

- New Scientific Questions/Specific Aims/Grant Applications: Whether the research using the provided tissues lead to any new scientific question, specific aims, and/or grant applications, and if so, with which institution is the aim/grant affiliated.
- Personnel/Hours: Whether there are new individuals in their group working in this research area (who were not previously doing so) as a result of the research using the provided tissues, and if so, how many.
- Project Complete: Whether all planned manuscripts have been officially published.
- Other Tissue Sources: Whether their research also utilized tissue provided from another source, in addition to the NBB-provided tissues, and if so, the type of tissue acquired and its source.
- Sharing Scientific Data: Whether data generated from the tissues have been submitted to a data repository, and if so, the name of the repository.

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.