Supporting Statement A for

The National Institutes of Health (NIH) NeuroBioBank Tissue Access Request Form, National Institute of Mental Health (NIMH), 0925-0723, EXTENSION

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- Attachment 3: NeuroBioBank HHS IT Systems Privacy Impact Assessment (PIA)

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 Institutes at the National Institutes of Health (NIH) 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 project 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. 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 a 3-year extension of OMB approval of the NBB Tissue Access Request Form (See Attachment 1). 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, (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.

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 information collected 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 potential 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 complete the web-based NBB Tissue Access Request Form on the NBB website (https://neurobiobank.nih.gov/) (See Attachment 1). The form requests the following information:

- Contact and shipping information for the investigator seeking access (the NBB 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;
- Summary/abstract and scientific rationale of the Research Project for which NBB 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 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 staff from the participating NIH Institutes (NIMH, NINDS and NICHD). When a tissue access request is approved, the requester is notified by e-mail and explained the conditions under which the approval is granted. A Privacy Impact Assessment (PIA) for the NBB was completed (see Attachment 3).

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 adhering to established biobanking best practices and standards. As this is a limited resource, there are both legal and ethical requirements which prevent the modification of tissue recipient information based on business type/size and 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 NBB Tissue Access Request Form does not ask investigators to generate additional information, because the type of information being requested is fundamental to conducting any research study. As previously stated, 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 for this extension request was published on April 20, 2018, pages 17558-17559 (83 FR 77), and allowed 60 days for public comment. No public 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. 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. No personally identifiable information is shared or collected by NBB program staff at the NIH. BTR's will continue stripping donor data collected of identifiers and assigning a code number. 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 NBB Tissue Access

Request Form 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.

A.11 Justification for Sensitive Questions

The NBB Tissue Access Request Form does not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. 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.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

The estimated annual burden hours to complete the NBB Tissue Access Request Form is 56 hours.

A.12-1: Estimated Annualized Burden Hours

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
NIH	Researchers	225	1	15/60	56

NeuroBioBank Tissue Access Request Form					
TOTAL		225			56

A.12-2: Estimated Annualized Cost to Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
Researchers	56	$51.53/hour	$2,885.68
TOTAL	56		$2,885.68

**Bureau of Labor Statistics: May 2017 National Occupational Employment and Wage Estimates https://www.bls.gov/oes/current/oes192099.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 $80,784.15.

Cost Descriptions	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight Staff					
Health Scientist Administrator (NIMH)	GS-14/1	$106,263	10%		$10,626.30
Health Scientist Administrator (NIDA)	GS-14/1	$106,263	10%		$10,626.30
Health Scientist Administrator (NICHD)	GS-14/1	$106,263	10%		$10,626.30
Program Analyst	GS-12/1	$75,621	25%		$18,905.25
Principal Investigator		$75,000	40%		$30,000
Contractor Cost					

Travel					n/a
Other Cost					n/a
TOTAL					**$80,784.15**

A.15 Explanation for Program Changes or Adjustments

There have been no changes to the information collected by the NBB Tissue Access Request Form or the time it takes respondents to complete the form. However, NIMH has made improvements to the NBB program to make the request process easier for researchers to understand and complete the form. The improvements include replacing the Tissue Access Policy with a Tissue Access Guidance document (see Attachment 2) and discontinuing use of the previously approved Pre-Mortem Donor Recruitment Form. The Tissue Access Guidance document is shorter, easier for requesters to understand and was incorporated to the request form on the NBB program webpage, so that respondents can easily reference it without having to open a different document/webpage while completing the form. NIMH has also developed a webpage for the NBB program with a step-by-step description of the request process for researchers at https://neurobiobank.nih.gov/researchers/. Since the donor recruitment process is solely managed, overseen and handled by the network of BTRs, the Pre-Mortem Donor Recruitment Form on the NBB website was replaced with general information about becoming a brain donor at https://neurobiobank.nih.gov/donors-how-become-donor/. The increase in estimated hourly burden hours and respondent cost noted in Section A.12 above, as compared to the estimates in our 2015 submission, is directly related to the growth and expanded use of the NBB within the scientific community.

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 burden statement and expiration date will be appropriately displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.