



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

DATE: September 3, 2026

TO: Office of Management and Budget (OMB)
Through: Project Clearance Chief, Mikia Currie, NIH
Project Clearance Liaison, Andrew A. Hooper, NIMH

FROM: Olivia Spicer
National Institute of Mental Health (NIMH)

SUBJECT: NIH Neurobiobank (NBB) Tissue Access Request and Progress Report (NIMH)
(OMB Control #0925-0723, Expiration Date 11/30/2027)

This is a request for OMB to approve non-substantive changes to the NIH Neurobiobank (NBB) data collection instruments approved on November 8, 2024, under the submission entitled, "NIH Neurobiobank (NBB) Tissue Access Request and Progress Report (NIMH)", OMB Control #0925-0723, Expiration Date 11/30/2027).

Through these instruments, NIMH, the National Institute of Neurological Diseases and Stroke (NINDS), the National Institute on Aging (NIA), the National Institute on Drug Abuse (NIDA), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), components of the National Institutes of Health (NIH), seek 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. Please note, these updates do not change the respondent time or cost burden estimates. The changes to the form will not meaningfully alter the content, scope, or method of the information collection; and are described in detail below.

Updates to the Data Collection Instruments:

- Mark the "Position Title" field in Section #1 as a required field and include a drop-down menu with the following options: Undergraduate Student, Graduate/Medical Student, Post Doc, Research Associate, Lab Assistant / Technician, Faculty Member, Other
- Added comment to Section #3, asking all international requestors to have all their customs documents ready so as to not delay shipment.
- Display the output of the request wizard at the top of the webpage (The request wizard type will be shown at the top of the page along with the requestor's name, request ID #, date submitted, and date modified).
- When the request wizard determines a specific request type, the following documents will be required as attachments:
 - o Full Study Request: PI CV, Power Analysis, Supporting Documentation Demonstrating Evidence of Proficiency in Proposed Methods
 - o Preliminary Study Request: PI CV, Supporting Documentation Demonstrating Evidence of Proficiency in Proposed Methods
 - o Methodological Proficiency Request: PI CV

- o Pathology Validation Request: PI CV
- In Section #5, depending on the request type that the request wizard provides, the following question may be automatically filled in and grayed out (so that the requestor cannot make any changes to the answer). Question A: Have you used the proposed methods with human post mortem tissue?
 - o If the request wizard says the request is a Full Study Request or a Preliminary Study Request, Question A will be automatically filled in as “yes.”
 - o If the request wizard says the request is a Methodological Proficiency Request or a Pathology Validation Request, Question A will be automatically filled in as “no.”
- In Section #5, we are removing the question “Is this a pilot study?” as this information will be provided by the determined request study type.

Change Table:

Current Data Elements	New Data Elements
Section 1: Requestor Information Position Title	Section 1: Requestor Information Position Title* (drop-down menu) Undergraduate Student Graduate/Medical Student Post Doc Research Associate Lab Assistant / Technician Faculty Member Other
Section 3: Specimen Shipping Information	Section 3: Specimen Shipping Information For international shipments, please make sure to have all necessary documentation in order according to your country policies to avoid delays and or tissue hold up at customs.
Section 5: Request Details Please attach a CV for the Principal Investigator* When you attach the file, please make sure the Document Type is set to “Principal Investigator CV” We also encourage uploading any supporting documentation that is relevant to your tissue request. Uploading supporting documentation	Section 5: Request Details Required Documents – Full Study Request Power Analysis Choose File Principal Investigator CV Choose File Rationale Supporting Documentation Choose File

for your rationale, power analysis, etc. may improve request review times.” Attach Files Document Type Principal Investigator CV Power Analysis Rationale Supporting Documentation Images Other Documentation	We also encourage uploading any additional supporting documentation that is relevant to your tissue request under “Other Documents” below. Other Documents Choose File
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Attachments:

NBB Updated Request Form.pdf (depicts updated version of form)

Att1_NBB Tissue Access Request_NIH_090326.pdf (depicts original version of form with comment bubbles noting changes)