



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request; National Institute of Health Neurobiobank Tissue Access Request

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on February 13, 2014, page 8723 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-

6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301-443-4335 or E-mail your request, including your address to: nimhprapubliccomments@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: National Institute of Health Neurobiobank Tissue Access Request – Existing without OMB Clearance – National Institute of Mental Health (NIMH), National Institute of Health (NIH).

Need and Use of Information Collection: 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 donor form will collect information from potential donors 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 tissue

access request form will collect information from researchers who wish to gain access to the tissue stored throughout the Neurobiobank network, The NIH Neurobiobank Tissue Access Request form is necessary to verify that the researcher “Recipient” Principal Investigators and their organization or corporations applying to use the tissue is qualified to conduct human tissue research and have approved assurance from the DHHS Office of Human Research Protections to access tissue or biospecimens from the National Neurobiobank for research purposes. The primary use of this information is to document, track, monitor, and evaluate the appropriate use of the Neurobiobank tissue and biospecimen resources, as well as to notify interested recipients of updates, corrections, or other changes to the system.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 38.

Estimated Annualized Burden Hours

Form	Number of Respondents	Frequency of Response	Average Burden per Response (in hours)	Total Annual Burden Hours
Neurobiobank Tissue Access Request	50	1	30/60	25
Pre-Mortem Donor Recruitment Form	50	1	15/60	13
Total	100			38

Dated: March 30, 2015.

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NIMH, NIH.

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