

opportunities to accelerate research through the power of combining large and information-rich datasets. To promote robust sharing of human and non-human data from a wide range of large-scale genomic research and provide appropriate protections for research involving human data, the NIH issued the NIH Genomic Data Sharing Policy (GDS Policy). Human genomic data submissions and controlled-access are managed through a central data repository, the database of Genotypes and Phenotypes (dbGaP) which is administered by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at the NIH.

Under the GDS Policy, all investigators who receive NIH funding to conduct large-scale genomic research are expected to register studies with human genomic data in dbGaP, no matter which NIH-designated data repository will maintain the data. As

part of the registration process, investigators must provide basic study information such as the type of data that will be submitted to dbGaP, a description of the study, and an institutional assurance (*i.e.* Institutional Certification) of the data submission which delineates any limitations on the secondary use of the data (*e.g.*, data cannot be shared with for-profit companies, data can be used only for research of particular diseases).

Investigators interested in using controlled-access data for secondary research must apply through dbGaP and be granted permission from the relevant NIH Data Access Committee(s). As part of the application process, investigators and their institutions must provide information such as a description of the proposed research use of controlled-access datasets that conforms to any data use limitations, agree to the Genomic Data User Code of Conduct, and agree to the terms of access through

a Data Use Certification agreement. Requests to renew data access and reports to close out data use are similar to the initial data access request, requiring sign-off by both the requestor and the institution, but also ask for information about how the data have been used, and about publications, presentations, or intellectual property based on the research conducted with the accessed data as well as any data security issues or other data management incidents.

The NIH has developed online forms, available through dbGaP, in an effort to reduce the burden for researchers and their institutional officials to complete the study registration, data submission, data access, and renewal and closeout processes.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,505.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Study Registration and Data Submission.	Investigator Submitting Data	150	1	1	150
	Institutional Official to Certify Submission.	150	1	30/60	75
Requesting Access to Data ...	Investigator Requesting Data	633	2	45/60	950
	Signing Official to Certify Request.	633	2	30/60	633
Renewal/project Close-out Process.	Investigator Requesting Data	633 (same individuals as listed above).	2	15/60	317
	Signing Official to Certify Request.	633 (same individuals as listed above).	2	18/60	380
Grand Total	1,566	5,064	2,505

Dated: March 10, 2016.

Lawrence A. Tabak,
Deputy Director, National Institutes of Health.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Neurological Disorders and Stroke, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors; National Institute of Neurological Disorders and Stroke.

Date: April 24–26, 2016.

Time: 6:00 p.m. to 11:30 a.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alan P. Koretsky, Ph.D., Scientific Director, Division of Intramural Research, National Institute of Neurological Disorders and Stroke, NIH, 35 Convent Drive, Room 6A 908, Bethesda, MD 20892, (301) 435-2232, koretskya@ninds.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS).

Dated: March 11, 2016.

Sylvia L. Neal,
Program Analyst, Office of Federal Advisory Committee Policy.

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