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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

NIH Information Collection Forms to Support Genomic Data Sharing for Research Purposes (Office of Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with 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.

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

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the

proposed project or to obtain a copy of the data collection plans and instruments, contact: Julia Slutsman, Ph.D. Director, Genomic Data Sharing Policy Implementation, OER, OD, NIH, Natcher Building, Room 3AN-44D, 6705 Rockledge Dr., Suite 750, Bethesda, MD 20892, or call non-toll-free number (301) 594-7783 or e-mail your request, including your address to: slutsmaj@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on September 21, 2022, pages 57705-57707 (87 FR 57705) 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 Office of the Director (OD), 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 November 30, 2022, unless it displays a currently valid OMB control number.

In compliance with 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.

Proposed Collection: NIH Information Collection Forms to Support Genomic Data Sharing for Research Purposes -0925-REVISION – expiration date 11/30/2022, Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Sharing research data supports the National Institutes of Health (NIH) mission and is essential to facilitate the translation of research results into knowledge, products, and procedures that improve human health. NIH has longstanding policies to make a broad range of research data, including genomic data, publicly available in a timely manner from the research activities that it funds. Genomic

research data sharing is an integral element of the NIH mission as it facilitates advances in our understanding of factors that influence health and disease, while also providing 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 (NIH 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 NIH. Under the NIH 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. 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 158,776.

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
dbGaP Registration and Submission	Investigator Submitting Data	1,050	1	1	1050
Institutional Certification	Investigator filling out Institutional Certificatio n	1,050	1	45/60	788
Institutional Certification	Institutional Official to Certify Submission	1,050	1	45/60	788
Provisional Institutional Certification	Investigator filling out Provisional Institutional Certificatio n	100	1	45/60	75
Provisional Institutional Certification	Institutional Official to Certify Provisional Submission	100	1	45/60	75
Data Access Request	Requester Submitting Request	3,900	10	1	39,000

Data Access Request	Institutional Signing Official to Certify Request	3,900	10	1	39,000
Project Renewal or Project Close-out form	Requester Submitting Request	3,900	10	1	39,000
Project Renewal or Project Close-out form	Institutional Signing Official to Certify Request	3,900	10	1	39,000
Total		18,950	159,350		158,776

Dated: November 21, 2022.

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Tara A. Schwetz,

Acting Principal Deputy Director,

National Institutes of Health.

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