: 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-day Comment Request

NIH Information Collection Web Interface and Forms to Support Genomic Data Sharing for Research Purposes (OD)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health Office of the Director (OD) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Julia Slutsman, Ph.D., Director, Data Sharing Policies Implementation, Office of Extramural Research, NIH, 6705 Rockledge Drive, Suite 800-C, Bethesda, MD 20892, or call non-toll-free number (301)-594-7783; or email your request including your address to: *sharing@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency,

including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information from those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: NIH Information Collection Web Interfaces and Forms to Support Genomic Data Sharing for Research Purposes - 0925-0670 - Expiration Date 03/31/2026 – REVISION - Office of the Director (OD), National Institutes of Health (NIH).

Need and Use of Information Collection: Sharing research data is integral to the mission of the National Institutes of Health (NIH) as it advances our understanding of factors that influence health and disease, while also providing opportunities to accelerate research through the power of combining large, information-rich datasets. To promote robust sharing of human and non-human genomic data from a wide range of large-scale genomic research, and to provide appropriate protections for research involving human data, NIH established the Database of Genotypes and Phenotypes (dbGaP) and issued the NIH Genomic Data Sharing (GDS) Policy (*https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html*). The Database of Genotypes and Phenotypes (dbGaP) was developed to archive and distribute the data results of eligible NIH-funded research studies that have investigated the interaction of genotype (the genetic constitution of an individual organism) and phenotype (the set of observable characteristics of an individual resulting from the interaction of its genotype with the environment) in humans. The NIH GDS Policy applies to NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research. Human genomic data submissions, controlled-access genomic data, and related phenotypic data are managed through the database of Genotypes and Phenotypes (dbGaP);

dbGaP 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. As part of the study registration process, investigators must provide basic study information, such as the types of data that will be submitted to dbGaP and a description of the study, via a form provided by the funding NIH institute. While individual NIH institutes currently use different forms, NIH seeks to harmonize the current forms into a single Study Registration Information Form. In addition, to keep pace with changes in genomics research, NIH has developed a Data Agnostic Submission Form to accept submission of non-genomic data generated with genomic data.

Requesters interested in using controlled-access human data for secondary research must apply through the dbGaP Authorized Access System and be granted permission from the relevant NIH Data Access Committee (DAC). As part of the application process, requesters and their institutions provide basic information, such as the proposed research use of the data, and agree to the terms of access delineated in the Data Use Certification agreement. Beginning on January 25, 2025, requesters and their institutions are expected to attest that their systems or, if applicable, their third-party IT system or Cloud Service Provider secure the data according to standards set for in the NIH Security Best Practices for Users of Controlled-Access Data (*https://sharing.nih.gov/sites/default/files/flmngr/NIH-Security-BPs-for-Users-of-Controlled-Access-Data.pdf*). This attestation will be a part of completing the request in the dbGaP Authorized Access System.

NIH has developed online forms and digital interfaces, available either as PDF files or through dbGaP, to minimize burden for researchers and their institutional officials completing the study registration (i.e., Study Registration Information Form), attesting to security standards in the data access request, and submitting data.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours for all respondents across all forms is 25,950 hours.

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**
Study Registration and Data Submission					
Data Agnostic Submission Certification	Investigator Submitting Data	9,000	1	30/60	4,500
Data Agnostic Submission Certification	Institutional Signing Official Certifying Data Submission	9,000	1	30/60	4,500
Study Registration Information Form	Investigator Submitting Data	400	1	1	400
Data Derivative Institutional Certification	Investigator Submitting Data	50	1	30/60	25
Data Derivative Institutional Certification	Institutional Signing Official Certifying Data Submission	50	1	30/60	25
Requesting Access to Data					
dbGaP Authorized Access System	Investigator Requesting Data	4,000	6	30/60	12,000
dbGaP Authorized Access System	Institutional Signing Official Certifying Data Request	1,500	6	30/60	4,500
	Total	24,000	51,500	-	25,950

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