: 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 30-Day Comment Request; NIH Information Collection Web Interface and Forms to Support Genomic Data Sharing and NIH Controlled-Access Data Repository Requirements (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 by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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: Jon Lorsch, Ph.D., Deputy Director for Extramural Research, Office of Extramural Research, NIH, 6705 Rockledge Drive, Suite 800-C, Bethesda, MD 20892, non-toll-free number (301)-594-7783; GDS@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:

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, the NIH issued the Genomic Data Sharing (GDS) Policy (*https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html*). 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.

The NIH GDS Policy expects large-scale human genomic and associated data generated using NIH funds to be submitted to an NIH-designated repository, which is an NIH Controlled-Access Data Repository (*https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/accessing-data/requirements*). As a part of that submission, the submitting institution certifies to NIH that the data are appropriate to share through the completion and submission of a data submission form. The data are then made available for secondary research use to qualified Principal Investigators and their institutions after submission of a Data Access Request (DAR) to the NIH Data Access Committee (DAC) for review and approval.

The database of Genotypes and Phenotypes (dbGaP), administered by the National Library of Medicine (NLM), the National Center for Biotechnology Information (NCBI), provides an online system to support data registration and submission as a NIH-designated repository, as well

as for providing an online system for access to these data through the Authorized Access System. As the NIH controlled-access data landscape has grown to include not just human genomic and associated data, and in order to meet the security and operational standards described in the NIH Guide Notice, "Required Security and Operational Standards for NIH Controlled-Access Data Repositories," (*https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-159.html*), some non-genomic NIH CADRs have leveraged the compliant dbGaP registration and submission system and then subsequently, the Authorized Access System to grant access to controlled-access data in accordance with the NIH CADR standards.

The dbGaP legacy data registration and submission system has been updated to accommodate the newly developed NIH Submission Registration Information Form and the legacy Authorized Access System collects information about data security standards. This collection also introduces modernized online interfaces of the dbGaP data registration and submission system and Authorized Access system to comply with national security directives, NIH CADR requirements, and reduce administrative burden while providing enhanced oversight.

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 9784 hours.

A.12-1 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 – Legacy System					
Study Registration Information Form (Attachment	Submitting Investigator	283	1	1	283

1) and Data Submission (Attachment 4)					
Institutional Certification (Attachment 3)	Institutional Signing Official	272	1	30/60	136
Data Submission Certification (Attachment 2)	Institutional Signing Official	11	1	30/60	6
Study Registration and Data Submission – New System					
Study Registration Information Form (Online) and Data Submission (Attachment 6)	Submitting Investigator	849	1	1	849
Institutional Certification (Attachment 3)	Institutional Signing Official	816	1	30/60	408
Data Submission Certification (Attachment 2)	Institutional Signing Official	33	1	30/60	17
Initial DAR Application – Legacy Authorized Access System					
dbGaP Authorized Access System (Attachment 5)	Principal Investigator	281	4	45/60	843

dbGaP Authorized Access System (Attachment 5)	Institutional Signing Official	281	4	30/60	562
Initial DAR Application – New Authorized Access System					
dbGaP Authorized Access System (Attachment 7)	Principal Investigator	842	4	45/60	2526
dbGaP Authorized Access System (Attachment 7)	Institutional Signing Official	842	4	30/60	1684
Renewal or Close-out – Legacy Authorized Access System					
Renewal or Close-out (Attachment 5)	Principal Investigator	281	4	15/60	281
Renewal or Close-out (Attachment 5)	Institutional Signing Official	281	4	18/60	337
Renewal or Close-out – New Authorized Access System					
Project Renewal or Project Close-out form (Attachment 7)	Principal Investigator	842	4	15/60	842

Project Renewal or Project Close-out form (Attachment 7)	Institutional Signing Official	842	4	18/60	1010
Total			20,232		9784

Dated: March 6, 2026.

Jon Lorsch,

Acting Deputy Director for Extramural Research,

National Institutes of Health.

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