

Supporting Statement A for

NIH Information Collection Web Interface and Forms to Support Genomic Data
Sharing and NIH Controlled-Access Data Repository Requirements (OD)

OMB# 0925-0670 and expiration date, 03/31/2026

Date: February 20, 2026

Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing

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A. ABSTRACT

This application is for a revision to an existing Office of Management and Budget (OMB) approved collection of information, 0925-0670, to continue supporting the National Institute of Health's (NIH's) goals for sharing of controlled-access genomic and associated data and HHS goals of enhancing data sharing. The updates to online forms and web interfaces described in this document support enhanced data security procedures, the modernization of the dbGaP Authorized Access System, and the streamlining of the registration/submission system.

Sharing research data is integral to the mission of the NIH as it advances 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, the NIH issued the Genomic Data Sharing (GDS) Policy ([NOT-OD-14-124](#)). 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 ([CADR](#)). 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 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), is responsible for the management of data registration and submission as a NIH-designated repository, as well as for providing 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," ([NOT-OD-25-159](#)), 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.

A.1 Circumstances Making the Collection of Information Necessary

The information collection activities set forth herein will be conducted under the authorities granted in Section 301 of the Public Health Service Act, 42 USC 241. Further, these information collection activities would be conducted in accordance with the policies and procedures set forth in the NIH GDS Policy and the Required Security and Operational Standards for NIH Controlled-Access Data Repositories.

The NIH GDS Policy expects large-scale human genomic data generated with NIH funds to be submitted to NIH. As a part of the submission process, the associated NIH-funded study is registered in dbGaP. This registration is expected even when the associated NIH-funded study cannot be submitted to NIH due to limitations on sharing. In this way, the dbGaP registration system supports transparency and findability of large-scale human genomic data studies subject to the NIH GDS Policy.

The dbGaP NIH-designated repository and its Authorized Access system are an NIH CADR and in scope of the NIH Guide notice ([NOT-OD-25-159](#)) that establishes standards for security, data oversight and access processes. Because of this, non-genomic NIH CADRs have leveraged dbGaP's registration system and its Authorized Access system to meet requirements in NOT-OD-25-159. As a result, dbGaP provides services to these non-genomic NIH CADRs whose data are registered in dbGaP, but stored at the non-genomic NIH CADR, but access granted through the dbGaP Authorized Access system.

As part of the registration process, Submitting Investigators must complete information in the NIH Study Registration Information (SRI) Form (Attachment 1) for the Legacy Registration and Submission System (Attachment 4). The Legacy Registration also has an option for some of the fields to be populated in its online system. However, not all fields of the SRI Form are incorporated into the Legacy Registration System, so the PI still must complete the SRI Form. In the New Registration System, the SRI Form is an online form that allows the Submitting PI to enter the information themselves (Attachment 6). Data submission is through the Submission Portal that is unchanged in the Legacy Registration System (Attachment 4) and the New Registration System (Attachment 6). Separately, the Submitting Investigator must also provide institutional assurance of data

submission (e.g., an Institutional Certification, Data Submission Certification) that data are appropriate to share with NIH taking into consideration the risks of sharing the data as well as any limitation on use (e.g., Data Use Limitations, DULs). NIH staff then enter information from the data submission form into the dbGaP registration (legacy and new system) which is transmitted to the dbGaP Authorized Access system (legacy and new system) so that the data are shared according to the limitations indicated by the Submitting Investigator and their institution.

Principal Investigators (PIs) interested in using controlled-access human and associated data or other controlled data for secondary research must first apply for access through the dbGaP Authorized Access by submitting an initial Data Access Request (DAR) application. The DAR application is reviewed by the NIH Data Access Committee (DAC), composed of federal employees with the appropriate expertise, who grant investigator access to the data. system As part of the DAR process, PIs and their institutions (through the Institutional Signing Official (SO)) provide information about the PI and their institution, internal or external collaborators, Information Technology (IT) Director, information about the proposed research use of the data, select data of interest, attest to secure the data according to the [NIH Security Best Practices for Users of Controlled-Access Data](#), and agree to the terms of access delineated in the Data Use Certification or similar agreements. Access is for 1 year and it is expected the PI submit a progress report in the form of a Renewal or Close-out. This is expected in the Legacy dbGaP Authorized Access System (Attachment 5) and the New dbGaP Authorized Access System (Attachment 7).

A.2 Purpose and Use of the Information Collection

Since the last OMB approval, NIH has made several necessary changes to the forms and web interfaces required for submitting data and requesting data access to be compliant with national security directives, security and operational standards for NIH CADR, and modernization of the Study Registration and Data Access Request application. These changes, and how they relate to existing dbGaP processes, are expanded upon below.

Study Registration and Data Submission

The required elements for study registration in dbGaP include basic study information submitted by an investigator. Required basic study information includes information about study personnel and funding, a description of the

study and its data, and a statement that secondary researchers can use to acknowledge the original data collection. Typically, NIH staff must communicate with submitting investigators to collect this information for recording via dbGaP. To standardize and streamline the collection of this information across NIH Institute, Center, and Offices (ICOs), NIH has developed a Study Registration Information (SRI) Form (Attachment 1) that can be completed by investigators. The dbGaP Legacy Registration system has been updated to match the datatype fields in the SRI form (Attachment 4 – slides 3 and 4). The new dbGaP registration system has integrated the SRI Form as a digital form in the registration system that allows the Submitting Investigator to register the study (Attachment 6).

Besides basic study information, the required elements for study registration in dbGaP also include the appropriate certification submitted by an investigator and approved by the Institutional Official certifying to NIH how the data are to be shared. For studies involving data subject to the NIH GDS Policy, this certification is an Institutional Certification. Depending on when genomic data from cell lines or clinical specimens were created or collected dictates which Institutional Certification is submitted (pre-2015 With or Without Consent; post-2015; or if an institution is waiting on a determination, a Provisional Institutional Certification) (Attachment 3). NIH has developed a similar form for those NIH ICOs that leverage the dbGaP Authorized Access System to provide access to controlled data that is not subject to the GDS Policy. The form is the Data Submission Certification documented in Attachment 2.

Through either the Institutional Certification or Data Submission Certification, the institution assures that study data submission is consistent with all applicable laws, regulations, and institutional policies; outlines data use limitations, if any; certifies that the identities of research participants will not be disclosed to dbGaP; and assures that different offices or components of an institution with appropriate roles and expertise (such as an Institutional Review Board (IRB), Privacy Board, Human Research Protection Program (HRPP), or equivalent body) has reviewed and approved the appropriateness of the investigator's proposal for data submission to NIH.

Data Access

To request access to controlled-access dbGaP data, PIs must submit a data access request (DAR) application to the relevant NIH DAC. The Legacy dbGaP Authorized

Access System made updates to the new DAR application web interfaces to comply with national security directives, security and operational standards published in the NIH Guide notice NOT-OD-25-159, and awareness for PIs and SOs that the information provided on the DAR application may be used for the evaluation of dbGaP operation, usage, and impact (Attachment 5). These updates were implemented on January 17, 2025, as a part of an OMB nonsubstantive change to a currently approved collection review. The screenshots of the Legacy dbGaP Authorized Access System indicate the nonsubstantive changes and other updates made since the last OMB review (Attachment 5 – slide 5). An online option was also created to allow PIs to transfer their DAR to another PI (e.g., an internal collaborator) at the same institution upon their leaving (Attachment 5 – slide 39). The Legacy dbGaP Authorized Access System will operate for 6 months concurrently with the New dbGaP Authorized Access System. The New dbGaP Authorized Access System is an entirely new data access interface informed by national security directives, operational and security standards, and improvements to the DAR application to decrease administrative burden while strengthening institutional oversight and modernizing the look and feel of the DAR application. These improvements were made for initial DAR applications, DAR application Renewals (Renewals), and DAR application Close-outs (Close-outs) for the PI and SO (Attachment 7).

- Searchable data fields in the DAR application such as the Institutional Signing Officials (SOs) on file in the institution or the Information Technology (IT) Director
- External collaborators no longer have to submit separate, identical DAR application requests. External collaborators can now be added to the same DAR application as the Principal Investigator and be allowed to sign off on the same DAR application as the Principal Investigator.
- Option to do a simple renewal to decrease administrative burden on the PI when submitting a Renewal without any changes to the project.
- In the Renewal, a searchable function to add publications resulting from approved datasets and a checkbox to select which datasets are represented in the publication.
- Enhanced options for PI to transfer projects to another PI at the same institution such that the PI can change the project SO, if necessary, and search at their institution for the new PI to transfer the data.

- Now SOs have the option to return the PI transfer request back to the PI where previously staff at dbGaP would have to provide technical support to do so.
- SOs now have the ability to transfer dbGaP applications to another SO at their organization. This option did not exist in the Legacy Authorized Access System.
- SOs now have the ability to transfer DAR applications to another PI at their institution without the PI initiating the transfer.
- Statement that the information provided on the DAR application may be used for the evaluation of dbGaP operation, usage, and impact.

DAR applications include information about the PI's credentials; the proposed use(s) of the data; an agreement to comply with the terms of the agreement and attest to secure data according to the NIH Security Best Practices for Users of Controlled-Access Data; certification that the requested data will not be sold, distributed, re-identified, or used by unauthorized users (including collaborators not named in the DAR). Before the NIH DAC can approve a PI's DAR application, it must also be approved by the Institutional Signing Official (SO) at the PI's institution, who is legally authorized to enter into an agreement on behalf of the institution. This workflow is consistent between the Legacy Authorized Access System (Attachment 5) and the New Authorized Access System (Attachment 7).

Investigators whose DARs are approved must submit annual requests to renew their data access; if they no longer need access to the dbGaP data, requesters must instead submit a close out. These Renewals and Close-outs ask for information about publications, presentations, or intellectual property based on the research conducted with the accessed data, as well as any data security issues or potential data management incidents.

A.3 Use of Information Technology and Burden Reduction

NCBI developed an online dbGaP system to register studies, submit data, and request access to data. The online system allows PIs to submit the required information directly to dbGaP, thereby minimizing burden not only for PIs and institutions, but also for NIH staff. The online system uses time-saving features, such as the use of pull-down and scrolling menus to fill data fields, "find as you type" (or "type ahead") functionality, and text fields that allow investigators and requesters to cut and paste information from other sources. Where possible, data

fields are automatically filled with information from other data sources, such as eRA Commons, which provides the PI's name, institution, and SO. Also, information from one online form can be used to pre-fill data fields on subsequent forms. Information in a DAR application will be used to pre-fill many of the data fields on the Renewal and Close-out forms. In addition, the data submission system has been designed to allow investigators to submit their data in any format based.

A Privacy Impact Assessment has been completed for the online dbGaP system to register studies, submit data, and request access to data (Attachment 8).

A.4 Efforts to Identify Duplication and Use of Similar Information

Currently, no comparable NIH CADR exists that registers and provides access to studies subject to the NIH GDS Policy and controlled data from NIH CADRs whose studies are not subject to the NIH GDS Policy. Because dbGaP accepts submission from data whose studies are not subject to the NIH GDS Policy, a data submission form was developed (the Data Submission Certification), to accommodate those submissions (Attachment 2)

A.5 Impact on Small Businesses or Other Small Entities

The information collection does not have a differential effect on small businesses.

A.6 Consequences of Collecting the Information Less Frequently

Delaying information submission to dbGaP would impede secondary research studies using data in dbGaP and lessen the value of NIH's investment. It would also limit NIH's ability to ensure that controlled-access data are secured with the controls commensurate with their sensitivity, jeopardizing the security of controlled-access data.

Each year following the initial request and approval to use controlled-access data, requesters must provide updates on their research progress and either close out or request to renew access to the dataset(s) for another year. There are two major consequences to NIH when requesters do not submit the required information annually: a reduced ability to provide oversight, and reduced knowledge of how the data are being used. Either consequence could lead to an increased rate of data management incidents.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This collection fully complies with 5 CFR 1320.5.

A.8.1 Comments in Response to the Federal Register Notice

In accordance with 5 CFR 1320.8(d), the proposed information collection was published in the *Federal Register* (FR) on July 8, 2025, (90 FR 30073) and allowed 60 days for public comment. No comments were received.

A.8.2 Efforts to Consult Outside Agency

Not applicable at this time.

A.9 Explanation of Any Payment of Gift to Respondents

No gifts or payments are to be offered in relation to this information collection.

A.10 Assurance of Confidentiality Provided to Respondents

The names and institutional affiliations of the respondents (both data submitters and data requesters) will be posted publicly on the dbGaP website, and thus there is no assurance of confidentiality afforded to the respondents. However, NIH requests no additional personal information beyond respondents' names and institutional affiliations. Further, most dbGaP data submitters and many dbGaP data requesters are NIH-funded investigators whose names and institutional affiliations are already a matter of public record. (See <http://projectreporter.nih.gov/reporter.cfm>.) Making these details about Submitting Investigators and PIs who seek access to data publicly available is an important ethical underpinning of the NIH GDS Policy. Doing so allows NIH to transparently inform research participants, the scientific community, and the general public of how genomic and associated data are being shared, with whom, and for what research purposes—in addition to helping to foster future research collaborations.

This data collection is covered by the following Privacy Act System of Records:

- 09-90-0777, Facility and Resource Access Control Records;
- 09-25-0200, 09-25-0200 Clinical, Basic, and Population-based Research Studies of the National Institutes of Health (NIH).

A.11 Justification for Sensitive Questions

No questions of a sensitive nature are included in this data collection.

A.12.1 Estimated Annualized Burden Hours

The burden associated with this information collection is calculated in two parts: the burden associated with registering genomic studies and submitting data to dbGaP and other controlled access repositories maintaining data outside the scope of the GDS Policy; and the burden associated with requesting for controlled-access data in dbGaP. Respondents are (1) Submitting Investigators who register and submit data to dbGaP; (2) Institutional Signing Officials who certify data submission through the data submission form; (3) Principal Investigators who request access to data in dbGaP, and (4) Institutional Signing Officials who, as a representative of the institution, authorizes that the institution will abide by the terms of access in the Data Use Certification or similar agreement.

Table A. 12-1 shows the estimated burden hours for Study Registration and Data Submission and Data Access Requests.

Study Registration and Data Submission

The burden associated with registering studies and submitting data to dbGaP involves the time and effort necessary for the Submitting Investigator to complete the SRI Form (Legacy Registration System – Attachment 4) or to complete the online SRI Form integrated into the New Registration System and submit data (Attachment 6). The burden for the Institutional Signing Official (SO) includes the time and effort to review and complete the data submission form (e.g., Institutional Signing Official; Data Submission Certification). NIH does not expect the number of registrations to increase significantly in the next three years. Based on prior experience, most Submitting Investigators do not make changes to their initial registration information but may add additional datasets. Since dbGaP accepts various data formats, additional datasets submitted after the initial registration for the same project do not require any reformatting and thus does not add additional burden to the registration process. Therefore, the average frequency of response per investigator is estimated to be one.

To estimate the annual number of registrations from studies subject to the NIH GDS Policy, NIH averaged the number of study registrations and data submissions received by the dbGaP Registration System in 2025, and the number of registrations anticipated for 2026, based on NIH funding allocated for genomic data research grants that will fall under the NIH GDS Policy. Based on this calculation, NIH estimates 2,176 respondents per year. However, since the Legacy and New dbGaP Registration Systems will run concurrently for 6 months,

assuming equal distribution of use of the systems, the estimated number of respondents were divided equally among the registration systems (272 Submitting Investigators and 272 Institutional Signing Officials that sign the Institutional Certification) for the first six months then for the remaining six months 544 Submitting Investigators and 544 Institutional Signing Officials that sign the Institutional Certification were allocated to the New Registration System. Based on these calculations, the Legacy Registration would expect 272 Submitting Investigators for the SRI Form and 272 SOs for the Institutional Certification. Based on these calculations, the New Registration System would expect 816 Submitting Investigators for the online SRI Form and 816 Submitting Investigators for the Institutional Certification.

Since the dbGaP Registration System services NIH CADR that share data from studies not subject to the NIH GDS Policy, NIH estimated the number of those studies registered and submitted in a year by determining how many of those studies were released in 2025 from these NIH CADR. NIH estimated 86 respondents. However, since the Legacy and New dbGaP Registration Systems will run concurrently for 6 months, the estimated number of respondents were divided equally among the registration systems (11 Submitting Investigators and 11 SOs) for the first six months, then for the remaining six months 22 Submitting Investigators and 22 Institutional Signing Official). Based on these calculations, the total number of Submitting Investigators for the Legacy System resulted in 283 Submitting Investigators for the SRI Form and 11 Institutional Signing Officials for the Data Submission Certification. Based on these calculations, the total number of Submitting Investigators for the New System resulted in 849 Submitting Investigators for the digital SRI form and 33 Institutional Signing Officials for the Data Submission form.

Table 12-1 provides the estimated burden hours for registration and data submission. Based on a simulation of the registration and submission processes using the SRI Form and the SRI online form, NIH estimates that it will take a Submitting Investigator, on average, 1 hour to enter the study information and upload the study data, and that it will take an SO, on average, 30/60 hours to certify the information. Multiplying the frequency of response (1) by the total number of Submitting Investigators by the time it takes a Submitting Investigator to register a study and submit data (1 hour), yields a total annual hour burden for Submitting Investigators for the Legacy System of 283 hours and for the New

System, 849 hours. The same formula was used to derive the total annual burden for SOs (i.e., the frequency was multiplied by the number of SOs by the time it takes an SO to carry out the certification process). The total annual burden for SOs to certify the Institutional Certification in the Legacy System is 136 hours, and for SOs to certify the Data Submission Certification in the Legacy System is 6 hours. The total annual hour burden for SOs to certify the Institutional Certification in the New System is 849 hours, and for SOs to certify the Data Submission Certification in the New System is 408 hours. The total annual burden for the Legacy System is 425 hours and for the New System is 1274 hours.

Data Access

On an annual basis, the PI completes only one of the three forms for a given project (i.e., initial DAR application, Renewal, or Close-out). In order to request data, a PI must complete an initial DAR application. This step also requires the Institutional Signing Official (SO) to review the initial DAR application, and both the PI and SO co-sign the Data Use Certification or similar agreement to use the data according to the terms of access for secondary research use. Upon approval of the initial DAR application, PIs are granted access to the data for one year. At the end of the year, PIs who wish to continue to use the data must complete a Renewal to extend the access period for another year. Information from the initial DAR application is automatically incorporated into the PI's Renewal, and the PI provides additional information such as a description of research progress, publications, presentations, if applicable, reporting of any data management incidents (DMIs), and intellectual property that are based on the secondary use of the data. This step also requires the SO to review the Renewal, and both the PI and SO co-sign the Data Use Certification or similar agreement to use the data according to the terms of access for secondary research use.

PIs who do not wish to renew their access complete a Close-out. Information from the initial DAR application or Renewal is automatically incorporated into the Close-out, and the PI provides additional information such as a description of research conducted over the project period, publications, presentations, if applicable, reporting of any data management incidents (DMIs), report on intellectual property that are based on the secondary use of the data, and attest that the data have been deleted according to the NIH Security Best Practices for Users of Controlled-Access Data. PIs co-sign the Close-out with their SO, who reviews the Close-out, that the reporting and action to delete data has been completed.

The annual time burden estimates are calculated separately for the initial DAR application and Renewal or Close-out. To estimate the number of respondents and the number of requests made per year, NIH totaled the number of respondents and DARs that were submitted over a two-year period and divided by two, for an average of 2246 respondents (1123 PIs and 1123 SOs) and 4430 DARs per year. Since the Legacy and New Authorized Access Systems will run concurrently for six months, assuming equal distribution for those months, the Legacy Authorized Access System average number of respondents is 562 respondents (281 PIs and 281 SOs). The New Authorized Access System average number of respondents is 1684 (842 PIs and 842 SOs)

To calculate the number of annual requests per respondent, NIH divided the number of DARs per year by the number of PIs and estimated four DARs per year. Since each DAR is either renewed or closed out at the end of the one-year access period, the Renewal or Close-out also involves four DARs per year.

Table 12-1 provides the estimated burden hours for completing an initial DAR application. Based on simulations, NIH estimates that it will take a PI an average of 45/60 hours to complete the initial DAR application and 30/60 hours for the SO to review and certify the initial DAR application. To derive the annual hour burden for PIs, NIH multiplied the number of DARs submitted per year (4) by the number of PIs by the time it takes a requester to complete a DAR (45/60 hour). The same formula was used to derive the total annual burden for SOs (i.e., the frequency was multiplied by the number of SOs by the time it takes an SO to complete the certification process). Based on these calculations, PIs submitting an initial DAR Application using the Legacy Authorized Access System had an estimated 843 burden hours and SOs signing off on these applications had an estimated 562 burden hours. Based on these calculations, PIs submitting an initial DAR Application using the New Authorized Access System had an estimated 2526 burden hours and SOs signing off on these applications had an estimated 1684 burden hours. The total annual estimated burden hours for submitting an initial DAR Application using the Legacy Authorized Access System is 1405 hours and using the New Authorized Access System is 4210 hours.

The burden associated with renewal and close-out involves the time and effort necessary for the PI to (1) prepare information on their research use of NIH datasets, (2) complete the Renewal or Close-out form, and (3) have the SO review and approve the form. Importantly, when PIs stop using the data, SOs verify the

data has been deleted according to the Data Use Certification or similar agreement. PIs, who are registered in eRA Commons or those who have made previous data requests or submitted data to dbGaP, will have information from those systems automatically transferred to the Renewal or Close-out forms, significantly reducing data entry time.

Based on simulations, NIH estimates that it will take an average of 15/60 hours for the PI to provide the required information for a Renewal or Close-out and 18/60 hours for the SO to review and certify. To derive the annual hour burden for PIs, NIH multiplied the frequency of response (4) by the number of PIs by the time it takes an PI to complete a Renewal or Close-out form (15/60 hour). The same formula was used to derive the total annual burden for SOs (i.e., the frequency was multiplied by the number of SOs by the time it takes an SO to complete the certification process). Based on these calculations, PIs submitting a Renewal or Close-out in the Legacy Authorized Access System had an estimated 281 burden hours and the SO signing off on the Renewal or Close-out had an estimated 337 burden hours. For the New Authorized Access System, based on these calculations, PIs submitting a Renewal or Close-out had an estimated 842 hours and SOs signing off on a Renewal or Close-out had an estimated 1010 burden hours. The total annual estimated burden hours for submitting a Renewal or Close-out in the Legacy Authorized Access System is 618 hours and in the New Authorized Access System is 1852 hours.

The total annual hour burden is 9784 hours for all respondents.

A.12-1 Estimated Annualized Burden Hours (Data Table)

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	Submitting Investigator	283	1	1	283

Form (Attachment 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	Principal	281	4	45/60	843

Authorized Access System (Attachment 5)	Investigator				
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

A.12-2 Annualized Cost to Respondents

To estimate the annual cost to respondents, NIH used statistics from the U.S. Bureau of Labor and Statistics, National Occupational Employment and Wage Estimates, May 2024¹. The mean hourly wage of \$49.01 for Life Scientists was used for investigators and requesters, and the mean hourly wage of \$59.83 for Education Administrators, Postsecondary, was used for Institutional Officials/Institutional Signing Officials.

Study Registration and Data Submission

Table 12-2 provides the estimated annualized cost to register a study and submit data. To calculate the estimated 'Respondent Cost', The Total Annual Burden Hours for a Type of Respondent was multiplied by the Hourly Respondent Wage Rate. To calculate the estimated cost to register a study and submit data in the Legacy Registration System, the Respondent Cost of the Legacy System was summed and the estimated annual cost is \$22,336. Using this same calculation to sum the estimated annual cost for the New Registration System an estimated annual cost

¹ [Occupational Employment and Wage Statistics](#)

of \$67,007 was calculated. The total estimated annual cost of study registration and data submission is \$89,343.

Data Access

Table 12-2 provides the estimated annual cost for respondents to complete an initial DAR application, a Renewal or a Close-out. To calculate the estimated 'Respondent Cost', The Total Annual Burden Hours for a Type of Respondent was multiplied by the Hourly Respondent Wage Rate. To calculate the estimated cost to submit an initial DAR application in the Legacy Authorized Access System, the Respondent Cost of the Legacy Authorized Access System was summed, and the estimated annual cost was \$74,940. To calculate the estimated cost to submit an initial DAR application in the New Authorized Access System, the Respondent Cost of the New Authorized Access System was summed, and the estimated annual cost is \$224,553. To calculate the estimated cost to submit a Renewal or Close-out in the Legacy Authorized Access System, the Respondent Cost of the Legacy Authorized Access System was summed, and the estimated annual cost is \$33,935. To calculate the estimated cost to submit a Renewal or Close-out in the New Authorized Access System, the Respondent Cost of the New Authorized Access System was summed, and the estimated annual cost is \$101,695. The total estimated annual cost of data access is \$435,122

The estimated annual cost to respondents is \$524,465.

A.12-2 Annualized Cost to the Respondents				
Form Name	Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate	Respondent Cost
Study Registration and Data Submission - Legacy System				
Study Registration Information Form and Data Submission	Submitting Investigator	283	\$49.01	\$13,870
Institutional Certification	Institutional Signing Official	136	\$59.83	\$8,137

Data Submission Certification	Institutional Signing Official	6	\$59.83	\$329
Study Registration and Data Submission - New System				
Study Registration Information Form (Online) and Data Submission	Submitting Investigator	849	\$49.01	\$41,609
Institutional Certification	Institutional Signing Official	408	\$59.83	\$24,411
Data Submission Certification	Institutional Signing Official	17	\$59.83	\$987
Initial DAR Application - Legacy Authorized Access System				
dbGaP Authorized Access System	Principal Investigator	843	\$49.01	\$41,315
dbGaP Authorized Access System	Institutional Signing Official	562	\$59.83	\$33,624
Initial DAR Application - New Authorized Access System				
dbGaP Authorized Access System	Principal Investigator	2526	\$49.01	\$123,799
dbGaP Authorized Access System	Institutional Signing Official	1684	\$59.83	\$100,754

	Renewal or Close-out – Legacy Authorized Access System			
Renewal or Close-out	Principal Investigator	281	\$49.01	\$13,772
Renewal or Close-out	Institutional Signing Official	337	\$59.83	\$20,163
	Renewal or Close-out – New Authorized Access System			
Project Renewal or Project Close-out form	Principal Investigator	842	\$49.01	\$41,266
Project Renewal or Project Close-out form	Institutional Signing Official	1010	\$59.83	\$60,428
	Total	9783	-	\$524,465

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

Other than the respondents’ time, there are no additional costs associated with this data collection.

A.14 Annualized Cost to the Federal Government

The estimated annualized cost to the Federal Government to support this information collection is \$7.5 million, which is comprised of program personnel costs and computer hardware/software costs associated with the project’s implementation and operation. The estimated personnel cost is \$4.78 million, based on 25 employees (contractors and federal) at an average annual rate of \$211,856 and \$218,760 respectively, (salary and benefits). The estimated cost of computer hardware and software is \$2.75 million. Of important, the estimated annualized cost to the Federal Government is not expected to change as a result of

operating the Legacy and New dbGaP Registration and Authorized Access System concurrently for six months.

A.14-4 Annualized Cost to the Federal Government					
Cost Descriptions	Grade/ Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
NIH Software Developer [Staff Scientist]	AD-00	\$234,507	2		\$469,014
Contractor Technical Lead		\$296,324	1		\$296,324
Contractor Content Specialist		\$199,875	4.5		\$899,436
Contractor Software Developer		\$238,390	5		\$1,191,954
Contractor Project Manager		\$291,889	0.6		\$175,133
Contractor Product Manager		\$259,591	0.4		\$103,836
Travel					0
Other Cost					0
Computer Hardware and Software					\$2,750,000
Total					\$7,532,596

A.15 Explanation for Program Changes or Adjustments

Since the last OMB approval, NIH has made several necessary changes to the forms and web interfaces required for registering and submitting data and requesting data access to be compliant with national security directives, security and operational standards for NIH CADR, and customer service improvements for

Principal Investigators (PIs) and Institutional Signing Officials submitting a DAR application.

NIH has developed a Study Registration Information (SRI) Form to standardize and streamline the collection of this information across NIH Institute, Center, and Offices (ICOs). To allow Submitting Investigators to enter the information for themselves by their own timing, NCBI incorporated the SRI Form into an online form that will be available through the New Registration System. To modernize the look and feel of study registration and data submission, NCBI developed the New Study Registration System.

The dbGaP NIH-designated repository and its Authorized Access system are an NIH CADR and in scope of the NIH Guide notice ([NOT-OD-25-159](#)) that establishes standards for security, data oversight and access processes. Because of this, non-genomic NIH CADRs have leveraged dbGaP's registration system and its Authorized Access system to meet requirements in NOT-OD-25-159. To accommodate the submission of non-genomic data to dbGaP, the Data Submission Certification, modeled after the Institutional Certification, was developed so that the Submitting Investigator and their institution can attest that the data submitted to NIH are appropriate to share and indicate any sharing limitations.

The Legacy dbGaP Authorized Access System made updates to the new DAR application web interfaces to comply with national security directives, security and operational standards published in the NIH Guide notice NOT-OD-25-159. These updates were implemented on January 17, 2025, as a part of an OMB nonsubstantive change. These updates included a PI attestation and an SO attestation that the data are secured according to the security standards in the NIH Security Best Practices for Users of Controlled-Access Data, and if using a third-party cloud resource, that the third-party is security data according to these security standards.

NCBI developed a New Authorized Access System to modernize the DAR interface, make it user friendly with additional options such as:

- Searchable data fields in the DAR application such as the Institutional Signing Officials (SOs) on file in the institution or the Information Technology (IT) Director

- External collaborators no longer have to submit separate, identical DAR application requests. External collaborators can now be added to the same DAR application as the Principal Investigator and be allowed to sign off on the same DAR application as the Principal Investigator.
- Option to do a simple renewal to decrease administrative burden on the PI when submitting a Renewal without any changes to the project.
- In the Renewal, a searchable function to add publications resulting from approved datasets and a checkbox to select which datasets are represented in the publication.
- Enhanced options for PI to transfer projects to another PI at the same institution such that the PI can change the project SO, if necessary, and search at their institution for the new PI to transfer the data.
- Now SOs have the option to return the PI transfer request back to the PI where previously staff at dbGaP would have to provide technical support to do so.
- SOs now have the ability to transfer dbGaP applications to another SO at their organization. This option did not exist in the Legacy Authorized Access System.
- SOs now have the ability to transfer DAR applications to another PI at their institution without the PI initiating the transfer.
- Statement that the information provided on the DAR application may be used for the evaluation of dbGaP operation, usage, and impact.

These improvements were made for new DAR applications, Renewals (Renewals), and Close-outs for the PI and SO.

The total annual hour burden significantly decreased from the previous OMB submission from 158,776 hours to 9783 hours. This is due to a decrease in the number of respondents submitting initial DAR applications and a Renewal or a Close-out. Additionally, due to the number of data access requests decreasing from the last submission from 10 to 4, this also resulted in a decrease in the annual burden hours for this submission.

A.16 Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested.

A.17 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.