Supporting Statement A for

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

OMB# 0925-0670 and expiration date, 11/31/2022

 Date: November 18, 2022

Check off which applies:

* New

X 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 NIH’s goals for sharing of genomic data and HHS goals of enhancing data sharing. The online forms described in the rest of this document reduce burden for investigators who submit data and for requesters who wish to access the data for secondary research.

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, the NIH issued the Genomic Data Sharing (GDS) Policy. 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 addresses data submission, maintenance, and access. Under the Policy, NIH-funded investigators generating large-scale genomic data are expected to submit these data and associated phenotypic data to a repository acceptable under the Genomic Data Sharing Policy. Human genomic data submission and access, is managed through the database of Genotypes and Phenotypes (dbGaP), administered by the National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH.

Controlled-access data in repositories acceptable under the Genomic Data Sharing Policy (e.g., dbGaP) are made available for secondary research after requesters have submitted a request and obtained approval from an NIH Data Access Committee (DAC) for a particular project. Approved requesters are granted access to millions of dollars of genomic research data without charge.

**A.1 Circumstances Making the Collection of Information Necessary**

The collection of information activities set forth herein would be conducted under the authorities granted in Section 301 of the Public Health Service Act, 42 USC 241 and in accordance with the policies and procedures set forth in the NIH GDS Policy.

Under the NIH GDS Policy, all investigators who receive NIH funding to conduct research studies generating large-scale human genomic data maintained in controlled access are expected to register the studies in dbGaP, no matter which repository acceptable under the Genomic Data Sharing Policy 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 (e.g., individual-level genotype data, aggregate-level association data) as documented in see attachment 2. They must also provide a description of the study and an institutional assurance of the data submission (i.e., an Institutional Certification) as documented in attachment 1, which delineates any limitations on the use of the data for secondary research (e.g., data can be used only for research on particular diseases).

Although NIH encourages genomic data sharing through this Policy, circumstances beyond the control of investigators may preclude submission of human genomic data to a repository acceptable under the Genomic Data Sharing Policy (e.g., country or state laws that prohibit data deposition in a U.S. database). In such cases, an exception to submit genomic data to a repository acceptable under the Genomic Data Sharing Policy may be granted. For transparency purposes, when exceptions are granted, studies will still be registered in dbGaP, the reason for the exception will be included in the registration record, and a reference will be provided to an alternative data-sharing plan or resource, if available.

Requesters interested in using controlled access human data for secondary research must apply for access through dbGaP and be granted permission to use the data from the appropriate NIH DAC. As part of the application process, requesters and their institution must provide information such as a description of the proposed research use of the data that conforms to the data use limitations, agree to secure the data according to the NIH Security Best Practices for Controlled Access Data Subject to the Genomic Data Sharing Policy and to the Genomic Data User Code of Conduct through the terms of access described in the Data Use Certification agreement.

## A.2 Purpose and Use of the Information Collection

Since the last approved PRA, minor changes have been made that focus on updating the systems and/or forms, which are described below. Changes have also been made to the Institutional Certification to clarify issues related to confidentiality and to update language. In addition, to address a need identified by NIH Institutes, Centers, and Offices, a provisional Institutional Certification form was created for NIH funding applicants in the process of obtaining IRB approval when the Institutional Certification Form is due. This need arises when applicants for NIH funding have received a score that indicates that they will receive funding pending changes requested by peer reviewers or NIH Program Officials. If those changes involve modifications to provisions related to data sharing to an IRB approved protocol the timing of submitting a protocol amendment for IRB review may not align with the grant cycle date, for making the award. In those cases, restricted awards are issued to allow for funding of research activities have already been approved by the IRB (e.g. participant recruitment) or do not require IRB approval to go forward, but funds will not be released for activities that have not yet received IRB approval. The submission of a provisional Institutional Certification to NIH allows NIH repositories and program staff to plan for and prepare for receiving data but not to register a study in dbGaP. Once any needed IRB approval is received and all requested changes are made, previously restricted funds can be released and awardees must submit a completed Institutional Certification so that registration in dbGaP can be completed.

In instances where the IRB disapproves provisions related to genomic data sharing as described in the application, investigators would need to revise their application to indicate the IRB determination and provide justification for requesting approval of the needed limitations on data submission. If possible, investigators should identify another approach to sharing data to the maximum extent possible (for instance, sharing aggregate data as opposed to individual level data) that can be approved by the IRB.

Note that, at any given time, a user would only need to submit either a completed Institutional Certification or a Provisional Institutional Certification to NIH staff. These changes are documented in Attachment 1.

Changes to the online registration system were made to reflect system updates and to accommodate modern workflows. For example, the system now accommodates users who wish to use cloud computing to perform research. These changes are documented in Attachment 2.

In addition, we note that the number of data access requests has increased on an annual basis, leading to an increased annual response burden per respondent (from 2 to 10).

*Study Registration and Data Submission*

The required elements for study registration in dbGaP include basic study information and the appropriate Institutional Certification submitted by an investigator and approved by the Institutional Official. Basic study information includes the name of the investigators, funding information, a description of the study and data, and a statement that secondary researchers can use to acknowledge the original data collection. Through the Institutional Certification form, the institution assures that study data submission is consistent with all applicable laws, regulations, and institutional policies; outlines data use limitations, if any, and certifies that the identities of research participants will not be disclosed to dbGaP; and documents that an Institutional Review Board (IRB) and/or Privacy Board reviewed and approved the plan to submit the data to dbGaP. Data files are submitted prior to registration. Attachment 2 illustrates the information that will be collected for dbGaP study registration and data submission.

*Data Access*

The initial data access request (DAR) application to request controlled-access dbGaP data includes information about the requesting investigator’s credentials; the proposed use of the data; an agreement to comply with NIH policies, the NIH Security Best Practices for Controlled Access Data Subject to the Genomic Data Sharing Policy, the Genomic Data User Code of Conduct;[[1]](#footnote-2) and certification by the requester and an Institutional Signing Official at the requester’s institution that data will not be sold, distributed, re-identified, or used by unauthorized users and collaborators not named in the DAR. Requests to renew data access and reports to close out data use are done annually and are similar to the initial DAR. Additional information obtained in the annual Project Renewal form and Project Close-out forms includes 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.

As a pre-requisite to applying for controlled-access data, the requester and an Institutional Signing Official must be registered in the NIH electronic Research Administration (eRA) Commons.[[2]](#footnote-3) The vast majority of requesters seeking access to dbGaP data have already registered with eRA Commons when applying for NIH funding. For requesters not previously registered in eRA Commons, this step is not expected to add significantly to the burden. Several of the mandatory fields in the DAR form will be automatically filled based on eRA registration information, and most fields in the Project Renewal and Project Close-out forms will be automatically filled from the initial DAR form. Attachment 2 illustrates the investigator and institutional information that will be collected for data access.

**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 investigators to submit the required information directly to dbGaP, thereby minimizing burden not only for investigators 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 investigators or requester’s name, institution, Institutional Official, and Institutional Signing Official. Also, information from one online form can be used to pre-fill data fields on subsequent forms. For example, information from an Institutional Certification will be used to pre-fill many data fields in the study registration system, and likewise, information in a DAR will be used to pre-fill many of the data fields on the Project Renewal and Project Close-out forms. In addition, the data submission system has been designed to allow investigators to submit their data in any format based on the genomics platform used.

A Privacy Impact Assessment has been completed for the online dbGaP system to register studies, submit data, and request access to data (Attachment 3).

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

Currently, no comparable genomic data registry and repository exists for submission and access. dbGaP is unique in that it provides a single site for NIH-funded human genomic research studies, as well as to many non-NIH-funded human genomic research studies.

**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 submission of the information to dbGaP would impede secondary research studies of data in dbGaP and lessen the value of NIH’s investment.

Following the initial request and approval to use controlled-access data, requesters must provide annual updates on their research progress and renew access to the dataset(s) for another year or close-out access to the dataset(s). The consequence of not submitting the required information annually is a reduction in NIH ability to provide oversight of dbGaP data, and reduced knowledge of how the data are being used, possibly leading 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 September 21, 2022, (87 FR 57705) and allowed 60 days for public comment. (COMMENTS IF ANY).

**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 regard 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, it is important to emphasize that no personal information is requested from investigators submitting or accessing data beyond their name and institutional affiliation. Submitters of data to dbGaP are largely NIH-funded investigators whose names and institutional affiliations are already a matter of public record (see <http://projectreporter.nih.gov/reporter.cfm>). Requesters of the data are both NIH-funded and non-NIH-funded investigators. Making the names of submitters and requesters of the data publicly available is an important ethical underpinning of the NIH GDS Policy as it allows NIH to be transparent in informing research participants, the scientific community, and the general public on how genomic data are being shared, with whom, and for what research purpose in addition to helping to foster future research collaborations.

A System of Records Notice (SORN) 09-25-0036, is in place for eRA Commons, which dbGaP uses for credentialing purposes of submitters and data requestors (<https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0036.htm>). Federal Register Notice published on September 26, 2002 (Vol. 67, No. 187, page 60751 -<https://www.federalregister.gov/articles/2002/09/26/02-23965/privacy-act-of-1974-annual-publication-of-systems-of-records#h-167>). Another SORN 09-90-1401 expanding the relevant data access enterprise, (e.g. NIH-designated data repositories and DACs) is in place (<https://www.federalregister.gov/documents/2018/03/14/2018-05176/privacy-act-of-1974-system-of-records>). Federal Register Notice published on March 14, 2018 (Vol. 83, No.50, page 11214 - <https://www.govinfo.gov/content/pkg/FR-2018-03-14/pdf/2018-05176.pdf>).

**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 the burden associated with applying for controlled-access data in dbGaP. Respondents are (1) investigators submitting data to dbGaP; (2) Institutional Officials who assure the data submission; (3) investigators who request and receive data (requesters); and (4) Institutional Signing Officials who certify that they will abide by the NIH GDS Policy.

Table A. 12-1 shows the estimated burden hours for Study Registration and Data Submission, Data Access Requests, and Project Renewal/Project Close-out forms.

*Study Registration and Data Submission*

The burden associated with registering genomic studies and submitting data to dbGaP involves the time and effort necessary for the investigator to complete the online form, and upload the data to dbGaP. The burden for the Institutional Official includes the time and effort to review and approve the registration and data submission, including completion of the Institutional Certification. Because NIH makes it possible to submit the information through tailored, user-friendly online forms, the time and effort is considerably reduced. Moreover, some of the information investigators will need to complete the forms will be automatically provided from eRA Commons and other information can be retrieved from the investigator’s NIH grant award.

*Data Access*

On an annual basis, the requester completes only one of the three forms for a given project (i.e., initial, Project Renewal, or Project Close-out). In order to request data from dbGaP, a requester must complete a data access request (DAR) form of the project request. This step also requires the Institutional Signing Official to review the DAR, and both the requester and Institutional Signing Official must certify that they agree to the terms and conditions for use of the data and will adhere to the NIH GDS Policy. Upon approval of their request, requesters are granted access to the data for one year. At the end of the year, investigators who wish to continue to use the data must complete a Project Renewal to extend the access period for another year. Information from the original DAR is automatically incorporated into the requester’s Project Renewal form, and the requester provides additional information such as a description of research progress, publications, presentations, and intellectual property that are based on the secondary use of dbGaP data.

Requesters who do not wish to renew their access request are expected to complete a Project Close-out. Information from the original DAR or Project Renewal is automatically incorporated into the Project Close-out form, and the requester provides additional information such as a description of publications, presentations, and intellectual property that are based on the secondary use of dbGaP data. Completion of the Project Close-out provides NIH with information on final project outcomes, and also provides the oversight mechanism by which the Institutional Signing Official confirms that the project has been discontinued and that all copies, versions, and data derivatives of the dataset(s), on both local servers and hardware, have been deleted to maintain privacy and assure secure data destruction.

**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** |
| dbGaP Registration and Submission | Investigator Submitting Data  | 1,050 | 1 | 1 | 1050  |
| Institutional Certification | Investigator filling out Institutional Certification | 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 Certification | 100 | 1 | 45/60 | 75 |
| Provisional Institutional Certification | Institutional Official to Certify Provisional Submission | 100 | 1 | 45/60 | 75 |
|  |
| **Requesting Access to Data** |
| 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** |
| 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 |

**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 2021, National Occupational Employment and Wage Estimates.3 The mean hourly wage of $44.80 for Life Scientists was used for investigators and requesters, and the mean hourly wage of $53.49 for Education Administrators, Postsecondary, was used for Institutional Officials/Institutional Signing Officials. The annual cost burden estimates are calculated separately for the initial DAR and Project Renewal or Project Close-out forms.

**A.12-2 Annualized Cost to the Respondents**

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Respondents  | Total Annual Burden Hours | Hourly Respondent Wage Rate8 | Respondent Cost |
| Study Registration and Data Submission |
| Investigator Submitting Data | 1,050 | $44.80 | $47,040 |
| Investigator filling out Institutional Certification | 788 | $44.80 | $47,040 |
| Institutional Official to Certify Submission | 788 | $53.49 | $42123.38 |
| Investigator filling out Provisional Institutional Certification | 75 | $44.80 | $3,360 |
| Institutional Official to Certify Provisional Submission | 75 | $53.49 | $4,011.75 |
|  |
| Requesting Access to Data |
| Requester Submitting Request | 39,000 | $44.80 | $1,747,200  |
| Institutional Signing Official to Certify Request | 39,000 | $53.49 | $2,086,110  |
|  |
| Project Renewal/Project Close-out Process |
| Requester Submitting Request | 39,000 | $44.80 | $1,747,200 |
| Institutional Signing Official to Certify Request | 39,000 | $53.49 | $2,086,110 |
| Total | 158,776 |  | $7,810,195.13 |

**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** A**nnualized 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.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Cost Descriptions** | **Grade/Step** | **Salary** | **% of Effort** | **Fringe** **(if applicable)** | **Total Cost to Gov’t** |
| **Federal Oversight** |  |  |  |  |  |
| **NIH Content Team Lead**[Staff Scientist] | AD-00 | $234,507 | 2.0 |  | $469,014 |
| **NIH Content Specialist**[Staff Scientist] | AD-00 | $196,306 | 5.0 |  | $981,530 |
| **NIH Data Specialist**[Staff Scientist] | AD-00 | $212,126 | 1.6 |  | $339,402 |
| **NIH Software Developer**[Staff Scientist] | AD-00 | $227,100 | 2.1 |  | $476,910 |
|  |  |  |  |  |  |
| **Contractor Technical Lead** |  | $279,551 | 1.0 |  | $279,551 |
| **Contractor Content Specialist** |  | $188,561 | 4.5 |  | $848,525 |
| **Contractor Software Developer** |  | $224,897 | 5.0 |  | $1,124,485 |
| **Contractor Project Manager** |  | $275,367 | 0.6 |  | $165,220 |
| **Contractor Product Manager** |  | $244,897 | 0.4 |  | $97,959 |
|  |  |  |  |  |  |
| Travel |  |  |  |  | 0 |
| Other Cost |  |  |  |  | 0 |
| Computer Hardware and Software |  |  |  |  | $2,750,000 |
| **Total** |  |  |  |  | $7,532,596 |

**A.15 Explanation for Program Changes or Adjustments**

This application is for a revision to an existing Office of Management and Budget (OMB) approved collection of information, 0925-0670. Changes in Attachments 1 and 2 are described below and noted in the attachments. Some changes focus on reducing redundancy among data submissions and access requests and increasing awareness of the ethical responsibilities associated with the responsible use of genomic information.

In the Institutional Certification forms (Attachment 1), we changed the form to address NIH/HHS (slide 2), added questions and language regarding the availability of individual-level data and asking whether the data will be covered by a Certificate of Confidentiality (slide 3). We also added a question in the Genomic Summary Results section regarding Certificates of Confidentiality (slide 3). In the same section, we added a field for researchers to explain why data may be sensitive (slide 3). On the signature page, we added language cautioning against making false or misleading statements (slide 4). We updated language on the reference page to bring it up to date and to clarify GDS policy (slide 5). In addition, to address a need identified by NIH Institutes, Centers, and Offices, a provisional Institutional Certification form was created for those in the process of obtaining IRB approval due to changes requested by NIH (slides 6, 7, 8) when the Institutional Certification Form is due. We anticipate that this form will be used sparingly.

We anticipate that the Provisional Certification will be used sparingly because restricted awards are relatively uncommon and because awards that are restricted due to IRB approval of changes related to genomic data sharing are expected by NIH Genomic Program Administrators to account for a very small proportion of restricted awards. We have anecdotal experience from the experiences of investigators (who are federal staff) in the NIH Intramural Research Program who have requested the ability to provide a provisional Institutional Certification Form and there have been a small number of such requests.

In the dbGaP registration and submission forms (Attachment 2): there is now an option to add an external data source (slide 3). There are new selectors for adding data types to dbGaP (slide 4).

In the dbGaP data access, renewal, and close-out forms (Attachment 2): there is a new select box to ask permission to use cloud computing (slide 5), removed decryption password entry from the Authorized Access System (due to the encryption now being automatic) (slide 5), the “types of research” selection form has been removed from the Project Request interface because the information will go elsewhere (slide 6), added a tab to input Cloud Providers if a requestor would like to use cloud computing to carry out the proposed research (slide 7), added ability to upload a single document for multiple requests (slide 8), and added a step to allow users to close out a subset of requests within a multi-request project (slide 9).

None of the changes are expected to result in a change in burden.

We do, however, note an increase in burden in the dbGaP data access, renewal, and close-out forms over the past three years. This is due to increased usage of the database from approximately 2 request per user per year to 10. Because each request must be either closed out or renewed on an annual basis (it is also possible for both to occur for the same request), for every request, there is always a corresponding increase in the number of close-out and renewals.

**A.16** **Plans for Tabulation and Publication and Project Time Schedule**

Information submitted to dbGaP to register studies or access genomic data will be made available to the public via the dbGaP website once the registration is complete and the study has been released. The only submitted information that will not be publicly displayed on the website is contact information of the submitting investigators and requesters (i.e., the investigator’s email addresses, and phone and fax numbers).

NIH will post on their public website, on a bi-annual basis, an analysis of data usage that would include summary statistics such as the number of registered studies, the number of submitted/approved DARs, trends in usage, and number of publications.

**A.17 Reason(s) Display of OMB Expiration Date is Inappropriate**

No exemption is requested.

**A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

No exceptions are requested.

1. NIH Genomic Data User Code of Conduct. See <https://sharing.nih.gov/sites/default/files/flmngr/Genomic_Data_User_Code_of_Conduct.pdf> [↑](#footnote-ref-2)
2. eRA Commons. See <https://www.era.nih.gov/>. [↑](#footnote-ref-3)