


**Attachment 1: Documentation of the dbGaP
registration and access system web forms, including
changes since 2019 PRA approval**

Submitting Investigator: Registration Web Form

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 dbGaP genotypes and phenotypes Logged in as **Michael L. Feolo** | [Log out of dbGaP](#)

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- OMB NO: 0925-0670
- EXPIRATION DATE: 11/30/2022
- [Burden statement](#)

Public reporting burden for this collection of information is estimated to vary from 30 to 60 minutes per response for initial registration of the required fields. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0670). Do not return the completed form to this address.

Register New Study

Submitting Investigator: Registration Web Form

Manage Study

RADx TEST STUDY

Study Registration Information

* Study Name Study Accession
phs .v .p

* Study Mode: Normal Collection

* Institutes or Centers supporting the study: [Show all NIH ICs](#)
 OD

Admin. IC:

Target data delivery date (YYYY-MM-DD) Target public release date (YYYY-MM-DD) Estimated number of study participants

Sequence Read Archive (SRA)

* Sequence Read Archive submission is expected:

* Data submission to dbGaP is expected:

External data source

Name of External DB

URL of External DB download interface

Help-desk of External DB

Will subject or sample ids be registered to dbGaP with minimally required metadata?

Will Sequence data be submitted to NCBI/SRA?

Will Genotype/Phenotype be submitted to NCBI?

Does External data source have data not at NCBI?

Added the option to add an external data source

Page continues on next slide

Submitting Investigator: Registration Web Form

* Data submission to dbGaP is expected:

Please check all data types expected for this study:

Study data type	Study data outline - expected data
1. Subjects and Samples	<input type="radio"/> yes <input checked="" type="radio"/> no
2. Phenotype	<input type="radio"/> yes <input checked="" type="radio"/> no
3. Molecular (doesn't include Next Generation Sequencing (NGC))	<input type="radio"/> yes <input checked="" type="radio"/> no
4. Links to public NCBI databases	<input type="radio"/> yes <input checked="" type="radio"/> no
5. Sequence	<input type="radio"/> yes <input checked="" type="radio"/> no
6. Association Analysis	<input type="radio"/> yes <input checked="" type="radio"/> no
7. Documents	<input type="radio"/> yes <input checked="" type="radio"/> no
8. Images	<input type="radio"/> yes <input checked="" type="radio"/> no
9. Other files not covered and / or any other notes about expected data	<input type="text"/>

Added new radio button selector for data types for those submitting data to dbGaP

Requesting Investigator: Access Web Form

Please make it clear whether you plan to combine requested datasets with other datasets outside of dbGaP, and, if so, whether you plan to analyze these datasets independently or together. If you do plan to combine datasets in any way, please describe your plan and also please discuss whether it creates any additional risks to participants. If you are focusing on outcomes or hypotheses that were not the focus of the primary study (or studies), please describe the outcomes you propose to examine.

Investigators do not need to submit a new project request unless the dataset will be used for research outside of the scope of the approved Research Use Statement

Please enter your RUS in the area below. The RUS should be one or two paragraphs in length and include research objectives, the study design, and an analysis plan (including the phenotypic characteristics that will be tested for association with genetic variants). If you are requesting multiple datasets, please describe how you will use them. Examples of RUS can be found at [GDS website](#). Please limit your RUS to 4500 characters.

use for test.
1111
222<2
333>3

New select box

I am requesting permission to use cloud computing to carry out the research as described in my Research Use Statement.

Cloud Use Statement

Describe the type(s) of cloud computing service(s) you wish to obtain (e.g., PaaS, SaaS, IaaS, DaaS) and how you plan to use it (them) to carry out the work described in your Research Use Statement (e.g., datasets to be included, process for data transfer, analysis, and storage, and tools and/or software to be used). Also describe the role of any collaborators. Please limit your statement to 2000 characters.

asdf

*Non-technical summary

Please enter below a non-technical summary of your RUS suitable for understanding by the general public (written at a high school reading level or below). Please limit your non-technical summary to 1300 characters.

asdf

*Choose your Signing Official (SO)

Your SO is typically the same person who signs your grant applications and is an individual listed in eRA Commons as a SO for your institution and who has the authority to certify your application on behalf of your institution.

Doe, Jane (sserqev@ncbi.nlm.nih.gov)

Applicant organization

*Institution Name	Department	Division
NIH		
*Street 1	Street 2	*City
easyggg		bethesda
		*State
		md
		*ZIP/Postal code
		12345
		*Country
		United States

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Feedback

Encryption options removed from page because encryption is now automatic

Requesting Investigator: Access Web Form

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Project renewal

Info: Announcement: dbGaP has implemented a new option for approved users to closeout individual DARs when doing a project

#2476: test5

SO: Jane Doe

[Project Details](#) [Choose Datasets](#) [Research Project](#) [Cloud Providers](#) [Collaborators](#) [IT Director](#) [Research Progress](#) [Presentations](#) [Feedback](#)

1/30/2022

[DUC](#) [Review DUL](#) [Review Applications](#)

“Types of research” checkboxes removed

*Descriptive Title of Project

Please note that coordinated requests by collaborating institutions should each use the same title.

test5

Copy and paste your Research Use Statement and non-technical summary below. All applications must be made in English.

*Research Use Statement (RUS)

A RUS is a brief description of the applicant's proposed use of dbGaP dataset(s). The RUS will be reviewed by all NIH Institutes and Centers responsible for data covered by this Data Access Request. Please note that if access is approved, you agree that the RUS, along with your name and institution, will be included on the dbGaP website to describe your research project to the public.

Please make it clear whether you plan to combine requested datasets with other datasets outside of dbGaP, and, if so, whether you plan to analyze these datasets independently or together. If you do plan to combine datasets in any way, please describe your plan and also please discuss whether it creates any additional risks to participants. If you are focusing on outcomes or hypotheses that were not the focus of the primary study (or studies), please describe the outcomes you propose to examine.

Investigators do not need to submit a new project request unless the dataset will be used for research outside of the scope of the approved Research Use Statement

Please enter your RUS in the area below. The RUS should be one or two paragraphs in length and include research objectives, the study design, and an analysis plan (including the phenotypic characteristics that will be tested for association with genetic variants). If you are requesting multiple datasets, please describe how you will use them. Examples of RUS can be found at [GDS website](#). Please limit your RUS to 4500 characters.

use for test.
1111
222<2
333>3

I am requesting permission to use cloud computing to carry out the research as described in my Research Use Statement.

Cloud Use Statement

Describe the type(s) of cloud computing service(s) you wish to obtain (e.g., PaaS, SaaS, IaaS, DaaS) and how you plan to use it (them) to carry out the work described in your Research Use Statement (e.g., datasets to be included, process for data transfer, analysis, and storage, and tools and/or software to be used). Also describe the role of any collaborators. Please limit your statement to 2000 characters.

asdf

Requesting Investigator: Access Web Form

New tab added for investigators who choose to use cloud platforms for data analysis

Project Request

#2476: test5

SO: Jane Doe

+ OMB control number: 0925-0670 Expiration date: 11/30/2022

[Project Details](#) [Choose Datasets](#) [Research Project](#) [Cloud Providers](#) [Collaborators](#) [IT Director](#) [Confirm Datasets](#) [Review DUC](#) [Review DUL](#) [Review Applications](#) [Feedback](#)

In order to be granted permission to use cloud computing to carry out the proposed research described in the Research Use Statement of this Data Access Request (DAR), below please provide the name of the cloud service provider, the type of cloud : (commercial or private), and describe the type of service you will be obtaining and how you will be using it.

Cloud Provider Information

*Name of Provider

asdf

*Type of Provider

Commercial ▼

Details

asdfcc

Remove

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Institutional Signing Official: Access Web Form

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Project Request

#21568: 2018 PRA Renewal NIH Information Collection Forms to Support Genomic Data Sharing for Research Purposes

+ OMB control number: 0925-0670 Expiration date: 03/31/2019

[Review DUC](#) [Review Applications](#)

Institutional Approval of Data Access Request(s) (DAR)

A Data Access Request(s) (DAR) application has been submitted for your review. Click on the PDF link below to download and review the complete application. The Data Use Certification Agreement(s) pertaining to the requested dataset(s) is appended to the DAR application. If you approve the DAR application, it will be transmitted to the [NIH Data Access Committee\(s\)](#) responsible for overseeing the requested dataset(s). The DAC(s) will review the DAR(s) and make a determination about whether access to the data should be granted.

[Data Access Request\(s\) Application](#)

[Return to PI](#)

Agreement to Adhere to the Provisions of the GDS Policy and the Terms Described by the Data Certification Agreement(s)

By signing below, I certify on behalf of this institution that the Information Technology Director, the Principal Investigator and other approved users under the DAR, and I have reviewed the terms of access governing the use of controlled-access data subject to the [GDS Policy](#) as described in the Data Use Certification Agreement(s) for the requested dataset(s) and the [Approved User Code of Conduct](#), and that we agree to adhere to all of the terms therein. We also understand that any violation of those terms may lead to termination of access and other penalties.

I agree

Agreement to Adhere to Data Security Expectations

By signing below, I certify on behalf of this institution that the Information Technology Director, the Principal Investigator and other approved users under the DAR, and I have reviewed the [NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy](#), and that we agree to manage and protect the requested dataset(s) by following those Best Practices as well as our own institutional IT security requirements and policies. I also certify that that this institution's IT security requirements and policies are sufficient to protect the confidentiality and integrity of the requested dataset(s) entrusted to this institution.

I agree

Acknowledgment of Responsibility

By signing below, I, on behalf of this institution, acknowledge that this institution is the sole responsible party for assuring our adherence to the terms of the Data Use Certification Agreement. I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

I agree

[Approve and Submit to DAC](#)

This project currently contains **1 active request** for data access. You can view individual applications and processing statuses in the table below.

Active (1)

#	Study, Consent	Status	Expiration	Application
79735-1	Glaucoma Exome Sequencing (phs000558.v1.p1) General Research Use (IRB) (phs000558.v1.p1.c1) , NEI	SO review		view

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Please **carefully review** submitted information by clicking on "Review Complete Application".









To revise: Use navigation tabs to return to any previous step and make the changes.

To approve: **Check the boxes** below to attach your electronic signature acknowledging agreement to the terms.

You need Adobe Reader installed to review PDF forms.



Requesting Investigator: Access Web Form

Alzheimer's Disease Genetics Consortium		
Local IRB approval is required, Do NOT include FULL protocol;	 download	<input type="button" value="Delete"/> (uploaded on 2021-10-05)
Alzheimer's Disease Sequencing Project (ADSP)		
Local IRB approval is required, Do NOT include FULL protocol;	 download	<input type="button" value="Delete"/> (uploaded on 2021-10-05)
CARDIA Cohort		
Local IRB approval is required, Do NOT include FULL protocol;	 download	<input type="button" value="Delete"/> (uploaded on 2021-10-05)
Exome Sequencing of Clear Cell Endometrial Tumors and Paired Non-tumor Samples		
Letter of Collaboration is required;	 download	<input type="button" value="Delete"/> (uploaded on 2021-10-05)
Framingham Cohort		
Local IRB approval is required, Do NOT include FULL protocol;	 download	<input type="button" value="Delete"/> (uploaded on 2021-10-05)
Glaucoma Exome Sequencing		
Local IRB approval is required, Do NOT include FULL protocol;	 download	<input type="button" value="Delete"/> (uploaded on 2021-10-05)
NHLBI TOPMed: Genomic Activities such as Whole Genome Sequencing and Related Phenotypes in the Framingham Heart Study		
Local IRB approval is required, Do NOT include FULL protocol;	 download	<input type="button" value="Delete"/> (uploaded on 2021-10-05)
NHLBI TOPMed: The Jackson Heart Study (JHS)		
Local IRB approval is required, Do NOT include FULL protocol;	 download	<input type="button" value="Delete"/> (uploaded on 2021-10-05)
San Francisco Bay Area Latina Breast Cancer Study		
Letter of Collaboration is required;	 download	<input type="button" value="Delete"/> (uploaded on 2021-10-05)

Load one document for all requests No file chosen

Only PDF files (up to 10M in size) accepted.

Please note that some of your data access requests require additional documentation. This documentation should be updated if they have expired. Please check the expiration dates of these documents before proceeding.

New check box allows requesting investigators to upload one document for multiple requests

Requesting Investigator: Access Web Form

New tab added to allow user to close out some DARs within a project during a project renewal.

Project renewal

Info: Announcement: dbGaP has implemented a new option for approved users to closeout individual DARs when doing a project annual renewal.

#2476: test5

SO: Jane Doe

+ [OMB control number: 0925-06](#) [Expiration date: 11/30/2022](#)

[Project Details](#) [Choose Datasets](#) [Research Project](#) [Cloud Providers](#) [Collaborators](#) [IT Director](#) [Research Progress](#) [Presentations](#) [Publications and Manuscripts](#) [Data Security](#) [Confirm Datasets](#) **[Closeout](#)** [Review DUC](#) [Review DUL](#) [Review Applications](#)
[Feedback](#)

You are selecting the option to close out a dataset (from a Data Access Request (DAR)) during your dbGaP Project renewal period. Initiating this process means that the dataset(s) you select to close out is/are no longer needed for the research objectives described in this Project's Research Use Statement, and the dataset(s) you wish to close out did not result in publishable findings. If your use of the dataset(s) did indeed result in publication, the publication(s) should be reported and the dataset(s) should not be closed out until you close out your entire Project. This is because you will not be allowed to retain data for any reason if you wish to close out an individual dataset during this renewal process.

If you wish to closeout a DAR, please select a DAR to closeout in your project. It is expected at DAR closeout that all data are destroyed according to NIH expectations described in the Data Use Certification (DUC) agreement and addendum. The closeout request will be routed to your SO for confirmation. Once your SO confirms that data were destroyed according to the DUC and addendum, the DAR will be closed and removed from your project. No further action will be needed on your part regarding the DAR closed out.

Reasons for dar closeout:

- Unable to download data
- Dataset(s) not needed for dbGaP Project research objectives/not renewing
- Other. List reason(s) below.

Please feel free to add comments about the reasons for closing out your DAR(s)

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Institutional Signing Official: Renewal

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[Data Access Request\(s\) Application](#)

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I agree

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I agree

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By signing below, I, on behalf of this institution, acknowledge that this institution is the sole responsible party for assuring our adherence to the terms of the Data Use Certification Agreement. I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

I agree

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[Active \(1\)](#)

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Please **carefully review** submitted information by clicking on "Review Complete Application".

To revise: Use navigation tabs to return to any previous step and make the changes.

To approve: **Check the boxes** below to attach your electronic signature acknowledging agreement to the terms.

You need Adobe Reader installed to review PDF forms.



Institutional Signing Official: Closeout

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db GaP genotypes and phenotypes Browse/Search Authorized Access Help

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Closeout Project

#2051: New Demo Project

Req: Daniel Dery

Certification of Project Closeout and Destruction of Controlled-Access Data Subject to the GDS Policy

Upon completion of a project, Principal Investigators must delete all controlled-access data downloaded from NIH-designated data repositories for the project according to the [NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy](#). All laboratory computers and staff/student personal laptops must be scanned to remove controlled-access data, and any copies of controlled-access data must be removed from institutional central servers, computer facilities, and back-up systems. If cloud computing was utilized, investigators must also destroy cloud images and delete controlled-access data from commercial or private cloud provider storage, virtual and physical machines, databases, and random access archives (i.e., archival technology that allows for deletion of specified records within the context of media containing multiple records).

I certify that the dataset(s) received by the Principal Investigator have been destroyed. I understand that the institution on whose behalf I am signing this form is solely responsible for the conduct of the Information Technology Director, the Principal Investigator and other approved users under the DAR.

I agree

[Review the close out report as Adobe PDF document](#)

[File Report and close project](#)

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