

**Attachment 2: Documentation of the dbGaP access system, including changes since 2013 PRA approval**

## **Screen Shots of Online Forms for Data Access Request**

# REQUESTER

NCBI Site map All databases PubMed Search

dbGaP genotypes and phenotypes Browse/Search Authorized Access Help

Authorized Access Portal

Log In to dbGaP

Reorganized and consolidated information and made application information more apparent and prominent.

### dbGaP Data Download

The management portal to request and download individual level data

Click [here](#) to login to the dbGaP controlled-access portal and to begin a project request. For guidance on the development of a data access request to complete project requests, please see [Tips for preparing a successful Data Access Request](#).

**Who can apply for access?**

**How does one apply?**

**Why is Access Controlled?**

### dbGaP Data Browser - View Only

With dbGaP Data Browser approval through the [simplified controlled-access application](#), users may view the collection "Compilation of individual-level data from general research use (GRU)."

**What is the purpose of the dbGaP Data Browser; why is it useful?**

**How does one apply?**

#### Additional help.

- For policies governing NIH Genomic Data Sharing (GDS), refer to [NIH GDS Policy](#)
- Questions regarding review, approval, and renewal of data access requests, as well as project annual progress report should be directed to the Data Access Committee (DAC). [DAC information can be found here](#).
- dbGaP maintains a **help desk** to assist investigators, institutional signing officials and NIH staff with authorized access management, and answer any questions related to the application process. Contact the help desk with your queries.
- [FAQs](#) and [tutorials](#) are also available.



# REQUESTER

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## My Research Projects

[Create New Research Project](#)

#	Project
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## My Research Project

### General Instructions

- This application will automatically generate a Data Access Request (DAR) number and a project number. Please keep track of this number for future communications with dbGaP and relevant Data Access Committee(s) (DAC)
- A completed request for data access includes this form as well as a review of and agreement to the terms, conditions, and statements in the Data Use Certification (DUC) for each respective dataset requested.
- Dataset requests are project-specific. If you were granted access to a dataset(s) for another project, that approval does not carry over to this new proposed project. You must request access to all datasets that you plan to use in the new project.
- Please note that fields marked as "\*" are required fields.

### Before You Get Started

In order to complete the application for data access you will need to collect the following information:

- A research statement and a nontechnical summary statement describing your planned use of the data.
- The name of the institutional signing official who will certify the terms of use assurances on behalf of your institution.
- A list of all internal investigators at your institution who will share access to the data for the proposed research.
- A list of external collaborating investigators.
- The name of the information technology (IT) Director.
- Some datasets may require local Institutional Review Board (IRB) approval for use. These are noted in the study list. Please check the individual study pages in dbGaP for these additional requirements.
- Some datasets may require supplemental documentation to accompany this standard application. Review the DUC\* instruction pages for detailed information about how to prepare these materials in a single PDF file.

\* You can navigate to each study DUC from the public study home page in dbGaP. Look for the "individual-level data" section.

### dbGaP APPROVED USER [CODE OF CONDUCT](#)

The following is the Code of Conduct that research investigators agree to abide by as Approved Users of data received through the database of Genotypes and Phenotypes (dbGaP). Failure to abide by any term within this Code of Conduct may result in revocation of approved access to any or all datasets obtained through dbGaP.

The elements of the NIH Code of Conduct for Data Use include:

1. Investigator(s) will use requested datasets solely in connection with the research project described in the approved Data Access Request for each dataset;
2. Investigator(s) will make no attempt to identify or contact individual participants from whom these data were collected without appropriate approvals from the relevant IRBs;
3. Investigator(s) will not distribute these data to any entity or individual beyond those specified in the approved Data Access Request;
4. Investigator(s) will adhere to computer security practices that ensure that only authorized individuals can gain access to data files;
5. Investigator(s) will not submit for publication or any other form of public dissemination analyses or other reports on work using or referencing NIH datasets prior to the embargo release date listed for the dataset (or dataset version) on dbGaP;
6. Investigator(s) acknowledge the Intellectual Property Policies as specified in the Data Use Certification; and,
7. Investigator(s) will report any inadvertent data release in accordance with the terms in the Data Use Certification, breach of data security, or other data management incidents contrary to the terms of data access.

[Begin New Research Project](#) ▶

# REQUESTER

## Project Request

[- OMB control number: 0925-0670 Expiration data: 7/31/2019](#)

Public reporting burden for this collection of information is estimated to vary from 15 to 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **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.

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

Please select datasets to request access to. If you have changed any common information (research statement, list of collaborators), all approved application and those being reviewed by DAC(s) will need to be resubmitted.  
For any study that has more than one consent group, there are no overlaps in subjects between the consent groups.

### Filter Consents

[Clear Filter](#)

Primary disease  Molecular data type  Study design

Approved for GRU  Approved for commercial use  Approved for method development  Health biomedical research  Exclude data or

Study lookup  Study accession   Exclude IRB re

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Consent Group	Data Use Limitations	Participants	DAR Status
<b>Glaucoma Exome Sequencing (phs000558.v1.p1)</b> <input type="checkbox"/> General Research Use (IRB) (phs000558.v1.p1.c1), <a href="#">NEJ</a>	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval. . <b>This consent group requires IRB approval attachment</b>	175	
<b>The 100-Person Wellness Project (HPWP) (phs001363.v1.p1)</b> <input type="checkbox"/> General Research Use (IRB, PUB, COL, NPU) (phs001363.v1.p1.c1), <a href="#">NIGMS</a>	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval. Requestor agrees to make results of studies using the data available to the larger scientific community. Requestor must provide a letter of collaboration with the primary study investigator(s). Use of the data is limited to not-for-profit organizations. .	108	



[Return to My Projects](#) [Add Selected and Continue](#)

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Study accession for preview:  [Add](#)

This input box is only for study investigators of studies that are currently in preview status. If you are a data submitter, please input the study accession.

# REQUESTER

## Project Request

#21568:

SO:

+ OMB control number: 0925-0670 Expiration data: 7/31/2019

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

### \*Descriptive Title of Project

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

2018 FRA Renewal

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.

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

### \*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.

### \*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.

Smith, Cheryl ([smithc16@mail.nih.gov](mailto:smithc16@mail.nih.gov))

### Applicant organization

\*Institution Name  Department  Division   
\*Street 1  Street 2  \*City  \*State  \*ZIP/Postal code  \*Country

### Create Decryption Password.

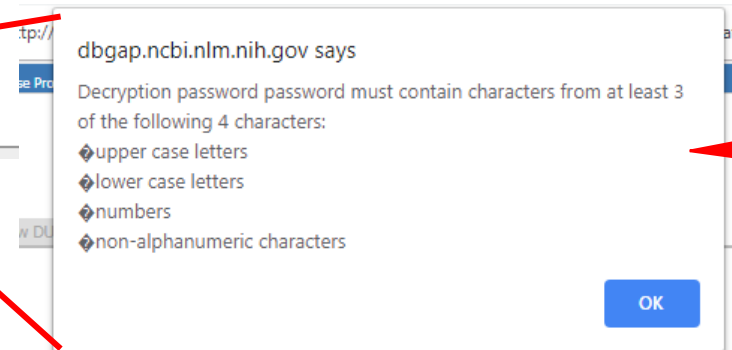
The files distributed through the dbGaP system are encrypted. A password is required for decrypting downloaded files. Please provide a decryption password for the project. Valid passwords must be at least 8 ASCII characters long and must contain at least 3 of the following 4 characters:

- upper case letters
- lower case letters
- numbers
- non-alphanumeric characters

\*Password for project:

\*Password confirmation:

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New pop-up reminders to alert requester additional information is needed

# REQUESTER

## Project Request

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

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Use this space to enter information about all additional investigators *from your institution* who will have access to the dataset(s). (Exclude trainees, who are covered under the [NIH policy](#)). By submitting names on this form, requestors and signing officials guarantee that these individuals have read and agreed to the terms, conditions, and statements of the respective Data Use Certification(s).

Internal Collaborator

Prefix	*First name	Middle name	*Last name	Suffix	
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
*Position/Title	Department	*Organization name	Division		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>		
*Street1	Street2	*City	State	*ZIP/Postal code	*Country
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
*E-mail	*Phone	Fax			
<input type="text"/>	<input type="text"/>	<input type="text"/>			

Click "Add collaborator" button to add another person to the list. Use "Remove" button to remove person from the list. Data **will not be saved** until you click the "Next" or "Save" button. Leave the form blank if you have no collaborators.

### Are you planning to collaborate with investigators from other institutions?

Please note that collaborators from other institutions must submit a separate Data Access Request(s) for this project from their respective institution(s). All collaborators must be approved users before data can be shared. Coordinated requests by collaborating institutions should each use the same project title and should each complete this section in their respective applications.

None

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## Project Request

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An information technology (IT) director's (or designee's) contact information is required to ensure data security policies and procedures are in place. This individual must have the authority to vouch for the IT capabilities at your institution.

#### IT Director

Prefix	*First name	Middle name	*Last name	Suffix	
Dr.	John	A.	Doe		
*Position/Title	Department	*Organization name	Division		
IT Director	Scientific Data Sharing Policy Divisi	NIH	National Institutes of Health		
*Street1	Street2	*City	State	*ZIP/Postal code	*Country
8705 Rockledge Drive	Suite 750	Bethesda	MD	20817	United States
*E-mail	*Phone	Fax			
cheryl.smith2@nih.gov	3014998838				

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## Project Request

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Approved individual data access request (DAR) cannot be removed from the projects in this system. All previously approved DARs must be either closed out or renewed. If you wish to close out a single DAR, then contact the data access committee and negotiate a close out by email.

You have selected the following datasets for this request.

To add a dataset click the "Back" button to return to the previous step. To remove a dataset, check the box next to the dataset you would like to remove and click the "Remove Selected" button.

When you are satisfied with the list on this page, click "Continue" button.

Consent Group	Data Use Limitations	Participants	DAR Status
<a href="#">Glaucoma Exome Sequencing</a> (phs000558.v1.p1) <input type="checkbox"/> <a href="#">General Research Use (IRB)</a> (phs000558.v1.p1.c1), <a href="#">NEI</a>	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval. . <b>This consent group requires IRB approval attachment</b>	175	

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## Project Request

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### Data use certifications and consent group restrictions on use

The Data Use Certification (DUC) is the agreement that you must sign and that must be co-signed by your designated institutional signing official. Although requirements within the DUC may vary by dataset, each DUC will include the following core elements that you agree to:

- to only use data as specified in the Research Use Statement
- to keep the data confidential
- to not share the data with unapproved users or sell the data
- to follow appropriate data security protections
- to not identify or contact individual research participants
- to be publicly listed as an approved user on the dbGaP website
- to not submit findings for publication until the embargo date (as listed in dbGaP)
- to acknowledge dbGaP, the accession number of the specific datasets analyzed, the contributing investigator(s), and the primary funding organization that supported the contributing study in all oral and written presentations and publications resulting from any analyses of the data, and
- to report violations of the GDS policy immediately to the appropriate Data Access Committee.

Below you will find PDFs of the DUCs for each dataset to which you have requested access. Please read the DUCs carefully, as they vary by study and you will be expected to follow the terms outlined in each.

Consent Group	Data Use Limitations	Participants	PDF
<a href="#">Glaucoma Exome Sequencing (phs000558.v1.p1)</a>			<a href="#">Data Use Certification Agreement</a>

### Program-specific required attachments

Some studies' DULs require additional documentation for approval (e.g., local IRB review, Letter of Collaboration). Below you will find any such requirements for the studies to which you have requested access. Please select the PDF file you would like to upload using the "Browse" button and then click "Upload".

Glaucoma Exome Sequencing  
Local IRB approval is required. Do NOT include FULL protocol;  No file chosen

Load one document for all requests

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

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

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## Project Request

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Data Use Limitations (DULs) were provided by the institution that submitted the respective dataset and reflect the informed consent given by those who participated in the original study. The DULs for each requested dataset appear below. To remove a dataset click the "Back" button to return to the previous step.

By checking the boxes and clicking on "I agree..." button below, I certify that I have read and agree to the terms, conditions, and statements of the DUL(s) for the request dataset(s), and understand that the relevant Data Access Committee(s) will be reviewing the Research Use Statement (RUS) for compliance with these DUL(s).

Consent Group	Data Use Limitations	Participants	DAR Status
<a href="#">Glaucoma Exome Sequencing</a> (phs000558.v1.p1) <a href="#">General Research Use (IRB)</a> (phs000558.v1.p1.c1), <a href="#">NEI</a>	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval. . <b>This consent group requires IRB approval attachment</b> <input type="checkbox"/> I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	175	

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## Project Request

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

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#### Review and submit data access requests

The following application is the official request document that will be sent to your signing official (SO). Please note that you **will not be allowed** to change your application while it is being reviewed by the SO. In order to make the changes after you have submitted your application for review you will have to contact your SO with a request to return it for your revision.

After approval by your SO, each application will be sent to the appropriate Data Access Committee (DAC). Multiple DACs may need to evaluate your application.

[Review Complete Application](#)

#### Check the "I agree" boxes to provide the required certifications and assurances.

By signing below, 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

By signing below, I certify that I have read and agreed to the terms, conditions, and statements in the Data Use Certification(s) for the request dataset(s). I agree to abide by the [Code of Conduct](#).

I agree

[Submit Application To Signing Official](#)

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
	<a href="#">Glaucoma Exome Sequencing (phs000558.v1.p1)</a> <a href="#">General Research Use (IRB) (phs000558.v1.p1.c1)</a> , <a href="#">NEI</a>	New		<a href="#">view</a>

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

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

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

You need Adobe Reader installed to review PDF forms.



# REQUESTER

## Project Request

#2954: test22

SO: Jane Doe

[- OMB control number: 0925-0670 Expiration data: 7/31/2019](#)

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### Reminder:

Please remember that the terms of your Data Use Certification(s) (DUC) continue to apply. In addition, please remember that anyone who leaves your institution is not permitted by the terms of the DUC to take NIH data with him/her. Individuals leaving the institution that has the approval must reapply to NIH for access with their new institution.

### Feedback:

Your comments and suggestions are welcome. Please feel free to use the space below to comment on the effectiveness of the dbGaP data portal (e.g., ease of access and use, appropriateness of data format, challenges in complying with NIH policies) and to suggest improvements to NIH data access, the NIH policy, or procedures in general.

Please also feel free to comment on any difficulties with downloading data, complying with security procedures, etc.

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# Institutional Signing Official

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## Project Request

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

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[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](#)

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#### 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	<a href="#">Glaucoma Exome Sequencing (phs000558.v1.p1)</a> <a href="#">General Research Use (IRB) (phs000558.v1.p1.c1)</a> , <a href="#">NET</a>	SO review		<a href="#">view</a>

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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.



**dbGaP Authorized Access**

**Project Renewal Web Forms**



## Project renewal

### #9308: Project Renewal Demonstration

- OMB control number: 0925-0670 Expiration data: 7/31/2019

SO: Jane Doe

- Project Details
- Research Project
- Collaborators
- IT Director
- Research Progress
- Presentations
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- Data Security
- Choose Datasets
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This form is for the renewal of access to approved dataset(s) for the project listed below. You may also use this form to add new datasets to this existing project; however, requesting additional datasets will also require amending the Research Use Statement (RUS). If you have completed your entire project, please submit a [Form for Project Closeout](#).

Some questions will ask you about your research progress while others will ask you about your plans for the next year of access to the datasets for which you are requesting renewal. The Data Access Committee(s) that reviewed your initial Data Access Request (DAR) will review your renewal. Elements of your original submission are provided as reference.

**Principal Investigator's (PI) Name:** John Doe

**Institutional Signing Official (SO):** Jane Doe

**Institutional Affiliation:** NIH

**Project ID:** 9308

**Project Name:** Project Renewal Demonstration


**Initial Request Date:**

**Date of Last Renewal:**

Research Use Statement for "Project Renewal Demonstration" [hide...](#)

Test Technical RUS

Datasets for research project "Project Renewal Demonstration" [hide...](#)

DAR #	Study, Consent	Status	Expiration	Application
38991-1	dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use General Research Use CDAC	✓ Approved EXPIRED	2015-08-05	 view

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### \*Descriptive Title of Project

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

Project Renewal Demonstration

### \*Type of Research

- Disease-related studies:** The primary purpose of the research is to learn more about a particular disease or disorder (e.g., type 2 diabetes), a trait (e.g., blood pressure), or a set of related conditions (e.g., autoimmune diseases, psychiatric disorders).
- Methods development and validation studies:** The primary purpose of the research is to develop and/or validate new methods for analyzing or interpreting data (e.g., developing more powerful methods to detect epistatic, gene-environment, or other types of complex interactions in genome-wide association studies). Data will be used for developing and/or validating new methods.
- Controls:** The reason for this request is to increase the number of controls available for a comparison group (e.g., a case-control study).
- Population structure or normal variation studies:** The primary purpose of the research is to understand variation in the general population (e.g., genetic substructure of a population).
- Other** (please specify below).

### \*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 2200 characters.

Test Technical RUS

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

Page continues on  
next slide ↓

Continuation of  
previous slide

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

**\*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 1100 characters.

Test Lay RUS

**\*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 ([ssergey@ncbi.nlm.nih.gov](mailto:ssergey@ncbi.nlm.nih.gov))

**Applicant organization**

*Institution Name	Department	Division			
NIH	NCBI	NLM			
*Street 1	Street 2	*City	*State	*ZIP/Postal code	*Country
6200	Rockville Pike	Bethesda	MD	20853	USA

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Use this space to enter information about all additional investigators *from your institution* who will have access to the dataset(s). (Exclude trainees, who are covered under the [NIH policy](#)). By submitting names on this form, requestors and signing officials guarantee that these individuals have read and agreed to the terms, conditions, and statements of the respective Data Use Certification(s).

#### Internal Collaborator

Prefix	*First name	Middle name	*Last name	Suffix	<input type="button" value="Look up"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
*Position/Title	Department	*Organization name	Division		
<input type="text"/>	<input type="text"/>	<input type="text" value="NIH"/>	<input type="text"/>		
*Street1	Street2	*City	State	*ZIP/Postal code	*Country
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
*E-mail	*Phone	Fax			
<input type="text"/>	<input type="text"/>	<input type="text"/>			

Click "Add collaborator" button to add another person to the list. Use "Remove" button to remove person from the list. Data **will not be saved** until you click the "Next" or "Save" button. Leave the form blank if you have no collaborators.

#### Are you planning to collaborate with investigators from other institutions?

Please note that collaborators from other institutions must submit a separate Data Access Request(s) for this project from their respective institution(s). All collaborators must be approved users before data can be shared. Coordinated requests by collaborating institutions should each use the same project title and should each complete this section in their respective applications.

None

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

An information technology (IT) director's (or designee's) contact information is required to ensure data security policies and procedures are in place. This individual must have the authority to vouch for the IT capabilities at your institution.

#### IT Director

Prefix	*First name	Middle name	*Last name	Suffix	
<input type="text"/>	<input type="text" value="Steve"/>	<input type="text"/>	<input type="text" value="Sherry"/>	<input type="text"/>	
*Position/Title	Department	*Organization name	Division		
<input type="text" value="Staff Scientist"/>	<input type="text" value="NCBI"/>	<input type="text" value="NIH"/>	<input type="text" value="NLM"/>		
*Street 1	Street 2	*City	State	*ZIP/Postal code	*Country
<input type="text" value="6200"/>	<input type="text" value="Rockville Pike"/>	<input type="text" value="Bethesda"/>	<input type="text" value="MD"/>	<input type="text" value="20853"/>	<input type="text" value="USA"/>
*E-mail	*Phone	Fax			
<input type="text" value="sherry@ncbi.nlm.nih.gov"/>	<input type="text" value="555-555-5555"/>	<input type="text"/>			

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**Research Progress:**  
Please summarize your research on this project since your initial request or most recent renewal in the space below, including the potential significance of any findings. Briefly describe whether and how the dataset(s) was used, including referencing the dataset(s) by name in your summary. Please limit your summary to 6000 characters.

Have you generated any intellectual property since your last renewal as a result of using the NIH data?

Yes  
 No

**Research Plans with Approved Dataset(s):**  
Please describe your proposed plans for further research utilizing the currently approved NIH dataset(s). (For reference click here to see your Research Use Statement [show...](#)). Please limit your description to 2000 characters.

Will your research plan include revised or new research questions that you propose to address using the current approved dataset(s)?  Yes  No  
**If "yes", Please amend your Research Use Statement.**

Will your research plan involve combining dataset(s) accessed under this research project with dataset(s) not described in the Research Use Statement?  Yes  No  
**If "yes", Please amend your Research Use Statement.**

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Section removed to reduce redundant information entered in the "Research Progress" section and the "Research Plans with Approved Datasets" section.

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Please list all completed and accepted scientific presentations since your initial approval or last renewal that include (or will include) findings made with the NIH data that were accessed through dbGaP. Please include title, authors, bibliographic citation (if any), and meeting/abstract submission date. If you have requested multiple datasets please specify which datasets were used and which were included in your presentation(s). If you had no presentations, please check the box below.

I had no presentations since my initial request or last renewal.

Remove

Add another presentation

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Please list all publications and manuscripts submitted since your initial approval or last renewal that include findings made with the NIH data. Please list manuscript submission dates. Please include PubMed ID, title, authors, and bibliographic citation. If you have requested multiple datasets please specify which datasets were used and which were included in your publication(s). If you had no publications, please check the box below.

I had no publications since my initial request or last renewal.

PubMed ID  Title

Date  Bibliographic Citation

Authors

Other



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#### Data Security:

For this analysis have you combined the datasets provided by dbGaP with datasets from other sources that were not described in the Research Use Statement (RUS)? If yes, briefly describe the source(s) of the datasets and amend your RUS.

- Yes
- No

Have you changed institutions since your initial data request or last project renewal?  Yes  No

The list of approved users from your project is below.

#### Approved Users and Internal Collaborators at NIH

First name	Last name	Institution Name	Position/Title	Role on Project
John	Doe	ministry of peace	Lab Chief	Principal Investigator
Steve	Sherry	NIH	Staff Scientist	IT Director or designee

Please list anyone not indicated above who has accessed the dataset(s) distributed under this approved project. Please note that trainees and staff under your supervision are covered under the [NIH policy](#) and need not be listed here.

None

Please describe any inappropriate data release incidents or other data security issues, including the date that the Data Access Committee (DAC) was first notified. *Inappropriate data release incidents should have been reported to the DAC as they occurred. If an incident was not reported at the time it occurred, please do so immediately, noting what was done to remedy the situation and what steps were taken to prevent future occurrences. Your DAC's contact information may be found in the Data Use Certification for the relevant datasets.*

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Please select datasets to request access to. If you have changed any common information (research statement, list of collaborators), all approved application and those being reviewed by DAC(s) will need to be resubmitted.  
For any study that has more than one consent group, there are no overlaps in subjects between the consent groups.

#### Filter Consents

Primary disease  Molecular data type  Study design

Approved for GRU  Approved for commercial use  Approved for method development  Health biomedical research

Study accession   Exclude IRB required

Consent Group	Data Use Limitations	Participants	DAR Status
<b>Up for a Challenge: African American Breast Cancer Consortium (AABC) Study</b> (phs000851.v1.p1)			
<input type="checkbox"/> Up for a Challenge (phs000851.v1.p1.c1), eNCI DAC	Use of this data is limited to research described for the National Cancer Institute (NCI) "Up for a Challenge" breast cancer genetic epidemiology competition. The goal of this challenge is to use innovative approaches to identify novel biology involved in breast cancer susceptibility including new genes, genetic variants, or sets of genomic features, leading to novel biological hypotheses. Individuals NOT participating in the challenge would NOT be granted access. Requestor agrees to make results of studies using the data available to the larger scientific community. .	4881	
<input type="checkbox"/> Up for a Challenge (Not for Profit Use Only) (phs000851.v1.p1.c2), eNCI DAC	Use of this data is limited to research described for the National Cancer Institute (NCI) "Up for a Challenge" breast cancer genetic epidemiology competition. The goal of this challenge is to use innovative approaches to identify novel biology involved in breast cancer susceptibility including new genes, genetic variants, or sets of	486	

Multiple studies are not shown  
for brevity



<input type="checkbox"/> Health/Medical/Biomedical (GSO) (phs000360.v2.p1.c4), NHGRI	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data is limited to genetic studies only. Investigators must state in the Data Use Request their intention to publish or otherwise broadly share any findings from his or her study with the scientific community.	3755	
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Study accession for preview:

This input box is only for study investigators of studies that are currently in preview status. If you are a data submitter, please input the study accession.

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You have selected the following datasets for this request.

To add a dataset click the "Back" button to return to the previous step. To remove a dataset, check the box next to the dataset you would like to remove and click the "Remove Selected" button.

When you are satisfied with the list on this page, click "Continue" button.

Consent Group	Data Use Limitations	Participants	DAR Status
<b>dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use</b>			
<input type="checkbox"/> General Research Use CDAC	Use of the data is limited only by the terms of the model Data Use Certification. .	0	✓ Approved EXPIRED

- Back
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- Remove Selected
- Remove Selected and Continue

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### Data use certifications and consent group restrictions on use

The Data Use Certification (DUC) is the agreement that you must sign and that must be co-signed by your designated institutional signing official. Although requirements within the DUC may vary by dataset, each DUC will include the following core elements that you agree to:

- to only use data as specified in the Research Use Statement
- to keep the data confidential
- to not share the data with unapproved users or sell the data
- to follow appropriate data security protections
- to not identify or contact individual research participants
- to be publicly listed as an approved user on the dbGaP website
- to not submit findings for publication until the embargo date (as listed in dbGaP)
- to acknowledge dbGaP, the accession number of the specific datasets analyzed, the contributing investigator(s), and the primary funding organization that supported the contributing study in all oral and written presentations and publications resulting from any analyses of the data, and
- to report violations of the GDS policy immediately to the appropriate Data Access Committee.

Below you will find PDFs of the DUCs for each dataset to which you have requested access. Please read the DUCs carefully, as they vary by study and you will be expected to follow the terms outlined in each.

Consent Group	Data Use Limitations	Participants	PDF
<b>dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use</b>			
General Research Use CDAC	Use of the data is limited only by the terms of the model Data Use Certification. .	0	 Data Use Certificate
			 Dataset Manifest

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Data Use Limitations (DULs) were provided by the institution that submitted the respective dataset and reflect the informed consent given by those who participated in the original study. The DULs for each requested dataset appear below. To remove a dataset click the "Back" button to return to the previous step.

By checking the boxes and clicking on "I agree..." button below, I certify that I have read and agree to the terms, conditions, and statements of the DUL(s) for the request dataset(s), and understand that the relevant Data Access Committee(s) will be reviewing the Research Use Statement (RUS) for compliance with these DUL(s).

Consent Group	Data Use Limitations	Participants	DAR Status
<b>dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use</b>			
General Research Use CDAC	Use of the data is limited only by the terms of the model Data Use Certification. . <input type="checkbox"/> I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	0	✓ Approved EXPIRED

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- I agree to the Data Use Limitation(s)

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#### Review and submit data access requests

The following application is the official request document that will be sent to your signing official (SO). Please note that you **will not be allowed** to change your application while it is being reviewed by the SO. In order to make the changes after you have submitted your application for review you will have to contact your SO with a request to return it for your revision.

After approval by your SO, each application will be sent to the appropriate Data Access Committee (DAC). Multiple DACs may need to evaluate your application.

 [Review Complete Application](#)

#### Check the "I agree" boxes to provide the required certifications and assurances.

By signing below, 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

By signing below, I certify that I have read and agreed to the terms, conditions, and statements in the Data Use Certification(s) for the request dataset (s). I agree to abide by the [Code of Conduct](#).

I agree

[Submit Application To Signing Official](#) ▶

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.



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
38991-1	dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use General Research Use CDAC	✓ Approved EXPIRED	2015-08-07	 view

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#### Reminder:

Please remember that the terms of your Data Use Certification(s) (DUC) continue to apply. In addition, please remember that anyone who leaves your institution is not permitted by the terms of the DUC to take NIH data with him/her. Individuals leaving the institution that has the approval must reapply to NIH for access with their new institution.

#### Feedback:

Your comments and suggestions are welcome. Please feel free to use the space below to comment on the effectiveness of the dbGaP data portal (e.g., ease of access and use, appropriateness of data format, challenges in complying with NIH policies) and to suggest improvements to NIH data access, the NIH policy, or procedures in general.

Please also feel free to comment on any difficulties with downloading data, complying with security procedures, etc.

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# Institutional Signing Official

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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 data: 7/31/2019](#)

[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](#)

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#### 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	<a href="#">Glaucoma Exome Sequencing (phs000558.v1.p1)</a> <a href="#">General Research Use (IRB) (phs000558.v1.p1.c1)</a> , <a href="#">NET</a>	SO review		<a href="#">view</a>

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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.





**dbGaP Authorized Access**

**Project Closeout Web Forms**

## Closeout Project

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SO: Jane Doe

[Project Details](#) [Research Progress](#) [Presentations](#) [Publications and Manuscripts](#) [Data Security](#) [Reasons for Project Closeout](#) [Review Closeout Application](#) [Feedback](#)

#### Research Progress:

Please summarize your research on this project since your initial request or most recent renewal in the space below, including the potential significance of any findings. Briefly describe whether and how the dataset(s) was used, including referencing the dataset(s) by name in your summary. Please limit your summary to 6000 characters.

Still working with the data

Have you generated any intellectual property since your last renewal as a result of using the NIH data?

- Yes  
 No

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## Closeout Project

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SO: Jane Doe

[Project Details](#) [Research Progress](#) [Presentations](#) [Publications and Manuscripts](#) [Data Security](#) [Reasons for Project Closeout](#) [Review Closeout Application](#) [Feedback](#)

Please list all completed and accepted scientific presentations since your initial approval or last renewal that include (or will include) findings made with the NIH data that were accessed through dbGaP. Please include title, authors, bibliographic citation (if any), and meeting/abstract submission date. If you have requested multiple datasets please specify which datasets were used and which were included in your presentation(s). If you had no presentations, please check the box below.

I had no presentations since my initial request or last renewal.

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### Closeout Project

**#9308: Project Renewal Demonstration**

[- OMB control number: 0925-0670 Expiration data: 7/31/2019](#)

SO: Jane Doe

- Project Details
- Research Progress
- Presentations
- Publications and Manuscripts
- Data Security
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- Review Closeout Application
- Feedback

Please list all publications and manuscripts submitted since your initial approval or last renewal that include findings made with the NIH data. Please list manuscript submission dates. Please include PubMed ID, title, authors, and bibliographic citation. If you have requested multiple datasets please specify which datasets were used and which were included in your publication(s). If you had no publications, please check the box below.

I had no publications since my initial request or last renewal.

PubMed ID	Title
<input type="text"/>	<input type="text"/>
<input type="button" value="Look up"/>	
Date	Bibliographic Citation
<input type="text"/>	<input type="text"/>
Authors	
<input type="text"/>	
Other	
<input type="text"/>	
<input type="button" value="Remove"/>	

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### Closeout Project

#### #9308: Project Renewal Demonstration

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**Reasons for project closeout:**

- Project completed
- Leaving institution
- Unable to complete project
- Unable to download data
- Not renewing
- Other. List reason(s) below.

Please feel free to add additional comments about the reasons for project closeout below.

- Back
- Cancel and return to My Projects
- Save and Continue

## Closeout Project

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#### \*Confirm your Signing Official (SO) for signing closeout application:

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 ([ssergey@ncbi.nlm.nih.gov](mailto:ssergey@ncbi.nlm.nih.gov))

Upon completion of a project, investigators must delete all data downloaded from dbGaP for the project. Investigators may retain only encrypted copies of the minimum data necessary to comply with their institutional scientific data retention policy. Retained data should be deleted at the appropriate time. Check with your institution's policy to determine your retention time. Ensure all laboratory computers and staff/student personal laptops are scanned to remove dbGaP data. Ensure that any copies of data are removed from central servers, computer facilities, and back-up systems. For further information on NIH data security best practices see [data security measures](#).

#### Step to review submitted information and certify data are deleted.


The "file report" will close the project and notify the signing official (SO) that a project close out request is pending.

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

**Check the assurance and click "File Report" below to complete this project close-out report. When you file this report, your access to the dataset(s) for this project in dbGaP will be closed and your report will be sent to your SO for processing. Please contact your Data Access Committee if you have any questions about this process.**

By signing below, I certify that the dataset(s) available to me (listed on Step 1 – project details of this form) have been destroyed unless required to be retained as described in the security best practices document at [Best Practices](#). I understand that my project will not be closed until the SO approves the closeout request.

I agree

[File Report and close project](#) 

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## Closeout Project

### #9308: Project Renewal Demonstration

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#### Reminder:

Please remember that anyone who leaves your institution is not permitted by the terms of the DUC to take NIH data with him/her. Individuals leaving the institution that has the approved Data Access Request must reapply to the NIH Data Access Committee(s) for access with their new institution.

#### Feedback:

Your comments and suggestions are welcome. Please feel free to use the space below to comment on the effectiveness of the dbGaP data portal (e.g., ease of access and use, appropriateness of data format, challenges in complying with NIH policies) and to suggest improvements to NIH data access or the NIH policy or procedures in general.

Please also feel free to comment on any difficulties with downloading data, complying with security procedures, etc.

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# Institutional Signing Official

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SO Projects Beacon My Profile

Logged in as Jane Doe | [Log out](#)

## 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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