

Legacy Authorized Access System

Principal Investigator (PI) initial Data Access Request (DAR) application

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 review the requirements.
- Some datasets may require supplemental documentation to accompany this standard application. Review the DUC* instructions for details. Supplemental 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](#)

that research investigators agree to abide by as Approved Users of data received through the database of Genotypes and Phenotypes. Failure to follow the Code of Conduct may result in revocation of approved access to any or all datasets obtained through dbGaP.

[Begin New Research Project](#) 

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OMB control Number: 0925-0670

Expiration Date: March 31, 2026

Public reporting burden for this collection of information is estimated to vary from 15-45 minutes per response including the time for reviewing instructions, choosing datasets, gathering and maintaining the information needed, reviewing the collection of information, and submitting the Data Access Request. 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.

[My Projects](#) [My Requests](#) [Downloads](#) [Downloaders](#) [My Profile](#)

Project Request

+ [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)[Research Project](#) [Cloud Providers](#) [Collaborators](#) [IT Director](#) [Confirm Datasets](#) [Review DUC](#) [Review DUL](#) [Review Applications](#) [Feedback](#)

Please select datasets to request access to. **Maximum 200 datasets per project.** 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 on cloud [?](#)

Study lookup enter study accession Study accession ☐ Exclude IRB required

Page 1 2 3 4 5 6 7 8 ... 43

Consent Group	Data Use Limitations	Participants	DAR Status
Glaucoma Exome Sequencing (phs000558.v1.p1)			
☐ General Research Use (IRB) (phs000558.v1.p1.c1), NEI	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval. . Public Posting of Genomic Summary Results - Undefined . This consent group requires IRB approval attachment Have data available in Amazon S3 Cloud Storage ? Have data available in Google Cloud Storage ?	175	
The 100-Person Wellness Project (HPWP) (phs001363.v1.p1)			
☐ General Research Use (IRB, PUB, COL, NPU) (phs001363.v1.p1.c1), NIH	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	
A Study of the Genetic Causes of Complex Pediatric Disorders (phs000490.v1.p1)			
☐ General Research Use (phs000490.v1.p1.c1), NHGRI	Use of the data is limited only by the terms of the model Data Use Certification. . Public Posting of Genomic Summary Results - Allowed .	7431	

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

Page 1 2 3 4 5 6 7 8 ... 43

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.

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DRAFT | DRAFT | DRAFT

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

Project Details Choose Datasets **Research Project** Cloud Providers Collaborators IT Director Confirm Datasets Review DUC Review DUL Review Applications Feedback

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

Test Project

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. All Data Access Request (DAR) submissions may be used for the evaluation of dbGaP operation, usage, and impact.

Investigators do not need to submit a new project request unless the data

Test RUS

Test RUS

By checking this box, I, as the PI requesting access to this data, attest that data will be secured, at a minimum, in accordance with [NIST SP 800-171](#) or the equivalent ISO/IEC 27001/27002 standards as stipulated by the [NIH Security Best Practices for Users of Controlled-Access Data](#).

Cloud Use Statement
State the name of the cloud service provider and/or third-party IT system, their security standard, and how they will be used to carry out the work described in your Research Use Statement.

State the name of the cloud service provider and/or third party IT system, their security standards, and how they will be used to carry out the work described in your Research Use Statement. Also, if applicable, describe the role of any collaborators. Please limit your statement to 2000 characters.

Test Cloud Use Statement

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.

Test Non-technical summary

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)

*Institution Name NIH		Department	Division		
*Street 1 123 Main Street	Street 2	*City Bethesda	*State MD	*ZIP/Postal code 12345	*Country United States

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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Project Request

#42853: Test Project

SQ: Jane Doe

New page/ tab for PIs to provide
Cloud Providers information

+ [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)

[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 service provider (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

Test Provider 1

*Type of Provider

Commercial ▼

Details

Test details

Remove

Cloud Provider Information

*Name of Provider

Test Provider 2

*Type of Provider

Commercial ▼

Details

Test details

Remove

Add another

Back

Return to My Projects

Save

Save and Continue ▶

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Project Request

#42853: Test Project

SQ: Jane Doe

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

Project Details Choose Datasets Research Project Cloud Providers Collaborators **IT Director** Confirm Datasets Review DUC Review DUL Review Applications Feedback

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
	Jacob		Doe	
*Position/Title		Department	*Organization name	Division
Principal Investigator			NIH	
*Street1	Street2	*City	State	*ZIP/Postal code
123 Main Street		Bethesda	MD	12345
*E-mail		*Phone	Fax	*Country
jacob.doe@nih.gov		1234567890		United States
Remove				

Add another collaborator

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?

☐ None

External Collaborator

*First name	*Last name	*Institution Name	*Position/Title	*Role on Project	*E-mail
Comment					
Remove					

Add another person

Back Return to My Projects Save **Save and Continue**

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Project Request

#42853: Test Project

SO: Jane Doe

+ [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)

[Project Details](#)

[Choose Datasets](#)

[Research Project](#)

[Cloud Providers](#)

[Collaborators](#)

[IT Director](#)

[Confirm Datasets](#)

[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
*Position/Title	Department	*Organization name		Division
		NIH		
*Street1	Street2	*City	State	*ZIP/Postal code
*Country				
*E-mail	*Phone	Fax		

[Back](#)

[Return to My Projects](#)

[Save](#)

[Save and Continue](#)

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Browse/Search

Authorized Access

Help

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My Projects

My Requests

Downloads

Downloaders

My Profile

Project Request

#42853: Test Project

SQ: Jane Doe

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

Project Details

Choose Datasets

Research Project

Cloud Providers

Collaborators

IT Director

Confirm Datasets

Review DUC

Review DUL

Review Applications

Feedback

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. You can request close out at annual renewal application.

You have selected the following datasets for this request.

To add a dataset please return to the "Choose Datasets" step. To remove a dataset, select "Remove" choice next to the datasets 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
Glaucoma Exome Sequencing (phs000558.v1.p1)			
General Research Use (IRB) (phs000558.v1.p1.c1), NEI	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval. . Public Posting of Genomic Summary Results - Undefined. This consent group requires IRB approval attachment	175	
The 100-Person Wellness Project (HPWP) (phs001363.v1.p1)			
General Research Use (IRB, PUB, COL, NPU) (phs001363.v1.p1.c1), NIGMS	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. . Public Posting of Genomic Summary Results - Allowed. This consent group requires IRB approval attachment This consent group requires Letter of Collaboration attachment	108	

Back

Return to My Projects

Remove Selected

Remove Selected and Continue

Continue

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Feedback

Feedback

NCBI

db GaP

genotypes and phenotypes

Browse/Search

Authorized Access

Help

Site map

All databases

PubMed

Search

Logged in as John Doe | Log out

My Projects

My Requests

Downloads

Downloaders

My Profile

Project Request

#42853: Test Project

SQ: Jane Doe

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

Project Details

Choose Datasets

Research Project

Cloud Providers

Collaborators

IT Director

Confirm Datasets

Review DUC

Review DUL

Review Applications

Feedback

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
Glaucoma Exome Sequencing (phs000558.v1.p1)			
General Research Use (IRB) (phs000558.v1.p1.c1), NEI	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval. . This consent group requires IRB approval attachment	175	 Data Use Certification Agreement  Dataset Manifest
The 100-Person Wellness Project (HPWP) (phs001363.v1.p1)			
General Research Use (IRB, PUB, COL, NPU) (phs001363.v1.p1.c1), NIGMS	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. . This consent group requires IRB approval attachment This consent group requires Letter of Collaboration attachment	108	 Data Use Certification Agreement  Dataset Manifest

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;

Choose File

No file chosen

The 100-Person Wellness Project (HPWP)

Letter of Collaboration is required; Local IRB approval is required, Do NOT include FULL protocol; Please combine all documents into a single pdf document and upload.

Choose File

No file chosen

☐ Load one document for all requests

Upload Selected files

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.

Back

Return to My Projects

Continue

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Feedback

Feedback

Project Request

#42853: Test Project

SQ: Jane Doe

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

Project Details Choose Datasets Research Project Cloud Providers Collaborators IT Director Confirm Datasets Review DUC Review DUL Review Applications Feedback

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
Glaucoma Exome Sequencing (phs000558.v1.p1)			
General Research Use (IRB) (phs000558.v1.p1.c1), NEI	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval. . Public Posting of Genomic Summary Results - Undefined. This consent group requires IRB approval attachment ☒ I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	175	
The 100-Person Wellness Project (HPWP) (phs001363.v1.p1)			
General Research Use (IRB, PUB, COL, NPU) (phs001363.v1.p1.c1), NIGMS	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. . Public Posting of Genomic Summary Results - Allowed. This consent group requires IRB approval attachment This consent group requires Letter of Collaboration attachment ☒ I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	108	

Back Return to My Projects I agree to the Data Use Limitation(s)

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Project Request

#42853: Test Project

SQ: Jane Doe

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

Project Details

Choose Datasets

Research Project

Cloud Providers

Collaborators

IT Director

Confirm Datasets

Review DUC

Review DUL

Review Applications

Feedback

Review and submit data access requests

Through the submission of this DAR, the Requester and Approved Users acknowledge receiving and reviewing a copy of the Addendum which includes Data Use Limitation(s) for each dataset requested. The Requester and Approved Users agree to comply with the terms listed in the Addendum.

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(DUC) Agreement and Addendum for the requested dataset. 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.

Get ADOBE® READER®

Feedback

Active (2)

#	Study, Consent	Status	Expiration	History
	Glaucoma Exome Sequencing (phs000558.v1.p1) General Research Use (IRB) (phs000558.v1.p1.c1), <u>NEI</u>	New		view
	The 100-Person Wellness Project (HPWP) (phs001363.v1.p1) General Research Use (IRB, PUB, COL, NPU) (phs001363.v1.p1.c1), <u>NIGMS</u>	New		view

Back

Return to My Projects

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Project Request

#42853: Test Project

SO: Jane Doe

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

Project Details

Choose Datasets

Research Project

Cloud Providers

Collaborators

IT Director

Confirm Datasets

Review DUC

Review DUL

Review Applications

Feedback

Check [status](#) of submitted applications

Your submission has been sent to your signing official who will verify the information before forwarding it to the appropriate Data Access Committee. You will receive several emails notifying you of every step in the process. To check on the status of an existing data access request, you may also use tab ["My Requests"](#), above.

Please note that you are not allowed to change your application while it is being reviewed. In order to make the changes you will have to contact your SO with a request to return application for your revision or use a "Recall Application" button to recall your application for revision.

If you have found that you need to send your application to a different SO, you can make the correction on the "Research Project" page. You will then need to review and confirm your application.

Recall Application

You need Adobe Reader installed to review PDF forms.



This project currently contains **2 active requests** for data access. You can view individual applications and processing statuses in the table below.

Active (2)

#	Study, Consent	Status	Expiration	History
153131-1	Glaucoma Exome Sequencing (phs000558.v1.p1) General Research Use (IRB) (phs000558.v1.p1.c1), NEI	SO review		view
153132-1	The 100-Person Wellness Project (HPWP) (phs001363.v1.p1) General Research Use (IRB, PUB, COL, NPU) (phs001363.v1.p1.c1), NIGMS	SO review		view

Back

Return to My Projects

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Feedback

Principal Investigator (PI) Renewal

Project renewal

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

#19872: Genome-wide association study of postpartum depression

+ [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)

SO: Diane Koltz

Project Details

Choose Datasets

Research Project

Collaborators

IT Director

Research Progress

Presentations

Publications and Manuscripts

Data Security

Confirm Datasets

Closeout

Review DUC

Review DUL

Review Applications

Feedback

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. Renewal of access to 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 were approved. The Access Committee(s) that reviewed your initial Data Access Request (DAR) will review your renewal. Elements of your original submission are provided as

Principal Investigator's (PI) Name: Patrick Sullivan

Institutional Signing Official (SO): Diane Koltz

Institutional Affiliation: UNIV OF NORTH CAROLINA CHAPEL HILL

Project ID: 19872

Project Name: Genome-wide association study of postpartum depression

Initial Request Date:

Date of Last Renewal:

Research Use Statement for "Genome-wide association study of postpartum depression" [show...](#)

Datasets for research project "Genome-wide association study of postpartum depression" [show...](#)

[Return to My Projects](#)

[Continue](#)

OMB control Number: 0925-0670

Expiration Date: March 31, 2026

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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 annual renewal.

#19872: Genome-wide association study of postpartum depression + [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)
SQ: Diane Koltz

- Project Details
- Choose Datasets
- Research Project
- Collaborators
- IT Director
- Research Progress
- Presentations
- Publications and Manuscripts
- Data Security
- Confirm Datasets
- Closeout
- Review DUC
- Review DUL
- Review Applications
- Feedback

Please select datasets to request access to. **Maximum 200 datasets per project.** 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 on cloud

Study lookup

enter study accession

 Study accession ☐ Exclude IRB required

Page 1 2 3 4 5 6 7 8 ... 43

Consent Group	Data Use Limitations	Participants	DAR Status
Glaucoma Exome Sequencing (phs000558.v1.p1)			
☐ General Research Use (IRB) (phs000558.v1.p1.c1), NEI	Use of the data is limited only by the terms of the model Data Use Certification. Requestor must provide documentation of local IRB approval. . Public Posting of Genomic Summary Results - Undefined . This consent group requires IRB approval attachment Have data available in Amazon S3 Cloud Storage Have data available in Google Cloud Storage	175	
The 100-Person Wellness Project (HPWP) (phs001363.v1.p1)			
☐ General Research Use (IRB, PUB, COL, NPU) (phs001363.v1.p1.c1), NIGMS	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. . Public Posting of Genomic Summary Results - Allowed . This consent group requires IRB approval attachment This consent group requires Letter of Collaboration attachment Have data available in Amazon S3 Cloud Storage Have data available in Google Cloud Storage	108	.
The Genetic Landscape of Metastasis and Recurrence in HNSCC (phs001007.v1.p1)			
☐ Disease-Specific (Cancer, MDS) (phs001007.v1.p1.c1), NCI DAC	Use of the data must be related to Cancer. Use of the data includes methods development research (e.g., development of software or algorithms). . Public Posting of Genomic Summary Results - Allowed . Have data available in Amazon S3 Cloud Storage Have data available in Google Cloud Storage	23	
Up for a Challenge: African American Breast Cancer Consortium (AABC) Study (phs000851.v1.p1)			
☐ Up for a Challenge (Publication required) (phs000851.v1.p1.c1), NCI 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	4881	

Feedback

NCBI

Site mapAll databasesPubMedSearch

dbGaP
genotypes and phenotypes

Browse/SearchAuthorized AccessHelp

My ProjectsMy RequestsDownloadsDownloadersMy Profile

Project renewal

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

#19872: Genome-wide association study of postpartum depression

SO: Diane Koltz

Project DetailsChoose DatasetsResearch ProjectCollaboratorsIT DirectorResearch ProgressPresentationsPublications and ManuscriptsData SecurityConfirm DatasetsCloseoutReview DUCReview DULReview ApplicationsFeedback

*Descriptive Title of Project

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

Genome-wide association study of postpartum depression

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.

The aim of this study is to gain knowledge of the genetic etiology of postpartum depression (PPD). We are conducting a genome-wide association study (GWAS) to identify common genetic variants implicated in PPD. GWAS has become a powerful technique for the discovery of previously unknown genetic and biological architecture underlying complex illnesses. Recruiting controls for psychiatric GWAS studies is expensive and has feasibility challenges. The purpose of this application is to obtain further controls for this study. The proposed uses are consistent with the data use limitations. The findings from this study will offer insights into the genetics of PPD by identifying genetic variants that increase liability to PPD.

☐ 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.

Postpartum depression (PPD) occurs in ~12% of women (PMID: 16268528) and carries health risks for mother and baby (PMID: 19962196). PPD is heritable but the genetic basis is not known. This genome-wide association study will compare the DNA of two groups: parous women with PPD (cases) and women without PPD (controls). By doing so, this study will help to understand the genetic and biological basis of PPD.

*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.

☐ Elliott, Amy (winnamy@email.unc.edu)

Applicant organization

*Institution Name

UNIV OF NORTH CAROLINA CHAPEL HILL

Department

Genetics

Division

*Street 1

120 Mason Farm Rd.

Street 2

*City

Chapel Hill NC

*State

nc

*ZIP/Postal code

27514

*Country

United States

Back

Return to My Projects

Save

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Feedback

NCBI

Site mapAll databasesPubMedSearch

dbGaP
genotypes and phenotypes

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My ProjectsMy RequestsDownloadersMy Profile

Project renewal

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

#19872: Genome-wide association study of postpartum depression

OMB control number: 0925-0670 Expiration date: 03/31/2026

SQ: Diane Koltz

Project DetailsChoose DatasetsResearch ProjectCollaboratorsIT DirectorResearch ProgressPresentationsPublications and ManuscriptsData SecurityConfirm DatasetsCloseoutReview DUC

Review DULReview ApplicationsFeedback

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

*Position/Title

Department

*Organization name

Division

*Street 1

Street 2

*City

State

*ZIP/Postal code

*Country

*E-mail

*Phone

Fax

Remove

Internal Collaborator

Prefix

*First name

Middle name

*Last name

Suffix

*Position/Title

Department

*Organization name

Division

*Street 1

Street 2

*City

State

*ZIP/Postal code

*Country

*E-mail

*Phone

Fax

Remove

Add another collaborator

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

BackReturn to My ProjectsSaveSave and Continue

Feedback

Project renewal

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

#19872: Genome-wide association study of postpartum depression

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

SO: Diane Koltz

- Project Details
- Choose Datasets
- Research Project
- Collaborators
- IT Director
- Research Progress
- Presentations
- Publications and Manuscripts
- Data Security
- Confirm Datasets
- Closeout
- 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
*Position/Title		Department	*Organization name	Division
*Street 1	Street 2	*City	State	*ZIP/Postal code
*E-mail		*Phone	Fax	

[Back](#)
[Return to My Projects](#)
[Save](#)
[Save and Continue](#)

Project renewal

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

#19872: Genome-wide association study of postpartum depression

+ [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)

SO: Diane Koltz

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

We hope to finalize a data freeze in Q2 2022 (we are close; everything has been delays due to COVID-19).

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

- ☐ Yes
☒ No

[Back](#) [Return to My Projects](#) [Save](#) [Save and Continue](#)



Project renewal

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

#19872: Genome-wide association study of postpartum depression

+ [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)

SO: Diane Koltz

[Project Details](#)

[Choose Datasets](#)

[Research Project](#)

[Collaborators](#)

[IT Director](#)

[Research Progress](#)

[Presentations](#)

[Publications and Manuscripts](#)

[Data Security](#)

[Confirm Datasets](#)

[Closeout](#)

[Review DUC](#)

[Review DUL](#)

[Review Applications](#)

[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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[Return to My Projects](#)

[Save](#)

[Save and Continue](#)

Project renewal

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Made this a structured field;
inserted a PubMed ID look up field

15-0670 Expiration date: 03/31/2026

#19872: Genome-wide association study of postpartum depression

SO: Diane Koltz

Project Details Choose Datasets Research Project Collaborators IT Director Research Progress Presentations Publications and Manuscripts Data Security Confirm Datasets Closeout Review DUC
Review DUL Review Applications 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

Date Bibliographic Citation

Authors

Other

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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 annual renewal.

#19872: Genome-wide association study of postpartum depression + [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)

SO: Diane Koltz

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

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

The list of approved users from your project is below.

Approved Users and Internal Collaborators at UNIV OF NORTH CAROLINA CHAPEL HILL

First name	Last name	Institution Name	Position/Title	Role on Project
		univ of north carolina chape	Distinguished Profes	Principal Investigator
		UNIV OF NORTH CAROLIN	Assistant Professor	Approved User
		UNIV OF NORTH CAROLIN	Assistant Professor	Approved User
		UNIV OF NORTH CAROLIN	Vice Chancellor for Informal	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.*

None.

[Back](#) | [Return to My Projects](#) | [Save](#) | [Save and Continue](#)

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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 annual renewal.

#19872: Genome-wide association study of postpartum depression

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

SO: Diane Koltz

Project Details Choose Datasets Research Project Collaborators IT Director Research Progress Presentations Publications and Manuscripts Data Security Confirm Datasets Closeout Review DUC
Review DUL Review Applications Feedback

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. You can request close out at annual renewal application.

You have selected the following datasets for this request.

To add a dataset please return to the "Choose Datasets" step. To remove a dataset, select "Remove" choice next to the datasets 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
GAIN: Genome-Wide Association Study of Schizophrenia (phs000021.v3.p2)			
General Research Use (phs000021.v3.p2.c1), JAAMH	Use of the data is limited only by the terms of the model Data Use Certification. May be used for any genetic studies. Public Posting of Genomic Summary Results - Allowed.	4589	✓ Approved GRANTED
Schizophrenia and Related Conditions (phs000021.v3.p2.c2), JAAMH	Limited to genetic studies of Schizophrenia and related conditions. Related conditions include conditions with evidence of genetic relationships to schizophrenia or schizoaffective disorder, such as acute psychoses, bipolar disorder, MDD, or "Cluster A" personality disorders (schizotypal, schizoid, paranoid). Public Posting of Genomic Summary Results - Allowed.	475	✓ Approved GRANTED
NHLBI TOPMed: Partners HealthCare Biobank (phs001024.v5.p1)			
Health/Medical/Biomedical (phs001024.v5.p1.c1), NHLBI	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Public Posting of Genomic Summary Results - Allowed.	128	✓ Approved GRANTED

Back Return to My Projects Remove Selected Remove Selected and Continue Continue

Project renewal

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

#19872: Genome-wide association study of postpartum depression

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

SO: Diane Koltz

[Project Details](#) | [Choose Datasets](#) | [Research Project](#) | [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)

To request close out a dataset, check the box to the left of the datasets you would like to close, provide a reason for close out and click the "Closeout Selected" or "Closeout Selected and Continue" buttons.

You have selected the following datasets for this request. If you are satisfied with the list on this page, click "Continue" button.

Consent Group	Data Use Limitations	Participants	DAR Status
GAIN: Genome-Wide Association Study of Schizophrenia (phs000021.v3.p2)			
☐ General Research Use (phs000021.v3.p2.c1), JAAMH	Use of the data is limited only by the terms of the model Data Use Certification. May be used for any genetic studies. Public Posting of Genomic Summary Results - Allowed .	4589	✓ Approved GRANTED
☐ Schizophrenia and Related Conditions (phs000021.v3.p2.c2), JAAMH	Limited to genetic studies of Schizophrenia and related conditions. Related conditions include conditions with evidence of genetic relationships to schizophrenia or schizoaffective disorder, such as acute psychoses, bipolar disorder, MDD, or "Cluster A" personality disorders (schizotypal, schizoid, paranoid). Public Posting of Genomic Summary Results - Allowed .	475	✓ Approved GRANTED
NHLBI TOPMed: Partners HealthCare Biobank (phs001024.v5.p1)			
☐ Health/Medical/Biomedical (phs001024.v5.p1.c1), NHLBI	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. . Public Posting of Genomic Summary Results - Allowed .	128	✓ Approved GRANTED

[Back](#) | [Return to My Projects](#) | [Request Closeout for Selected](#) | [Request Closeout for Selected and Continue](#) | [Continue](#)

Project renewal

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

#19872: Genome-wide association study of postpartum depression

+ [OMB control number: 0925-0670](#) Expiration date: 03/31/2026

SO: Diane Koltz

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

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
GAIN: Genome-Wide Association Study of Schizophrenia (phs000021.v3.p2)			
General Research Use (phs000021.v3.p2.c1), JAAMH	Use of the data is limited only by the terms of the model Data Use Certification. May be used for any genetic studies.	4589	 Data Use Certification Agreement
Schizophrenia and Related Conditions (phs000021.v3.p2.c2), JAAMH	Limited to genetic studies of Schizophrenia and related conditions. Related conditions include conditions with evidence of genetic relationships to schizophrenia or schizoaffective disorder, such as acute psychoses, bipolar disorder, MDD, or "Cluster A" personality disorders (schizotypal, schizoid, paranoid).	475	 Dataset Manifest
NHLBI TOPMed: Partners HealthCare Biobank (phs001024.v5.p1)			
Health/Medical/Biomedical (phs001024.v5.p1.c1), NHLBI	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. .	128	 Data Use Certification Agreement
			 Dataset Manifest

[Back](#) [Return to My Projects](#) [Continue](#)

Project renewal

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

#19872: Genome-wide association study of postpartum depression

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

SQ: Diane Koltz

Project Details Choose Datasets Research Project Collaborators IT Director Research Progress Presentations Publications and Manuscripts Data Security Confirm Datasets Closeout Review DUC
Review DUL Review Applications Feedback

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
GAIN: Genome-Wide Association Study of Schizophrenia (phs000021.v3.p2)			
General Research Use (phs000021.v3.p2.c1), JAAMH	Use of the data is limited only by the terms of the model Data Use Certification. May be used for any genetic studies. Public Posting of Genomic Summary Results - Allowed . ☐ I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	4589	✓ Approved GRANTED
Schizophrenia and Related Conditions (phs000021.v3.p2.c2), JAAMH	Limited to genetic studies of Schizophrenia and related conditions. Related conditions include conditions with evidence of genetic relationships to schizophrenia or schizoaffective disorder, such as acute psychoses, bipolar disorder, MDD, or "Cluster A" personality disorders (schizotypal, schizoid, paranoid). Public Posting of Genomic Summary Results - Allowed . ☐ I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	475	✓ Approved GRANTED
NHLBI TOPMed: Partners HealthCare Biobank (phs001024.v5.p1)			
Health/Medical/Biomedical (phs001024.v5.p1.c1), NHLBI	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Public Posting of Genomic Summary Results - Allowed . ☐ I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	128	✓ Approved GRANTED

◀ Back Return to My Projects **I agree to the Data Use Limitation(s)** ▶

Project renewal

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

#19872: Genome-wide association study of postpartum depression

+ [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)

SQ: Diane Koltz

[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](#)

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.

[Return to My Projects](#)

[Save and return to My Projects](#)

Principal Investigator (PI) Close-out

Closeout Project

#2476: test5

SQ: Jane Doe

+ [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)

Project Details

Research Progress

Presentations

Publications and Manuscripts

Data Security

Reasons for Project Closeout

Review Closeout Application

Feedback

This form is for closing out a project. Complete and submit this form when you no longer need any of the data for the project listed below. **Please note that information in this form applies to all datasets you requested under this project (also listed below).**

Please follow this link for important instructions on data destruction at the completion of your project: [Best Practices](#).

Principal Investigator's (PI) Name: John Doe**Institutional Signing Official (SO):** Jane Doe**Institutional Affiliation:** NIH**Project ID:** 2476**Project Name:** test5**Initial Request Date:****Date of Last Renewal:**Research Use Statement for "test5" [show...](#)Datasets for research project "test5" [show...](#)[Return to My Projects](#)[Begin close out process](#)

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Closeout Project

#2476: test5

+ [OMB control number: 0925-0670 Expiration date: 03/31/2026](#)

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.

group The Bone Mineralization working group that is part of TOPMed has been meeting monthly, has completed phenotype harmonization plans for dual energy x-ray absorptiometry (DXA) bone mineral density of the spine and hip. Data from several participating cohorts (Framingham Study, Genetics of Cardiometabolic Health in the Amish, Women's Health Initiative, Cardiovascular Health Study, San Antonio Family Heart Study) were loaded into the TOPMed Exchange Area in dbGaP. Data analysis has been completed for common variants, rare variants, and gene based analyses as well as beginning the fine mapping of previous GWAS loci from other initiatives. Analyses have been performed for common variants using

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

#2476: test5

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[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

#2476: test5

SQ: Jane Doe

+ [OMB control number: 0925-0670 Expiration date: 03/31/2026](#)

Project Details

Research Progress

Presentations

Publications and Manuscripts

Data Security

Reasons for Project Closeout

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

30367091

Look up

Title

Transcriptomic and functional network features of lung squamous cell carcinoma through integrative analysis of GEO

Date

2018 Oct 26

Bibliographic Citation

Sci Rep; 2018 Oct 26;8(1):15834

Authors

Li Y, Gu J, Xu F, Zhu Q, Ge D, Lu C

Other

phs000189 is used for this publication

Remove

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Closeout Project

#2476: test5

SQ: Jane Doe

+ OMB control number: 0925-0670 Expiration date: 03/31/2026

Project Details

Research Progress

Presentations

Publications and Manuscripts

Data Security

Reasons for Project Closeout

Review Closeout Application

Feedback

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

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	NIH;	System Account	Principal Investigator

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.*

none

Back

Cancel and return to My Projects

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Closeout Project

#2476: test5

SQ: Jane Doe

+ [OMB control number: 0925-0670 Expiration date: 03/31/2026](#)

[Project Details](#)

[Research Progress](#)

[Presentations](#)

[Publications and Manuscripts](#)

[Data Security](#)

[Reasons for Project Closeout](#)

[Review Closeout Application](#)

[Feedback](#)

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 comments about the reasons for closing out your project

Test of closing DARs.

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Downloads

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My Profile

Closeout Project

#2476: test5

SO: Jane Doe

+ [OMB control number: 0925-0670](#) [Expiration date: 03/31/2026](#)

Project Details

Research Progress

Presentations

Publications and Manuscripts

Data Security

Reasons for Project Closeout

Review Closeout Application

Feedback

*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)

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

Back

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Feedback

Feedback

**Principal Investigator (PI) Transfer DAR
Application**

Transfer Project

#2954: test22

SO: Jane Doe

You can transfer this project only to user:

- Have an eRA Commons account.
- This eRA account have a PI role.
- This eRA account have affiliation to NIH.
- Successfully logged into the dbGaP Authorized Access System at least once.

Request for this transfer will be sent to current SO for approval. You can [change SO](#) before, if it needed.

☐ I agree transfer this project to:

Comments:

[Submit Transfer Request To Signing Official](#)

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Institutional Signing Official Close-out

Signing Official's Projects

Projects to Review

- [#2051: New Demo Project](#)

Daniel Dery

Annual renewal is due on:

Approved Requests (by Project)

- [#425: Download test](#)

James Doe, Last application  approved on 2022-03-31

- [#484\(closed\): TEST::1-15-08 acceptance test](#)

Get list of all [projects/requests](#) for NIH. (CSV format)

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Project Request

#34402: Test

Req: John Doe

+ [OMB control number: 0925-0670](#) Expiration date: 03/31/2026

Review DUC

Review Applications

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 Study of the Genetic Causes of Complex Pediatric Disorders (phs000490.v1.p1)			 Data Use Certification Agreement
General Research Use (phs000490.v1.p1.c1), NHGRI	Use of the data is limited only by the terms of the model Data Use Certification. .	7431	 Dataset Manifest

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DRAFT | DRAFT | DRAFT

DRAFT | DRAFT | DRAFT

Closeout Project

#2051: New Demo Project

Reg: 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

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[Return to PI](#)

[File Report and close project](#) ▶

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