

# Legacy Authorized Access System

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



## 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  Study accession   Exclude IRB required

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

Consent Group	Data Use Limitations	Participants	DAR Status
<b>Glaucoma Exome Sequencing</b> (phs000558.v1.p1)			
<input type="checkbox"/> General Research Use (IRB) (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. . Public Posting of <a href="#">Genomic Summary Results</a> - <b>Undefined.</b>  <b>This consent group requires IRB approval attachment</b> <b>Have data available in Amazon S3 Cloud Storage</b> <a href="#">?</a> <b>Have data available in Google Cloud Storage</b> <a href="#">?</a>	175	
<b>The 100-Person Wellness Project (HPWP)</b> (phs001363.v1.p1)			
<input type="checkbox"/> General Research Use (IRB, PUB, COL, NPU) (phs001363.v1.p1.c1), <a href="#">NIHGMIS</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	
<b>A Study of the Genetic Causes of Complex Pediatric Disorders</b> (phs000490.v1.p1)			
<input type="checkbox"/> General Research Use (phs000490.v1.p1.c1), <a href="#">NHGRI</a>	Use of the data is limited only by the terms of the model Data Use Certification. . Public Posting of <a href="#">Genomic Summary Results</a> - <b>Allowed.</b>	7431	

[Feedback](#)

[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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[Feedback](#)

DRAFT | DRAFT | DRAFT

DRAFT | DRAFT | DRAFT

### Project Request

#42853: + OMB control number: 0925-0670 Expiration date: 03/31/2026

SO: 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.  
Test Project

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

Please make it clear whether you plan to combine requested datasets with you do plan to combine datasets in any way, please describe your plan at hypotheses that were not the focus of the primary study (or studies), please. Investigators do not need to submit a new project request unless the data are requested independently or together. If using on outcomes or results, please specify.

Please enter your RUS in the area below. The RUS should be one or two characteristics that will be tested for association with genetic variants. If you have a RUS that can be found at GDC, please provide the GDC website. Please limit your RUS to 4500 characters.  
Test RUS

Added text to comply with NIH Guide Notice NOT-OD-24-157 'Updated Security Best Practices', including two new check boxes

NIH expects that Approved Users of NIH controlled-access data under the GDS Policy systems comply with [NIH Security Best Practices for Users of Controlled-Access Data](#) and maintain such data on institutional IT systems, cloud service providers, and/or third-party IT systems with security standards that meet or exceed NIST SP 800-171 "Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations" or the equivalent ISO/IEC 27001/27002 standards.

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](#).

By checking this box, I am requesting permission to use cloud computing to carry out the research as described in my Research Use Statement and attest that the cloud service provided and/or third-party IT system used for data analysis and/or storage will secure data, 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. Also, if applicable, describe the role of any collaborators. Please limit your statement to 2000 characters.  
Test Cloud Use Statement

New text box to insert cloud 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.  
Test Non-technical summary

**\*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 (s sergey@ncbi.nlm.nih.gov)

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

**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: .....

Back Return to My Projects Save Save and Continue

### 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  \*Type of Provider

Details

Remove

#### Cloud Provider Information

\*Name of Provider  \*Type of Provider

Details

Remove

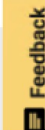
Add another

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

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# Project Request

## #42853: Test Project

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

SQ: Jane Doe

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"/>	<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"/>			

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## Project Request

### #42853: Test Project

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

SQ: Jane Doe

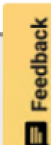
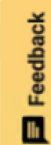
Approved individual data access request (DAR) cannot be removed from the projects in this system. All previously approved DARs must be either closed out or renewed. You can request close out at annual renewal application.

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
<b>Glaucoma Exome Sequencing</b> (phs000558.v1.p1)			
<input type="checkbox"/> 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 <a href="#">Genomic Summary Results</a> - <b>Undefined</b> .  <b>This consent group requires IRB approval attachment</b>	175	
<b>The 100-Person Wellness Project (HPWP)</b> (phs001363.v1.p1)			
<input type="checkbox"/> 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 <a href="#">Genomic Summary Results</a> - <b>Allowed</b> .  <b>This consent group requires IRB approval attachment</b> <b>This consent group requires Letter of Collaboration attachment</b>	108	



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DRAFT | DRAFT | DRAFT





[Browse/Search](#)

[Authorized Access](#)

[Help](#)

**My Projects**

[My Requests](#)

[Downloads](#)

[Downloaders](#)

[My Profile](#)

## Project Request

### #42853: Test Project

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

SQ: Jane Doe

[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
<b>Glaucoma Exome Sequencing (phs000558.v1.p1)</b> General Research Use (IRB) (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. . Public Posting of <a href="#">Genomic Summary Results</a> - <b>Undefined</b> .  <b>This consent group requires IRB approval attachment</b>  <input checked="" type="checkbox"/> I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	175	
<b>The 100-Person Wellness Project (HPWP) (phs001363.v1.p1)</b> 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. . Public Posting of <a href="#">Genomic Summary Results</a> - <b>Allowed</b> .  <b>This consent group requires IRB approval attachment</b> <b>This consent group requires Letter of Collaboration attachment</b>  <input checked="" type="checkbox"/> 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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[Feedback](#)



## 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.

You need Adobe Reader installed to review PDF forms.



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](#)

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), <a href="#">NEI</a>	SO review		<a href="#">view</a>
153132-1	The 100-Person Wellness Project (HPWP) (phs001363.v1.p1) General Research Use (IRB, PUB, COL, NPU) (phs001363.v1.p1.c1), <a href="#">NIGMS</a>	SO review		<a href="#">view</a>

[Back](#)

[Return to My Projects](#)

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DRAFT | DRAFT | DRAFT

DRAFT | DRAFT | DRAFT

# 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 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 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**  
 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.



## Project renewal

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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

#### \*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](mailto:winnamy@email.unc.edu))

#### Applicant organization

\*Institution Name Department Division  
UNIV OF NORTH CAROLINA CHAPEL HILL Genetics

\*Street 1 Street 2 \*City \*State \*ZIP/Postal code \*Country  
120 Mason Farm Rd. Chapel Hill NC nc 27514 United States

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](#)

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"/>	<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"/>		
*Street 1	Street 2	*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"/>				

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

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- 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

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- 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.

Remove

Add another presentation

◀ 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 they are no longer needed.

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

## #19872: Genome-wide association study of postpartum depression

SO: Diane Koltz

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- 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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+ 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
[redacted]	[redacted]	univ of north carolina chape	Distinguished Profes	Principal Investigator
[redacted]	[redacted]	UNIV OF NORTH CAROLIN	Assistant Professor	Approved User
[redacted]	[redacted]	UNIV OF NORTH CAROLIN	Assistant Professor	Approved User
[redacted]	[redacted]	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

## 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
<b>GAIN: Genome-Wide Association Study of Schizophrenia</b> (phs000021.v3.p2)			
<input type="button" value="v"/> <a href="#">General Research Use</a> (phs000021.v3.p2.c1), <a href="#">JAAMH</a>	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 <a href="#">Genomic Summary Results</a> - <b>Allowed</b> .	4589	✓ Approved <a href="#">GRANTED</a>
<input type="button" value="v"/> <a href="#">Schizophrenia and Related Conditions</a> (phs000021.v3.p2.c2), <a href="#">JAAMH</a>	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 <a href="#">Genomic Summary Results</a> - <b>Allowed</b> .	475	✓ Approved <a href="#">GRANTED</a>
<b>NHLBI TOPMed: Partners HealthCare Biobank</b> (phs001024.v5.p1)			
<input type="button" value="v"/> <a href="#">Health/Medical/Biomedical</a> (phs001024.v5.p1.c1), <a href="#">NHLBI</a>	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Public Posting of <a href="#">Genomic Summary Results</a> - <b>Allowed</b> .	128	✓ Approved <a href="#">GRANTED</a>

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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

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
<b>GAIN: Genome-Wide Association Study of Schizophrenia</b> (phs000021.v3.p2)			
<input type="checkbox"/> 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 - <b>Allowed</b> .	4589	✓ Approved GRANTED
<input type="checkbox"/> 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 - <b>Allowed</b> .	475	✓ Approved GRANTED
<b>NHLBI TOPMed: Partners HealthCare Biobank</b> (phs001024.v5.p1)			
<input type="checkbox"/> 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 - <b>Allowed</b> .	128	✓ Approved GRANTED

- Back
- Return to My Projects
- Request Closeout for Selected
- Request Closeout for Selected and Continue**
- 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](#)

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>GAIN: Genome-Wide Association Study of Schizophrenia</b> (phs000021.v3.p2)			
General Research Use (phs000021.v3.p2.c1), <a href="#">JAAMH</a>	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 <a href="#">Genomic Summary Results</a> - <b>Allowed</b> .  <input type="checkbox"/> I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	4589	✓ Approved <a href="#">GRANTED</a>
Schizophrenia and Related Conditions (phs000021.v3.p2.c2), <a href="#">JAAMH</a>	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 <a href="#">Genomic Summary Results</a> - <b>Allowed</b> .  <input type="checkbox"/> I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	475	✓ Approved <a href="#">GRANTED</a>
<b>NHLBI TOPMed: Partners HealthCare Biobank</b> (phs001024.v5.p1)			
Health/Medical/Biomedical (phs001024.v5.p1.c1), <a href="#">NHLBI</a>	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Public Posting of <a href="#">Genomic Summary Results</a> - <b>Allowed</b> .  <input type="checkbox"/> I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	128	✓ Approved <a href="#">GRANTED</a>

◀ [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

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](#)

#### 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.



This project currently contains **3 active requests** for data access. You can view individual applications and processing statuses in the table below.

Active (3)				
#	Study, Consent	Status	Expiration	History
77950-4	GAIN: Genome-Wide Association Study of Schizophrenia (phs000021.v3.p2) General Research Use (phs000021.v3.p2.c1), <a href="#">JAAMH</a>	✓ Approved <a href="#">GRANTED</a>	2023-02-25	<a href="#">view</a>
77951-4	GAIN: Genome-Wide Association Study of Schizophrenia (phs000021.v3.p2) Schizophrenia and Related Conditions (phs000021.v3.p2.c2), <a href="#">JAAMH</a>	✓ Approved <a href="#">GRANTED</a>	2023-02-25	<a href="#">view</a>
77952-4	NHLBI TOPMed: Partners HealthCare Biobank (phs001024.v5.p1) Health/Medical/Biomedical (phs001024.v5.p1.c1), <a href="#">NHLBI</a>	✓ Approved <a href="#">GRANTED</a>	2023-04-07	<a href="#">view</a>

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

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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
- 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

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

SO: Jane Doe

### 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

## 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

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

Back Cancel and return to My Projects Save and Continue

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Feedback





# Closeout Project

#2476: test5

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

SQ: Jane Doe

## 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.

Back Cancel and return to My Projects Save and Continue



## Closeout Project

#2476: test5

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

SO: Jane Doe

### \*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**

**Back**

Cancel and return to My Projects



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

DRAFT | DRAFT | DRAFT

DRAFT | DRAFT | DRAFT

## 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**

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DRAFT | DRAFT | DRAFT

## 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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**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.





## 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](#)

[Return to PI](#)

[File Report and close project](#) ▶

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