

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

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

Public reporting burden for this collection of information is estimated to vary from 15 to 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return the completed form to this address.

## dbGaP Authorized Access

dbGaP Authorized Access is **the management portal for individual-level data.** This site can be used to submit a data access request, manage access requests, and download approved data sets.

[Log In](#)  
to the Authorized Access  
system

### How does one apply?

Click on the “log in” link (upper right side of this page) and follow the instructions. In order to log in and apply for authorized access to dbGaP studies you must have one of the following accounts:

- eRA Commons (for NIH extramural principal investigators, grantees, or other extramural investigators). If you do not have a pre-existing account, [register here](#).
- NIH Login (for intramural NIH scientists and staff)

For additional information, see [request procedures](#) for principal investigators and signing officials.

### Who can apply?

## Who can apply?

Researchers from outside of NIH need to be identified as principal investigators (PIs) in the eRA Commons system. If you are not a PI, when you log in, the system will advise you to contact your local supervisor to apply on your behalf.

NIH intramural employees can apply if they are registered in the NIH Intramural Database (NIDB) as a PI, PI-eligible, or Lead Investigator. NIH administrative and extramural staff can apply if they meet specified criteria. When NIH employees log in, the system will recognize their status and direct them to obtain any necessary approvals and fill out any required forms. For further information, see NIH February 6, 2008, memo on [Requesting Access to Data in the NIH GWAS Data Repository](#).

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

## Why is access restricted?

NIH is committed to respecting the privacy and intentions of research participants with regard to how data pertaining to their individual information is used. Data access is therefore intended only for scientific investigators pursuing research questions that are consistent with the informed consent agreements provided by individual research participants. Furthermore, investigators provided access will be expected to utilize appropriate [data security measures](#).

## Who is an authorized user within the data access request system?

Authorized users include the researchers who may request data sets for specific research uses, the institutional signing officials from the PI's home organization who certify and submit such requests, and the NIH staff who review and process requests (e.g., members of the Data Access Committees).

## Do you need further help?

dbGaP also maintains a **help desk** to assist investigators, institutional signing officials and NIH staff with authorized access management, and answer any questions related to the application process. [Contact the help desk](#) with your queries.

## My Research Projects

[Create New Research Project](#) ▶

# My Research Project

## General Instructions

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

## Before You Get Started

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

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

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

## dbGaP APPROVED USER CODE OF CONDUCT

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

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

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

[Begin New Research Project](#) ▶

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

### Filter Consents

Primary disease 
 Molecular data type 
 Study design

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

Study accession 
 Exclude IRB required

Consent Group	Data Use Limitations	Participants	DAR Status
<b>Up for a Challenge: African American Breast Cancer Consortium (AABC) Study (phs000851.v1.p1)</b>			
<input type="checkbox"/> Up for a Challenge (phs000851.v1.p1.c1), eNCI DAC	Use of this data is limited to research described for the National Cancer Institute (NCI) "Up for A Challenge" breast cancer genetic epidemiology competition. The goal of this challenge is to use innovative approaches to identify novel biology involved in breast cancer susceptibility including new genes, genetic variants, or sets of genomic features, leading to novel biological hypotheses. Individuals NOT participating in the challenge would NOT be granted access. Requestor agrees to make results of studies using the data available to the larger scientific community. .	4881	
<input type="checkbox"/> Up for a Challenge (Not for Profit Use Only) (phs000851.v1.p1.c2), eNCI DAC	Use of this data is limited to research described for the National Cancer Institute (NCI) "Up for A Challenge" breast cancer genetic epidemiology competition. The goal of this challenge is to use innovative approaches to identify novel biology involved in breast cancer susceptibility including new genes, genetic variants, or sets of genomic features, leading to novel biological hypotheses. Individuals NOT participating in the challenge would NOT be granted access. Use of the data is limited to not-for-profit organizations. Requestor agrees to make results of studies using the data available to the larger scientific community. Requestor should not use these data to apply for any patent or generate any products that may have any potential commercial value.	486	
<b>dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use</b>			
<input type="checkbox"/> General Research Use CDAC	Use of the data is limited only by the terms of the model Data Use Certification. .	0	
<b>dbGaP Collection: Autism Omics studies</b>			
<input type="checkbox"/> General Research Use NDAR	Use of the data is limited only by the terms of the model Data Use Certification. .	0	
<input type="checkbox"/> Disease-Specific (Autism Spectrum Disorder) NDAR	Use of the data must be related to Autism Spectrum Disorder. .	0	
<b>A Genome-Wide Association Study of Peripheral Arterial Disease (phs000203.v1.p1)</b>			
<input type="checkbox"/> Health Research - Mayo Clinic (phs000203.v1.p1.c1), NHGRI	Mayo Clinic Data may only be used for genetic studies to learn about, prevent, or treat health problems. Investigators must state in the Data Use Request their intention to publish or otherwise broadly share any findings from his or her study with the scientific community.	3337	
<b>A Genome-wide Association Study (GWAS) of Risk for Osteosarcoma (phs000734.v1.p1)</b>			
<input type="checkbox"/> General Research Use (phs000734.v1.p1.c1), INCI DAC	Use of the data is limited only by the terms of the model Data Use Certification. .	694	
<b>A genome wide study of lung cancer in never smokers (phs000634.v1.p1)</b>			
<input type="checkbox"/> General Research Use (MDC) (phs000634.v1.p1.c1), eNCI	Use of the data is limited only by the terms of the model Data Use Certification. Use of the data includes method development	1000	



Study accession for preview:

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



### Project Request

#### #6422: Test to see how recall application works

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

- Project Details
- Research Project
- Cloud Providers
- Collaborators
- IT Director
- Choose Datasets
- 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 to see how recall application works

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

#### \*Type of Research

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

asdf

#### \*Research Use Statement (RUS)

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

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

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

Please enter your RUS in the area below. The RUS should be one or two paragraphs in length and include research objectives, the study design, and an analysis plan (including the phenotypic characteristics that will be tested for association with genetic variants). If you are requesting multiple datasets, please describe how you will use them. Examples of RUS can be found at [GDS website](#). Please limit your RUS to 2200 characters.

asdf

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

##### Cloud Use Statement

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

rsdrsrdr

New section for details of cloud use.

#### \*Non-technical summary

Please enter below a non-technical summary of your RUS suitable for understanding by the general public (written at a high school reading level or below). Please limit your non-technical summary to 1100 characters.

asdf



## Project Request

### #6422: Test to see how recall application works

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

Project Details Research Project Cloud Providers Collaborators IT Director Choose Datasets 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 Service Provider Information

\*Name of Provider Amazon Web Services \*Type of Provider Commercial

Details I will be using elastic compute service to compute on data obtained directly from SRA and stored on the AWS S3 service.

Remove

Add another Back Return to My Projects Save Save and Continue



**\*Choose your Signing Official (SO):**

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

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

**Applicant organization**

*Institution Name	Department	Division			
<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"/>

**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 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:

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

### Internal Collaborator

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

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

### External Collaborator

*First name	*Last name	*Institution Name	*Position/Title	*Role on Project	*E-mail	Comment
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="button" value="Remove"/>						

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"/>		
*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"/>			

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

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

**Filter Consents**

Primary disease  Molecular data type  Study design

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

Study accession   Exclude IRB required

Consent Group	Data Use Limitations	Participants	DAR Status
<b>Up for a Challenge: African American Breast Cancer Consortium (AABC) Study (phs000851.v1.p1)</b>			
<input type="checkbox"/> Up for a Challenge (phs000851.v1.p1.c1), eNCI DAC	Use of this data is limited to research described for the National Cancer Institute (NCI) "Up for A Challenge" breast cancer genetic epidemiology competition. The goal of this challenge is to use innovative approaches to identify novel biology involved in breast cancer susceptibility including new genes, genetic variants, or sets of genomic features, leading to novel biological hypotheses. Individuals NOT participating in the challenge would NOT be granted access. Requestor agrees to make results of studies using the data available to the larger scientific community. .	4881	
<input type="checkbox"/> Up for a Challenge (Not for Profit Use Only) (phs000851.v1.p1.c2), eNCI DAC	Use of this data is limited to research described for the National Cancer Institute (NCI) "Up for A Challenge" breast cancer genetic epidemiology competition. The goal of this challenge is to use innovative approaches to identify novel biology involved in breast cancer susceptibility including new genes, genetic variants, or sets of genomic features, leading to novel biological hypotheses. Individuals NOT participating in the challenge would NOT be granted access. Use of the data is limited to not-for-profit organizations. Requestor agrees to make results of studies using the data available to the larger scientific community. Requestor should not use these data to apply for any patent or generate any products that may have any potential commercial value.	486	
<b>dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use</b>			
<input checked="" type="checkbox"/> General Research Use CDAC	Use of the data is limited only by the terms of the model Data Use Certification. .	0	
<b>dbGaP Collection: Autism Omics studies</b>			
<input type="checkbox"/> General Research Use NDAR	Use of the data is limited only by the terms of the model Data Use Certification. .	0	
<input type="checkbox"/> Disease-Specific (Autism Spectrum Disorder) NDAR	Use of the data must be related to Autism Spectrum Disorder. .	0	
<b>A Genome-Wide Association Study of Peripheral Arterial Disease (phs000203.v1.p1)</b>			
<input checked="" type="checkbox"/> Health Research - Mayo Clinic	Mayo Clinic Data may only be used for genetic studies to learn about, prevent, or treat health problems. Investigators must state	3337	to review



<input type="checkbox"/> Health/Medical/Biomedical - Genetic Studies Only-No Insurance Companies (phs000360.v2.p1.c3), NHGRI	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data is limited to genetic studies only. No permitted use: Insurance Companies.	6100	
<input checked="" type="checkbox"/> Health/Medical/Biomedical (GSO) (phs000360.v2.p1.c4), NHGRI	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data is limited to genetic studies only. Investigators must state in the Data Use Request their intention to publish or otherwise broadly share any findings from his or her study with the scientific community.	3755	

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

**Study accession for preview:**

This input box is only for study investigators of studies that are currently in preview status. If you are a data submitter, please input the study accession. form.page.value='newprj\_confirmdatasets';

# Project Request

#2476: test5

SO: Jane Doe

OMB control number: 0925-0670 Expiration date: March 31, 2016

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

You have selected the following datasets for this request.

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

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

Consent Group	Data Use Limitations	Participants	DAR Status
<b>Up for a Challenge: African American Breast Cancer Consortium (AABC) Study (phs000851.v1.p1)</b>			
<input type="checkbox"/> Exchange Area (phs000851.v1.p1.c999), eNCI DAC	Pre-release exchange area for use by study investigators only.	0	to review GRANTED
<b>1000 Genomes Used for Cloud Testing (phs000710.v1.p1)</b>			
<input type="checkbox"/> Exchange Area (phs000710.v1.p1.c999), CDAC	There are no Restrictions on the use of these data.	0	to review GRANTED
<b>dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use</b>			
<input type="checkbox"/> General Research Use CDAC	Use of the data is limited only by the terms of the model Data Use Certification. .	0	
<b>A Genome-Wide Association Study of Peripheral Arterial Disease (phs000203.v1.p1)</b>			
<input type="checkbox"/> Health Research - Mayo Clinic (phs000203.v1.p1.c1), NHGRI	Mayo Clinic Data may only be used for genetic studies to learn about, prevent, or treat health problems. Investigators must state in the Data Use Request their intention to publish or otherwise broadly share any findings from his or her study with the scientific community.	3337	to review
<b>Acquired Copy Number Alterations in Adult Acute Myeloid Leukemia Genomes (phs000201.v2.p1)</b>			
<input type="checkbox"/> Disease-Specific (Hematologic Disease, MDS, GSO) (phs000201.v2.p1.c1), eNCI DAC	Use of the data must be related to Hematologic Disease. Use of the data includes methods development research (e.g., development of software or algorithms). Use of the data is limited to genetic studies only. .	86	to review
<b>Alcohol Research using Australian twins and their families (OZ-ALC) (phs000181.v1.p1)</b>			
<input type="checkbox"/> Research on Alcohol and Tobacco Related Phenotypes (phs000181.v1.p1.c1), JAAMH	Consented to general research use with respect to alcohol and tobacco related phenotypes. <b>This consent group requires IRB approval attachment</b>	6775	to review GRANTED
<b>Alzheimer's Disease Genetics Consortium (phs000372.v1.p1)</b>			
<input type="checkbox"/> Alzheimer's Disease Genetics Consortium (phs000372.v1.p1.c1), JAAMH	Alzheimer's Disease Research Only. <b>This consent group requires IRB approval attachment</b>	6065	to review GRANTED
<b>Alzheimer's Disease Sequencing Project (ADSP) (phs000572.v5.p3)</b>			



<input type="checkbox"/> Exchange Area with IRB (phs000200.v10.p3.c999), NHLBI	Pre-release exchange area for use by study investigators only. <b>This consent group requires IRB approval attachment</b>	0	to review
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[Back](#) [Return to My Projects](#) [Remove Selected](#) [Remove Selected and Continue](#)

#2954: test22

SO: Jane Doe







[Project Details](#)
[Research Project](#)
[Cloud Providers](#)
[Collaborators](#)
[IT Director](#)
[Choose Datasets](#)
[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
<b>GENEVA GWAS of Lung Cancer and Smoking</b> (phs000093.v2.p2)			 <a href="#">Data Use Certificate</a>
Research related to adult diseases and methods (phs000093.v2.p2.c1), INCI DAC	The informed consent document signed by the PLCO study participants allows use of these data by investigators for discovery and hypothesis generation in the investigation of the genetic contributions to cancer and other adult diseases as well as development of novel analytical approaches for GWAS. .	1629	 <a href="#">Dataset Manifest</a>
<b>Genentech whole-genome sequencing of a non-small cell lung carcinoma</b> (phs000299.v2.p1)			 <a href="#">Data Use Certificate</a>
Health/Medical/Biomedical (MDS) (phs000299.v2.p1.c1), eNCI DAC	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data includes methods development research (e.g., development of software or algorithms). .	21	 <a href="#">Dataset Manifest</a>
<b>TCGA - The Cancer Genome Atlas</b> (phs000178.v9.p8)			 <a href="#">Data Use Certificate</a>
General Research Use (phs000178.v9.p8.c1), TCGA	The Cancer Genome Atlas permits use of these data for biomedical and/or methods research by qualified investigators.	356	 <a href="#">Dataset Manifest</a>

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

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

Consent Group	Data Use Limitations	Participants	DAR Status
<b>GENEVA GWAS of Lung Cancer and Smoking</b> (phs000093.v2.p2) Research related to adult diseases and methods (phs000093.v2.p2.c1), INCI DAC	The informed consent document signed by the PLCO study participants allows use of these data by investigators for discovery and hypothesis generation in the investigation of the genetic contributions to cancer and other adult diseases as well as development of novel analytical approaches for GWAS. .  <input type="checkbox"/> I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	1629	to review
<b>Genentech whole-genome sequencing of a non-small cell lung carcinoma</b> (phs000299.v2.p1) Health/Medical/Biomedical (MDS) (phs000299.v2.p1.c1), eNCI DAC	Use of this data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry. Use of the data includes methods development research (e.g., development of software or algorithms). .  <input type="checkbox"/> I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	21	to review <b>EXPIRED</b>
<b>TCGA - The Cancer Genome Atlas</b> (phs000178.v9.p8) General Research Use (phs000178.v9.p8.c1), TCGA	The Cancer Genome Atlas permits use of these data for biomedical and/or methods research by qualified investigators.  <input type="checkbox"/> I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	356	to review <b>EXPIRED</b>

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[I agree to the Data Use Limitation\(s\)](#)



#2954: test22

SO: Jane Doe

- Project Details
- Research Project
- Cloud Providers
- Collaborators
- IT Director
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- Confirm Datasets
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- Feedback

## Review and submit data access requests

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

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

John Doe: "ww"

 [Review Complete Application](#)

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

By signing below, I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

I agree




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

I agree

[Submit Application To Signing Official](#) ▶

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

Active (3)

#	Study, Consent	Status	Expiration	Application
25313-1	<a href="#">GENEVA GWAS of Lung Cancer and Smoking</a> (phs000093.v2.p2) Research related to adult diseases and methods (phs000093.v2.p2.c1), INCI DAC	to review		 <a href="#">view</a>
11972-2	<a href="#">TCGA - The Cancer Genome Atlas</a> (phs000178.v9.p8) General Research Use (phs000178.v9.p8.c1), TCGA	to review EXPIRED	2014-01-18	 <a href="#">view</a>
11973-2	<a href="#">Genentech whole-genome sequencing of a non-small cell lung carcinoma</a> (phs000299.v2.p1) Health/Medical/Biomedical (MDS) (phs000299.v2.p1.c1), eNCI DAC	to review EXPIRED	2014-01-18	 <a href="#">view</a>

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

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

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

You need Adobe Reader installed to review PDF forms.



# Project Request

#2954: test22

[OMB control number: 0925-0670](#) [Expiration date: March 31, 2016](#)

SO: Jane Doe

[Project Details](#) [Research Project](#) [Cloud Providers](#) [Collaborators](#) [IT Director](#) [Choose Datasets](#) [Confirm Datasets](#) [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](#) ▶

JavaScript Comparison an x dbGaP: Authorized Access x

intrawebdev2.be-md.ncbi.nlm.nih.gov:6224/staff/godynsk/wga/wga.cgi?page=newprj\_reviewappl&wlid=4168&filter=wlid&\_log

NCBI Site map All databases PubMed Search

dbGaP genotypes and phenotypes Browse/Search Authorized Access Help

SO Projects Beacon My Profile

Project Request

#4168: Test project1

Req: John Doe

OMB control number: 0925-0670 Expiration date: March 31, 2016

Review DUC Review Applications

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

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

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

Return to PI

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

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

I agree

**Agreement to Adhere to Data Security Expectations**

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

I agree

If the Principal Investigator has requested use of cloud computing, I also certify on behalf of this institution that the Information Technology Director, the Principal Investigator and other approved users under the DAR, and I have reviewed the cloud computing guidelines found in the [NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy](#) and the Principal Investigator's proposed use of cloud computing as outlined in the Principal Investigator's Research and Cloud Computing Use Statements, and we agree to manage and protect the requested dataset(s) by following those Best Practices as well as our own institutional IT security requirements and policies.

I agree

**Acknowledgment of Responsibility**

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

I agree

Approve and Submit to DAC

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

#	Study, Consent	Status	Expiration	Application
35013-2	AGP Consortium - GWAS and CNV - Stage I (phs000267.v4.p2) Disease-Specific (Autism Spectrum Disorder) (phs000267.v4.p2.c1), NDAR	SO review		<a href="#">view</a>
35014-2	A pilot study using next generation sequencing in advanced cancers: feasibility and challenges (phs000657.v1.p1) General Research Use (MDS) (phs000657.v1.p1.c1), eNCI DAC	SO review		<a href="#">view</a>
35015-2	ALL Relapse GWAS (phs000638.v1.p1) Health/Medical/Biomedical (phs000638.v1.p1.c1), NIGMS	SO review		<a href="#">view</a>


NIH Genotype and Phenotype database is a service of NCBI. Please [contact us](#) with any questions.  
National Center for Biotechnology Information | U.S. National Library of Medicine  
[Privacy Notice](#) | [Disclaimer](#) | [Accessibility](#)

Please **carefully review** submitted information by clicking on "Data Access Request(s) Application".

To **reviser**: Click the "Return to PI" button to ask the PI to make the desired changes.

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

You need *Adobe Reader* installed to review PDF forms.



New section for details on data security expectations including cloud use.

**dbGaP Authorized Access**

**Project Renewal Web Forms**

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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

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

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

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

**Institutional Affiliation:** NIH

**Project ID:** 9308

**Project Name:** Project Renewal Demonstration

**Initial Request Date:**

**Date of Last Renewal:**

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

Test Technical RUS

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

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

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## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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### \*Descriptive Title of Project

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

Project Renewal Demonstration ?

### \*Type of Research

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

### \*Research Use Statement (RUS) ?

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

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

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

Please enter your RUS in the area below. The RUS should be one or two paragraphs in length and include research objectives, the study design, and an analysis plan (including the phenotypic characteristics that will be tested for association with genetic variants). If you are requesting multiple datasets, please describe how you will use them. Examples of RUS can be found at [GDS website](#). Please limit your RUS to 2200 characters.

Test Technical RUS

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

Page continues on  
next slide ↓

# Continuation of previous slide



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

**\*Non-technical summary**

Please enter below a non-technical summary of your RUS suitable for understanding by the general public (written at a high school reading level or below). Please limit your non-technical summary to 1100 characters.

Test Lay RUS

**\*Choose your Signing Official (SO):**

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

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

**Applicant organization**

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

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dbGaP genotypes and phenotypes

Browse/Search Authorized Access Help

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Project Request

#6422: Test to see how recall application works [OMB control number: 0925-0670 Expiration date: March 31, 2016](#)

SO: Jane Doe

Project Details Research Project Cloud Providers Collaborators IT Director Choose Datasets 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 to see how recall application works

**\*Type of Research**

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

asdf

**\*Research Use Statement (RUS)**

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

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

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

Please enter your RUS in the area below. The RUS should be one or two paragraphs in length and include research objectives, the study design, and an analysis plan (including the phenotypic characteristics that will be tested for association with genetic variants). If you are requesting multiple datasets, please describe how you will use them. Examples of RUS can be found at [GDS website](#). Please limit your RUS to 2200 characters.

asdf

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

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

fgdfgdfg

**\*Non-technical summary**  
Please enter below a non-technical summary of your RUS suitable for understanding by the general public (written at a high school reading level or below). Please limit your non-technical summary to 1100 characters.

asdf

New section for details of cloud use.





## Project Request

### #6422: Test to see how recall application works

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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 Service Provider Information

\*Name of Provider  \*Type of Provider

Details

Remove

Add another



## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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

### Internal Collaborator

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

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

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

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

None

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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

### IT Director

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

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# Project renewal

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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### Research Progress:

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

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

- Yes
- No

### Research Plans with Approved Dataset(s):

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

Will your research plan include revised or new research questions that you propose to address using the current approved dataset(s)?  Yes  No

If "yes", Please amend your Research Use Statment.

Will your research plan involve combining dataset(s) accessed under this research project with dataset(s) not described in the Research Use Statment?  Yes  No

If "yes", Please amend your Research Use Statment.

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# Project renewal

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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

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

Remove

Add another presentation

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# Project renewal

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

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

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

PubMed ID  Title

Date  Bibliographic Citation

Authors

Other

SO: Jane Doe

- Project Details
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### Data Security:

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

- Yes
- No

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

The list of approved users from your project is below.

### Approved Users and Internal Collaborators at NIH

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

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

- None

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

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SO: Jane Doe

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Please select datasets to request access to. If you have changed any common information (research statement, list of collaborators), all approved application and those being reviewed by DAC(s) will need to be resubmitted.

For any study that has more than one consent group, there are no overlaps in subjects between the consent groups.

### Filter Consents

Primary disease  Molecular data type  Study design

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

Study accession   Exclude IRB required

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

*Multiple studies are not shown for brevity* ↓

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

- Back
- Return to My Projects
- Add Selected
- Add Selected and Continue

Study accession for preview:

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



# Project renewal

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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

You have selected the following datasets for this request.

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

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

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

SO: Jane Doe



- Project Details
- Research Project
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- IT Director
- Research Progress
- Presentations
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- Data Security
- Choose Datasets
- 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
<b>dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use</b>			 <a href="#">Data Use Certificate</a>
General Research Use CDAC	Use of the data is limited only by the terms of the model Data Use Certification. .	0	 <a href="#">Dataset Manifest</a>

- Back
- Return to My Projects
- Continue

# Project renewal

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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

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

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

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

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

- Project Details
- Research Project
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- Confirm Datasets
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- Review Applications
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### Review and submit data access requests

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

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

 [Review Complete Application](#)

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

By signing below, I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

I agree

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

I agree

[Submit Application To Signing Official](#) ▶

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

Active (1)

#	Study, Consent	Status	Expiration	Application
38991-1	dbGaP Collection: Compilation of Individual-Level Genomic Data for General Research Use General Research Use CDAC	✓ Approved EXPIRED	2015-08-07	 view

[Back](#)

[Return to My Projects](#)

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.



# Project renewal

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

- Project Details
- Research Project
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- Confirm Datasets
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- 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 ▶

JavaScript Comparison an x dbGaP: Authorized Access x

intrawebdev2.be-md.ncbi.nlm.nih.gov:6224/staff/godynsk/wga/wga.cgi?page=newprj\_reviewappl&wlid=4168&filter=wlid&\_log

NCBI Site map All databases PubMed Search

dbGaP genotypes and phenotypes Browse/Search Authorized Access Help

SO Projects Beacon My Profile

## Project Request

**#4168: Test project1**  
Req: John Doe

OMB control number: 0925-0670 Expiration date: March 31, 2016

Review DUC Review Applications

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

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

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

[Return to PI](#)

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

I agree

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

I agree

If the Principal Investigator has requested use of cloud computing, I also certify on behalf of this institution that the Information Technology Director, the Principal Investigator and other approved users under the DAR, and I have reviewed the cloud computing guidelines found in the [NIH Security Best Practices for Controlled-Access Data Subject to the GDS Policy](#) and the Principal Investigator's proposed use of cloud computing as outlined in the Principal Investigator's Research and Cloud Computing Use Statements, and we agree to manage and protect the requested dataset(s) by following those Best Practices as well as our own institutional IT security requirements and policies.

I agree

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

I agree

[Approve and Submit to DAC](#)

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

#	Study, Consent	Status	Expiration	Application
35013-2	AGP Consortium - GWAS and CNV - Stage I (phs000267.v4.p2) Disease-Specific (Autism Spectrum Disorder) (phs000267.v4.p2.c1), NDAR	SO review		<a href="#">view</a>
35014-2	A pilot study using next generation sequencing in advanced cancers: feasibility and challenges (phs000657.v1.p1) General Research Use (MDS) (phs000657.v1.p1.c1), eNCI DAC	SO review		<a href="#">view</a>
35015-2	ALL Relapse GWAS (phs000638.v1.p1) Health/Medical/Biomedical (phs000638.v1.p1.c1), NIGMS	SO review		<a href="#">view</a>


NIH Genotype and Phenotype database is a service of NCBI. Please [contact us](#) with any questions.  
National Center for Biotechnology Information | U.S. National Library of Medicine  
[Privacy Notice](#) | [Disclaimer](#) | [Accessibility](#)

Please **carefully review** submitted information by clicking on "Data Access Request(s) Application".

To **reviser**: Click the "Return to PI" button to ask the PI to make the desired changes.

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

You need *Adobe Reader* installed to review PDF forms.



New section for details on data security expectations including cloud use.

**dbGaP Authorized  
Access**

**Project Closeout Web  
Forms**

# Closeout Project

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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

### Research Progress:

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

Still working with the data

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

- Yes
- No

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



## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

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

# Closeout Project

## #9308: Project Renewal Demonstration

[OMB control number: 0925-0670 Expiration date: March 31, 2016](#)

SO: Jane Doe

[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   Title

Date  Bibliographic Citation

Authors

Other

SO: Jane Doe

[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 additional comments about the reasons for project closeout below.

[Back](#)

[Cancel and return to My Projects](#)

[Save and Continue](#)

## #9308: Project Renewal Demonstration

OMB control number: 0925-0670 Expiration date: March 31, 2016

SO: Jane Doe

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

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

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

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

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


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

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

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

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

I agree

[File Report and close project](#) 

[Back](#)

[Cancel and return to My Projects](#)

### Reminder:

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

### Feedback:

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

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

[Return to My Projects](#)

[Save and return to My Projects](#) ▶

## Closeout Project

### #2051: New Demo Project

Req: Daniel Dery

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

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

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

I agree

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

[File Report and close project](#) ▶

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