Screen Shots of Online Forms for Data Access Request, Renewal, and Close-out

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?

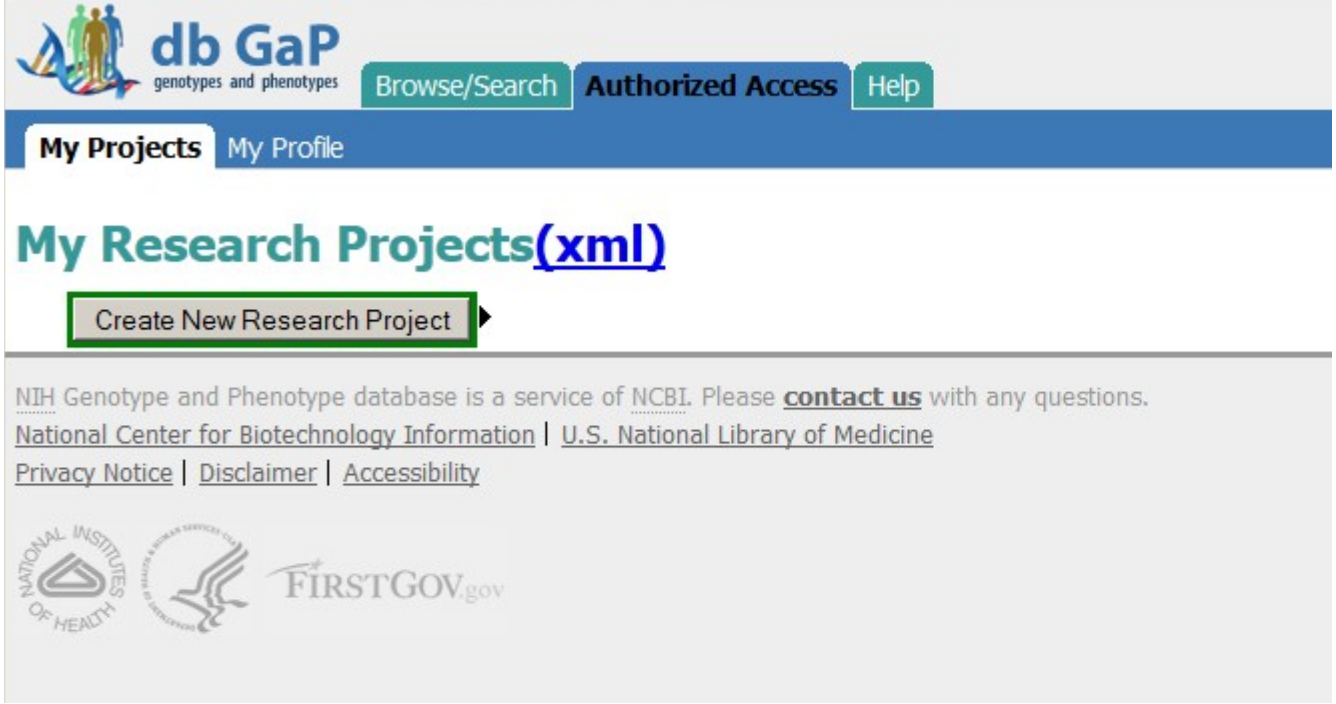
NIH is committed to respecting the privacy and intentions of research participants with regard to how data pertaining to their individual information is used. Data access is therefore intended only for scientific investigators pursuing research questions that are consistent with the informed consent 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.


db GaP
genotypes and phenotypes
Browse/Search
Authorized Access
Help
My Projects
My Profile
My Research Projects(xml)
Create New Research Project
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
NATIONAL INSTITUTES OF HEALTH
FIRSTGOV.gov

My Research Projects

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

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

My Projects | My Requests | Downloads | Downloaders | My Profile

Project Request(xml)

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.

#3194: New Project Demo

SO: Jane Doe

1. Project Details | 2. Choose Datasets | 3. Research Project | 3a. Collaborators | 3b. IT Director(s)
4a. Confirm Datasets | 4b. Review DUL | 4c. Review DUC | 5. Review Applications | 6. Data Security | 7. Feedback

Please use this form to submit a Project Request to the NIH for the first time or if you are asked to make changes to your original submission. If this is a renewal in which you are seeking an additional approval period on a previously approved project, please go to renewal form(s). If you are submitting a final report at the end of your approved access period and are not seeking renewal, please go to close out project.

Principal Investigator's (PI) Name: John Doe

Institutional Signing Official (SO): Jane Doe

Institutional Affiliation: NIH

Project ID: 3194

Project ID: 3194

Project Name: New Project Demo

Initial Request Date:

Date of Last Renewal:

Research Use Statement for *"New Project Demo"* show...

Datasets for research project *"New Project Demo"* show...

Return to My Projects | Save and Continue

Project Request(xml)

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#3194: New Project Demo

SO: Jane Doe

Please select datasets you would like to request for this project.

Consent group	Data Use Limitations	Participants	DAR Status
A Genome Wide Scan of Lung Cancer and Smoking (phs000093.v1.p1), CGEMS			
☐ Cancer and other diseases in adults only	Use of the dataset is limited to scientific genetic research related to cancer and other diseases appropriate to the age group.	1651	
☐ Research related to smoking or lung disease	Use of the dataset is limited to scientific genetic research related to the etiology, molecular basis, and outcome of lung disease and smoking.	3937	
Age-Related Eye Disease Study (AREDS) (phs000001.v1.p1), NEI			

Whole Genome Association Study of Bipolar Disorder version 3 (phs000017.v3.p1), GAIN			
☐ Bipolar disorder only (BDO)	Limited to genetic studies of bipolar disorder.	653	
☐ Bipolar and related disorders (BARD)	Limited to genetic studies of bipolar and related disorders. Related disorders include any psychiatric disorder as defined in DSM-IV or ICD-10.	841	
☐ General research use (GRU)	May be used for any genetic studies.	1767	
Whole Genome Association Study of Systemic Lupus Erythematosus (phs000122.v1.p1), JARDE ***This study contains aggregate level analysis data only!***			
☐ Systemic Lupus Erythematosus - General Research Use	Users must observe the terms of the Data Use Certification.	4651	

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

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.

Project Request(xml)

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#3194: New Project Demo

SO: Jane Doe

***Descriptive Title of Project**

Please reference the specific dataset(s) to which you are seeking access.
Please note that coordinated requests by collaborating institutions should each use the same title.

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

New Project Demo

***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 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.

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 GWAS website. Please limit your RUS to 800 words.

GWAS website. Please limit your RUS to 800 words.

***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 100 words.

*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 autority to certify your application on behalf of your institution.

- Doe, Jane (ssergey@ncbi.nlm.nih.gov)

Applicant organization

*Institution Name	Department	Division
NIH	PROJECT_Department	PROJECT_Division

*Street 1	Street 2	*City	*State	*ZIP/Postal code	*Country
PROJECT_Street 1	PROJECT_Street 2	PROJECT_City	PROJE	PROJE	PROJECT_Count

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

Project Request(xml)

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#3194: New Project Demo

SO: Jane Doe

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
	fake_fname		fake_lname	

*Position/Title	Department	*Organization name	Division
fake_title		NIH	

*Street 1	Street 2	*City	State	*ZIP/Postal code

*Street 1: fake_street | Street 2: | *City: fake_city | State: MD | *ZIP/Postal code: 20854

*Country: USA

*E-mail: fake_email@fake.fake | *Phone: 111-111-1111 | Fax:

Remove

Add another collaborator

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

Are you planning to collaborate with investigators from other institutions?

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

☐ None

External Collaborator

*First name | *Last name | *Name Institution | *Position/Title | *Role on Project

*E-mail | Comment

Remove

Add another person

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

My Projects | My Requests | Downloads | Downloaders | My Profile

Project Request(xml)

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SO: Jane Doe

1. Project Details | 2. Choose Datasets | 3. Research Project | 3a. Collaborators | 3b. IT Director(s)
4a. Confirm Datasets | 4b. Review DUL | 4c. Review DUC | 5. Review Applications | 6. Data Security | 7. 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
	fake_itd_fname		fake_itd_lname	

*Position/Title	Department	*Organization name	Division
IT Director		NIH	

*Street 1	Street 2	*City	State	*ZIP/Postal code
fake_street		fake_city	MD	20854

*Country: USA

*E-mail	*Phone	Fax
fake_email@fake.fake	111-111-1111	

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

Project Request(xml)

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#3194: New Project Demo

SO: Jane Doe

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
Age-Related Eye Disease Study (AREDS) (phs000001.v1.p1), NEI			
☐ Eye Disease Research Only	Consent given for for eye disease research purposes only	70	to review revised
☐ General Research Purposes	Consent given for general research purposes.	530	to review revised

Back | Return to My Projects | Remove Selected | Continue

Project Request(xml)

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#3194: New Project Demo

SO: Jane Doe

1. Project Details | 2. Choose Datasets | 3. Research Project | 3a. Collaborators | 3b. IT Director(s)
4a. Confirm Datasets | 4b. Review DUL | 4c. Review DUC | 5. Review Applications | 6. Data Security | 7. 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
Age-Related Eye Disease Study (AREDS) (phs000001.v1.p1), NEI			
Eye Disease Research Only	Consent given for for eye disease research purposes only ☐ I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	70	to review revised
General Research Purposes	Consent given for general research purposes. ☐ I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	530	to review revised

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

Project Request(xml)

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#3194: New Project Demo

SO: Jane Doe

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

- 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 GWAS 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.

Data use certification	Description
Age-Related Eye Disease Study (AREDS)	
NEI Data Use Certification	Age-Related Eye Disease Study (AREDS) (phs000001.v1.p1), NEI
Dataset Manifest	Data from 70 individuals in AREDS consented for eye disease research only are contained in these files (phs000001.v1p1). These individuals are either cases or controls and are not available in any other AREDS distribution set. These individuals were classified by the AREDS Data Coordinating
Dataset Manifest	Data from 530 individuals in AREDS consented for general research use are contained in these files (phs000001.v1p1). These individuals are either cases or controls and are not available in any other AREDS distribution set. These individuals were classified by the AREDS Data Coordinating Center as follows: 146 Pure Control (no evidence of disease during course of study), 26 Control Questionable (originally thought to be a pure control but later photographs provided evidence of very mild disease), 13 Large Drusen (originally thought to have advanced AMD but later photographs provided evidence to the contrary), 117 Geographic Atrophy, 180 Neovascular AMD, and 48 Both (Geographic Atrophy and Neovascular AMD). This distribution set includes genotype data from two platforms with the following sample compositions: Illumina 100K - 525 individuals/8 blind duplicates/19 CEPH controls; Affymetrix 100K - 462 individuals/5 blind duplicates/14 CEPH controls.

Back | Return to My Projects | Review Application

Project Request(xml)

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#3194: New Project Demo

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1. Project Details | 2. Choose Datasets | 3. Research Project | 3a. Collaborators | 3b. IT Director(s)
4a. Confirm Datasets | 4b. Review DUL | 4c. Review DUC | 5. Review Applications | 6. Data Security | 7. 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.

Jane Doe: "**333**"

Review Complete Application

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

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

☐ I agree

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

☐ I agree

Submit Application To Signing Official

Please **carefully review** submitted information either by clicking on "Review Complete Application" or by clicking every link in the "Application" column below.

To approve: Please **check the box** to attach your electronic signature acknowledging the accuracy of this application.

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

You need Adobe Reader installed to review PDF forms.

Project Request(xml)

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Reset Decryption Password.

A decryption password had been previously created for the project. You can reset the password and use the "Next" button to save the change.

Password:

Password confirmation:

Return to My Projects | Change Password

Project Request(xml)

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1. Project Details | **2.** Choose Datasets | **3.** Research Project | **3a.** Collaborators | **3b.** IT Director(s)
4a. Confirm Datasets | **4b.** Review DUL | **4c.** Review DUC | **5.** Review Applications | **6.** Data Security | **7.** 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

dbGaP Authorized Access

Project Renewal Web Forms

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.

#376: Project Renewal Demo

SO: Jane Doe

1. Project Details | 2. Research Project | 2a. Collaborators | 2b. IT Director(s) | 3. Research Progress | 3a. Presentations | 3b. Publications and Manuscripts | 4. Data Security | 5. Choose Datasets | 5a. Confirm Datasets | 5b. Review DUL | 5c. Review DUC | 6. Review Applications | 7. Feedback

This form is for the renewal of access to approved dataset(s) for the project listed below. You may also use this form to add new datasets to this existing project; 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 datesets 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

Institutional Affiliation: NIH

Project ID: 376

Project Name: Project Renewal Demo

Initial Request Date:

Date of Last Renewal:

Research Use Statement for *"Project Renewal Demo"* hide...

Test Statement

Datasets for research project *"Project Renewal Demo"* hide...

DAR #	Study/Dataset/Consent Group(s)	Component Status	Embargo date(s) of approved dataset(s)	See application
3322-2	The Framingham Heart Study (phs000007), NHLBI • General_research_use	to review revised		view
2306-4	A Genome Wide Scan of Lung Cancer and Smoking (phs000093), CGEMS • Cancer and other diseases in adults only	to review revised,GRANTED		view
2312-4	NIDDK IBDGC Crohn's Disease Genome-Wide Association Study (phs000130), NIDDK • General Research Use (GRU)	to review revised		view
2313-4	NIDDK IBDGC Crohn's Disease Genome-Wide Association Study (phs000130), NIDDK • Inflammatory Bowel Disease Only (IBDO)	to review revised		view
3323-2	The Cancer Genome Atlas (TCGA) (phs000178), TCGA • General Research Use	to review revised,GRANTED		view

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Project renewal(xml)

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***Descriptive Title of Project**

Please reference the specific dataset(s) to which you are seeking access.
Please note that coordinated requests by collaborating institutions should each use the same title.

Project Renewal Demo

***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 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).

111

***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.

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 GWAS website. Please limit your RUS to 800 words.

GWAS website. Please limit your RUS to 800 words.

Test 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 100 words.

Test Statement

*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 autority to certify your application on behalf of your institution.

- Doe, Jane (ssergey@ncbi.nlm.nih.gov)

Applicant organization

*Institution Name	Department	Division
NIH		

*Street 1	Street 2	*City	*State	*ZIP/Postal code	*Country
6200 Rockiville Pike		Rockville	MD	20853	USA

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Project renewal(xml)

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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 | Look up

*Position/Title | Department | *Organization name (NIH) | Division

*Street1 | Street2 | *City | State | *ZIP/Postal code

*Street1 | Street2 | *City | State | *ZIP/Postal code

*Country

*E-mail | *Phone | Fax

Remove

Add another collaborator

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

Are you planning to collaborate with investigators from other institutions?

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

☐ None

External Collaborator

*First name | *Last name | *Name Institution | *Position/Title | *Role on Project

*E-mail | Comment

Remove

Add another person

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Project renewal(xml)

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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
	tr		rt	

*Position/Title	Department	*Organization name	Division
IT Director		NIH	

*Street 1	Street 2	*City	State	*ZIP/Postal code
rt		rt		rt

*Country: rt

*E-mail	*Phone	Fax
w@ee.ee	rt	

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Project renewal(xml)

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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 800 words.

test

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

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

(•) Yes ( ) No

test

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 300 words.

test

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(xml)

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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.

test

Remove

test

Remove

Add another presentation

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Project renewal(xml)

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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

PubMed ID

21849791 Look up

Title

Including additional controls from public databases improves the power of a genome-wide associat

Date

Including ad

Bibliographic Citation

Hum Hered; 2011;72(1):21-34

Authors

Mukherjee S, Simon J, Bayuga S, Ludwig E, Yoo S, Orlow I, Viale A, Offit K, Kurtz RC, Olson SH, Klein RJ

Other

test

Remove

Add another publication

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SO: Jane Doe

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

test

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.

The list of approved users from your project is below.

Approved Users and Internal Collaborators at NIH

First name	Last name	Name Institution	Position/Title	Role on Project
John	Doe	ministry of peace;	PI_Title	Principal Investigator
tr	rt	NIH	IT Director	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

*First name	*Last name	*Name Institution	*Position/Title	*Role on Project

*E-mail	Comment

Remove

Add another person

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.*

test

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Please select any additional datasets you would like to request for this project

Consent group	Data Use Limitations	Participants	DAR Status
A Genome Wide Scan of Lung Cancer and Smoking (phs000093.v1.p1), CGEMS			
☑ Cancer and other diseases in adults only	Use of the dataset is limited to scientific genetic research related to cancer and other diseases appropriate to the age group.	1651	to review revised, GRANTED
☐ Research related to smoking	Use of the dataset is limited to scientific genetic research related to	3937	

This study contains aggregate level analysis data only!

☑ Systemic Lupus Erythematosus - General Research Use	Users must observe the terms of the Data Use Certification.	4651	

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

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.

Project renewal(xml)

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You have selected the following datasets for this request.

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

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

Consent group	Data Use Limitations	Participants	DAR Status
A Genome Wide Scan of Lung Cancer and Smoking (phs000093.v1.p1), CGEMS			
☐ Cancer and other diseases in adults only	Use of the dataset is limited to scientific genetic research related to cancer and other diseases appropriate to the age group.	1651	to review revised, GRANTED
Age-Related Eye Disease Study (AREDS) (phs000001.v1.p1), NEI			

The Cancer Genome Atlas (TCGA) (phs000178.v4.p4), TCGA			
☐ General Research Use	The Cancer Genome Atlas permits use of these data for biomedical and/or methods research by qualified investigators.	2876	to review revised, GRANTED
The Framingham Heart Study (phs000007.v2.p1), NHLBI			
☐ General Research Use	The informed consent document signed by the Framingham Heart Study Participants allows use of these data by investigators employed by non-profit and for-profit organizations. These data may be used by private companies in the development of diagnostics and therapeutics under the current consent.	6907	to review revised
Whole Genome Association Study of Systemic Lupus Erythematosus (phs000122.v1.p1), JARDE *This study contains aggregate level analysis data only!*			
☐ Systemic Lupus Erythematosus - General Research Use	Users must observe the terms of the Data Use Certification.	4651	

Back | Return to My Projects | Remove Selected | Continue

Project renewal(xml)

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#376: Project Renewal Demo

SO: Jane Doe

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

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

Consent group	Data Use Limitations	Participants	DAR Status
A Genome Wide Scan of Lung Cancer and Smoking (phs000093.v1.p1), CGEMS			
Cancer and other diseases in adults only	Use of the dataset is limited to scientific genetic research related to cancer and other diseases appropriate to the age group. ☐ I understand and agree to the terms and conditions of the	1651	to review revised, GRANTED

	I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.		
The Framingham Heart Study (phs000007.v2.p1), NHLBI			
General Research Use	The informed consent document signed by the Framingham Heart Study Participants allows use of these data by investigators employed by non-profit and for-profit organizations. These data may be used by private companies in the development of diagnostics and therapeutics under the current consent. ☐ I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	6907	to review revised
Whole Genome Association Study of Systemic Lupus Erythematosus (phs000122.v1.p1), JARDE ***This study contains aggregate level analysis data only!***			
Systemic Lupus Erythematosus - General Research Use	Users must observe the terms of the Data Use Certification. ☐ I understand and agree to the terms and conditions of the Data Use Limitations for this dataset.	4651	

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

Project renewal(xml)

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Data use certifications and consent group restrictions on use

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

- to only use data as specified in the Research Use Statement
- to keep the data confidential
- to not share the data with unapproved users or sell the data
- to follow appropriate data security protections
- to not identify or contact individual research participants
- to be publicly listed as an approved user on the dbGaP website
- to not submit findings for publication until the embargo date (as listed in dbGaP)
- to acknowledge dbGaP, the accession number of the specific datasets analyzed, the contributing investigator(s), and the

- 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 GWAS 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.

Data use certification	Description
A Genome Wide Scan of Lung Cancer and Smoking	
Data Use Certificate	A Genome Wide Scan of Lung Cancer and Smoking (phs000093.v1.p1), CGEMS
Dataset Manifest	The data of this distribution set (phs000093.v1.p1.c1) is collected from 1651 participants who gave the data access consent for Cancer and other diseases in adults only (CODAO).
Age-Related Eye Disease Study (AREDS)	
NEI Data Use Certification	Age-Related Eye Disease Study (AREDS) (phs000001.v1.p1), NEI
Dataset Manifest	Data from 70 individuals in AREDS consented for eye disease research only are contained in these files (phs000001.v1p1). These individuals are either cases or controls and are not available in any other AREDS distribution set. These individuals were classified by the AREDS Data Coordinating Center as follows: 26 Pure Control (no evidence of disease during course of study), 2 Control Questionable (originally thought to be a pure control but later photographs provided evidence of very mild disease), 1 Large Drusen (originally thought to have advanced AMD but later photographs provided evidence to the contrary), 21 Geographic Atrophy, 18 Neovascular AMD, and 2 Both (Geographic Atrophy and Neovascular AMD). This distribution set includes genotype data from two platforms with the following sample compositions: Illumina 100K - 68 individuals/3 blind duplicates; Affymetrix 100K - 62 individuals/2 blind duplicates.
CIDR: Collaborative Study on the Genetics of Alcoholism (COGA)	

genotype intensity files (Affymetrix CEL format).

This consent group requires IRB approval attachment

Whole Genome Association Study of Systemic Lupus Erythematosus	
Data Use Certificate	Whole Genome Association Study of Systemic Lupus Erythematosus (phs000122.v1.p1), JARDE *This study contains aggregate level analysis data only!*
Dataset Manifest	The data of this distribution set (phs000122.v1.p1.c1) only includes summary level analysis data

Program-specific required attachments

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

Program Study	Description
CIDR: Collaborative Study on the Genetics of Alcoholism (COGA) *	
Browse...	Upload Only PDF files (up to 10M in size) accepted.
NIDDK IBDGC Crohn's Disease Genome-Wide Association Study *	
download	Delete
The Framingham Heart Study *	
download	Delete

* One or more consent group requires IRB approval

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Project renewal(xml)

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#376: Project Renewal Demo

SO: Jane Doe

1. Project Details | 2. Research Project | 2a. Collaborators | 2b. IT Director(s) | 3. Research Progress | 3a. Presentations | 3b. Publications and Manuscripts | 4. Data Security | 5. Choose Datasets | 5a. Confirm Datasets | 5b. Review DUL | 5c. Review DUC | **6. Review Applications** | 7. Feedback

Your application is missing some required information and therefore cannot be submitted to your signing official (SO) for approval. Please review steps 1-5 of the wizard and provide missing parts such as supplemental PDF attachments or IT Director.

You need Adobe Reader installed to review PDF forms.

Get ADOBE READER

Review Application

This project currently contains **8 active requests** for data access. You can view individual applications and processing statuses in the table below.

Active (8)

#	Data/Participant sets	Status	Date	Application
	Age-Related Eye Disease Study (AREDS) (phs000001.v1.p1)	New		view

	• Eye Disease Research Only			
3322 -2	The Framingham Heart Study (phs000007.v2.p1), NHLBI • General_research_use	to review revised	2009-08-07 19:12	view
	CIDR: Collaborative Study on the Genetics of Alcoholism (COGA) (phs000125.v1.p1), JAAMH • Health Research (HR)	New		view
2306 -4	A Genome Wide Scan of Lung Cancer and Smoking (phs000093.v1.p1), CGEMS • Cancer and other diseases in adults only	to review revised,GRANTED	2009-08-18 16:42	view
2312 -4	NIDDK IBDGC Crohn's Disease Genome-Wide Association Study (phs000130.v1.p1), NIDDK • General Research Use (GRU)	to review revised	2009-07-28 15:24	view
2313 -4	NIDDK IBDGC Crohn's Disease Genome-Wide Association Study (phs000130.v1.p1), NIDDK • Inflammatory Bowel Disease Only (IBDO)	to review revised	2009-07-28 15:24	view
3323 -2	The Cancer Genome Atlas (TCGA) (phs000178.v4.p4), TCGA • General Research Use	to review revised,GRANTED	2009-08-07 19:19	view
	Whole Genome Association Study of Systemic Lupus Erythematosus (phs000122.v1.p1), JARDE *This study contains aggregate level analysis data only!* • Systemic Lupus Erythematosus - General Research Use	New		view

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Project renewal(xml)

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#376: Project Renewal Demo

SO: Jane Doe

1. Project Details | 2. Research Project | 2a. Collaborators | 2b. IT Director(s) | 3. Research Progress | 3a. Presentations | 3b. Publications and Manuscripts | 4. Data Security | 5. Choose Datasets | 5a. Confirm Datasets | 5b. Review DUL | 5c. Review DUC | 6. Review Applications | **7. 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

dbGaP Authorized Access

Project Closeout Web Forms

Logged in as **John Doe** | Log out

Browse/Search | **Authorized Access** | Help

My Projects | My Requests | Downloads | Downloaders | My Profile

Closeout Project(xml)

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#378(closed): Project Closeout Demo

SO: Jane Doe

1. Project Details | **2.** Research Progress | **2a.** Presentations | **2b.** Publications and Manuscripts | **3.** Data Security | **4.** Reasons for Project Closeout | **5.** Review Closeout Application | **6.** Feedback

This form is for closing out a project. Complete and submit this form when you no longer need any of the data for the project listed below. **Please note that information in this form applies to all datasets you requested under this project (also listed below).**
Please follow this link for important instructions on data destruction at the competition of your project Best Practices.

Principal Investigator's (PI) Name: John Doe

Institutional Signing Official (SO): Jane Doe

Institutional Signing Official (SO): Jane Doe

Institutional Affiliation: NIH

Project ID: 378

Project Name: Project Closeout Demo

Initial Request Date:

Date of Last Renewal:

Research Use Statement for *"Project Closeout Demo"* hide...

project to ftyyttyind and document changes to DAR system

Datasets for research project *"Project Closeout Demo"* hide...

DAR #	Study/Dataset/Consent Group(s)	Component Status	Embargo date(s) of approved dataset(s)	See application
851-1	International Multi-Center ADHD Genetics Project (phs000016), GAIN • ADHD_Only	DAC review revised	2009-02-04	view
852-1	Major Depression: Stage 1 Genomewide Association in Population-Based Samples (phs000020), GAIN • Psychiatric and related somatic conditions (PRSC)	DAC review revised	2009-02-04	view
853-1	Search for Susceptibility Genes for Diabetic Nephropathy in Type	DAC review	2009-02-04	view

	first stage analysis (phs000101), NINDS • General Research Use	revised		
867-1	Ischemic Stroke Genetics Study (ISGS) (phs000102), NINDS • General Research Use	DAC review revised	2009-02-04	view
868-1	Ischemic Stroke Genetics Study (ISGS) (phs000102), NINDS • Stroke and Related Disorders	DAC review revised	2009-02-04	view
869-1	Study of Irish Amyotrophic Lateral Sclerosis (SIALS) (phs000127), NINDS • Non-profit use(NPU)	DAC review revised	2009-02-04	view
870-1	A Genome Wide Scan of Lung Cancer and Smoking (phs000093), CGEMS • Cancer and other diseases in adults only	DAC review revised	2009-02-04	view
871-1	A Genome Wide Scan of Lung Cancer and Smoking (phs000093), CGEMS • Research related to smoking or lung disease	DAC review revised	2009-02-04	view

Return to My Projects | Begin close out process

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Closeout Project(xml)

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#378(closed): Project Closeout Demo

SO: Jane Doe

1. Project Details | **2.** Research Progress | **2a.** Presentations | **2b.** Publications and Manuscripts | **3.** Data Security | **4.** Reasons for Project Closeout | **5.** Review Closeout Application | **6.** 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 800 words.

test

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

Closeout Project(xml)

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#378(closed): Project Closeout Demo

SO: Jane Doe

1. Project Details | 2. Research Progress | **2a.** Presentations | 2b. Publications and Manuscripts | 3. Data Security | 4. Reasons for Project Closeout | 5. Review Closeout Application | 6. 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

Remove

Add another presentation

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

Closeout Project(xml)

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#378(closed): Project Closeout Demo

SO: Jane Doe

1. Project Details | 2. Research Progress | 2a. Presentations | **2b. Publications and Manuscripts** | 3. Data Security | 4. Reasons for Project Closeout | 5. Review Closeout Application | 6. 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

PubMed ID

44 Look up

Title

The origin of the alkaline inactivation of pepsinogen.

Date

The origin of

Bibliographic Citation

Biochemistry; 1975 Dec 2;14(24):5253-6

Authors

McPhie P

Other

Remove

Add another publication

Back Cancel and return to My Projects Save and Continue

Closeout Project(xml)

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1. Project Details | 2. Research Progress | 2a. Presentations | 2b. Publications and Manuscripts | 3. Data Security | 4. Reasons for Project Closeout | 5. Review Closeout Application | 6. Feedback

Data Security:

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

- ○ Yes
- ◉ No

The list of approved users from your project is below.

Approved Users and Internal Collaborators at NIH

Approved Users and Internal Collaborators at NIH

First name	Last name	Name Institution	Position/Title	Role on Project
John	Doe	ministry of peace:	PI_Title	Principal Investigator
4	4	NIH	34	Approved User
34	43	NIH	34	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

*First name	*Last name	*Name Institution	*Position/Title	*Role on Project
1	2	3	4	5

*E-mail	Comment
test@mail.org	

Remove

Add another person

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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Closeout Project(xml)

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#378(closed): Project Closeout Demo

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1. Project Details | 2. Research Progress | 2a. Presentations | 2b. Publications and Manuscripts | 3. Data Security | 4. Reasons for Project Closeout | 5. Review Closeout Application | 6. Feedback

Reasons for project closeout:

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

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#378(closed): Project Closeout Demo

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1. Project Details | 2. Research Progress | 2a. Presentations | 2b. Publications and Manuscripts | 3. Data Security | 4. Reasons for Project Closeout | **5. Review Closeout Application** | 6. Feedback

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

Back | Cancel and return to My Projects | File Report and close project

Closeout Project(xml)

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