



This handout is for extramural and NIH intramural investigators with eRA Commons-based dbGaP accounts. NIH intramural investigators, particularly those with CIT-based accounts, need to follow a specific set of steps outlined in this document <https://go.usa.gov/xVmNb>

### Authorized Access of Data from dbGaP

Genome Wide Association Studies (GWAS) are registered in the NCBI's dbGaP database. While information about the studies and some summary statistics are publicly available, access to participant-level data by investigators interested in performing secondary analysis requires an application process to protect the privacy of study participants.

In order to apply for access to dbGaP data, you must be a principal investigator (PI) employed by an eRA Commons-registered institution or entity, have an active eRA Commons account and be classified as a PI in that system. Please note that the PI-affiliated institute is legally liable for the downloaded data, even though the downloading privilege is granted to the requesting PI.

An overview of the application process:

- Identify a study, or studies, of interest that has been released to the public
- Login to dbGaP with your eRA Commons credentials at <https://go.usa.gov/xVVrS>
- Make sure your profile is up to date, and do so by using the "My profile" tab
- Create a new project using the "My projects" tab
- Fill in the multi-tabbed form, including selection of your datasets of interest using study accession as filter in the "Choose Datasets" tab
- Complete all tabs, upload IRB letter if required, then submit to your Signing Official (SO) for local approval
- SO approval moves the application to Data Access Committee (DAC) review
- After DAC approval, login to dbGaP and create a KART file for download by clicking on "My requests" >> "Approved" >> "Request files"
- Download the NCBI SRAtoolkit and use the kart file to download the data <https://go.usa.gov/xpt8a>

### Renewal or Closeout of a Approved Project

The approval for the authorized access to data for a dbGaP project is limited to an one-year term. On the anniversary date, you needs to submit an Annual Renewal Application if you are still interested in maintain your access to the datasets for continued research need.

Here are the steps for doing the annual renewal:

- On the anniversary date, click the "Renew Project" link
- Fill out all tabs in the renewal form
- Provide a summary of your research progress made in the past year in the "Research Progress" tab
- Submit the completed renewal form to your SO for certification
- Your SO's approval, it will be moved to final review and approval by DAC

**Note:** *Data access will be interrupted until DAC approval is granted.*

When a project is completed, or you are no longer interested in carry it forward, you need to close it out:

- Securely delete all datasets downloaded from dbGaP. Derivative data from your analyses without personal identifiable information can be retained
- Click the "Close Out Project" link to complete the closeout form
- Submit the form for your SO to certify
- SO signature marks the official closeout of the project

### Relevant Acronyms Used in dbGaP System

- **eRA:** electronic Research Administration, an electronic platform for grant management provided by NIH Office of Extramural Research.
- **AA:** Authorized access to dataset(s) from dbGaP studies.
- **PI:** Principal Investigator, who is eligible to initiate new dbGaP project and requesting dataset from dbGaP.
- **SO:** Signing Official, an official representing the PI's affiliated institution in the dbGaP project application or its closeout process.
- **DAR:** Data Access Request, a request for specific dataset. A given dbGaP project contains one or more of DAR.
- **DAC:** Data Access Committee, an entity set up by the NIH institute, given the custodial responsibility GWAS studies sponsored by that institute. Its key task is to

review submitted projects and data requests, and grant approval based on their merit and other considerations.

- **DUC:** Data Use Certification agreement, which governs how data from specific study and consent group should be used in a dbGaP project.
- **IRB:** local Institutional Review Board. IRB approval may be required for the proposed research and data requests included in a dbGaP project.
- **OSP:** NIH Office of Science Policy, which sets the dbGaP data access policy. See <https://osp.od.nih.gov/>
- **GPA:** Genomic project administrator, a staff member from an NIH institute who coordinates the registration of dbGaP Studies funded or sponsored by that institute. A list of GPA is at: <https://go.usa.gov/xVVfz>

### Frequently Asked Questions

**Q: I cannot log into my dbGaP account, what can I do?**

When facing login issues, you may need to reset your eRA Commons password at: <https://go.usa.gov/xVVfR>

Wait for 48 hours before using the new password to login to the dbGaP site: <https://go.usa.gov/xpt8h>

**Q: My dbGaP project was rejected. What should I do and how can I resubmit my project for reconsideration?**

A submitted project may have one or more Data Access Requests (DARs). A rejection by the DAC is prompted by decisions at the level of individual DARs, thus a project may be rejected in full or only partially.

For reconsideration, you should first understand the reason for rejection which is detailed in the decision email sent by the DAC through the dbGaP AA system. Contact your SO to discuss any issues of qualification, who can directly address this with the DAC or DACs. Once you and your SO have addressed all issues, you will need to use the "Revise project" link to resubmit the project along with necessary modifications, first to your SO for local approval, then onward for reconsideration by the DAC.

For other project-specific issues, you can contact DAC to clarify their concerns and reasons for rejection, then use the "Revise project" link to provide edits to address the

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DAC's concern, submit it for you SO approval, and then to DAC for their reconsideration.

### Q: My account was suspended, what should I do?

The dbGaP AA system may suspend an account if certain conditions are violated, such as data usage violation, or not renewing or closing out inactive project.

If your account is suspended, a highlighted message will appear at the top of the login page identifying the issue and providing guidance on any needed action.

If you are interested in continuing your project beyond the initial timeframe, you will need to use the [“Renew project”](#) link to initiate and submit the renewal to your SO. The dbGaP system will lift the suspension once your SO signs and approves the renewal.

If you are no longer interested in continuing the project, you need to perform a closeout using the [“Close out project”](#) link, then complete the form and submit it to your SO for certification. The dbGaP system will lift the suspension once your SO certifies the closeout. NOTE that the closeout requires that you securely delete all data downloaded from dbGaP. You may keep any derivative data from your own analyses if they do not include PII.

For suspension reasons other than renewal or closeout, please contact NIH OSP at: [GDS@mail.nih.gov](mailto:GDS@mail.nih.gov)

### Q: I am moving to a different institute, can I transfer my existing dbGaP project over to that institute?

Unfortunately, there is no mechanism to do this since the legal liability for your current project is assumed by the institute or organization on your original application. This cannot be transferred. The steps to address this are:

- Destroy the data you downloaded from dbGaP. You may keep the derivative data produced by your own analyses as long as they do not include PII.
- Close out your current project(s) and have the SO certify the closeout.
- Update the affiliation listed on your eRA Commons account.
- Update your dbGaP account profile (under the [“My Profile”](#) tab)
- Initiate a new project from the updated account.

### Q: I am a laboratory staff member (or an internal collaborator) working with a PI on an approved dbGaP project. How can I get access to the approved dataset?

As a laboratory staff member (or an internal collaborator) with the same affiliation as that of the PI, you can ask your PI to add you as a designated downloader (using the **Downloaders** tab) to that approved project. This requires that you have an eRA Commons account and use the credentials for login to dbGaP AA before.

If you do not have an eRA Commons account, register for one at: <https://go.usa.gov/xV9ng>

You need to wait for 48 hours before using the credentials to log into dbGaP to do the above.

### Q: Do I need to get local IRB approval for my dbGaP project?

You can examine the [“Authorized Access”](#) section of a dbGaP study record to find out if a local IRB approval letter is required for your proposed use of that dataset.

If this is the case, you need to obtain a copy of this letter before you submit your project or a renewal for approval. The approval needs to be valid for **6 months** or longer at the time of application or renewal.

Your dbGaP project's [“DUC”](#) tab will have a file upload button for you to include a PDF copy of your IRB approval letter. When requesting datasets from multiple studies with local IRB requirement, make sure to get approval for each and combine the letters in a single letter, or you can combine multiple letters into a single PDF file for upload.

### Q: What common issues should I pay attention to so I can avoid delay in the DAC approval of my dbGaP project application or its subsequent renewal?

Pay attention to the following details to avoid delays:

- Include your official job title in the [“My profile”](#) tab
- Use work email address (update should be done at eRA side)
- Provide the official job title in the IT Director tab
- Ensure that IRB document is valid for 6 months or longer

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- Provide updated content in the [“Research Progress”](#) tab for any renewal submitted
- Have your SO process the application in a timely manner through communication outside of dbGaP system
- Limit the scope of DARs
- Coordinate with external collaborators if your project involves such collaboration

### Q: As a submitter with a study in dbGaP, how can I get access to my study's data?

You can use the streamlined access mechanism that allows submitters access to their own submitted datasets. If you are not the PI, work with him or her and communicate with the GPA of your registered study, so that you can be added to the streamlined access list. Then, your dbGaP study will appear in your account as a project with no expiration date (annual renewal will not be necessary).

### Additional Information

The NIH's Office of Science Policy is in charge of the Genome Data Sharing Policy. You can refer to their web site for more details: <https://go.usa.gov/xVVfs>

For any questions, issues or concerns, contact them at: [GDS@mail.nih.gov](mailto:GDS@mail.nih.gov)

NCBI dbGaP provides a comprehensive set of FAQs at <https://www.ncbi.nlm.nih.gov/books/NBK5295/>

The next-gen sequencing reads for dbGaP studies are brokered by the SRA database. Increasing number of dbGaP studies now have their reads stored in the cloud. To access dbGaP study data in the cloud, see: <https://go.usa.gov/xVVf6>

You can write to [dbgap-help](mailto:dbgap-help@ncbi.nlm.nih.gov) directly. Please include as much details as possible, so we can provide the most helpful response: [dbgap-help@ncbi.nlm.nih.gov](mailto:dbgap-help@ncbi.nlm.nih.gov)

If you are Interested in submitting your GWAS data to dbGaP, see the workflow here: <https://go.usa.gov/xVVGd>

For non-NIH funded studies, you need select a sponsoring institute and contact the GPA for registration: <https://go.usa.gov/xVVfz>