Icahn School of Medicine at Mount Sinai

Grants and Contracts Office
One Gustave L. Levy Place Box 1075
New York, NY 10029-6574
Phone: 212.824-8300
Facsimile: 212.241-3294
Email: grants@mssm.edu

GCO Requirements for Restricted Access to Incoming Data from a Federal Genomic Data Repository or a Data Repository Subject to NIST SP 800-171

For investigators requesting access to genomic data from a federal data repository or other data from a data repository that requires NIST SP 800-171 cybersecurity controls, your designated ISMMS Authorized Organizational Representative (AOR) approves these requests by signing an agreement for data access from a data repository portal, including Data Use Certifications (DUCs), Data Use Agreements (DUAs), Data Transfer Use Agreements (DTUAs), and/or Data Provision Agreements (DPAs), referred to in this guidance document as the "Agreement."

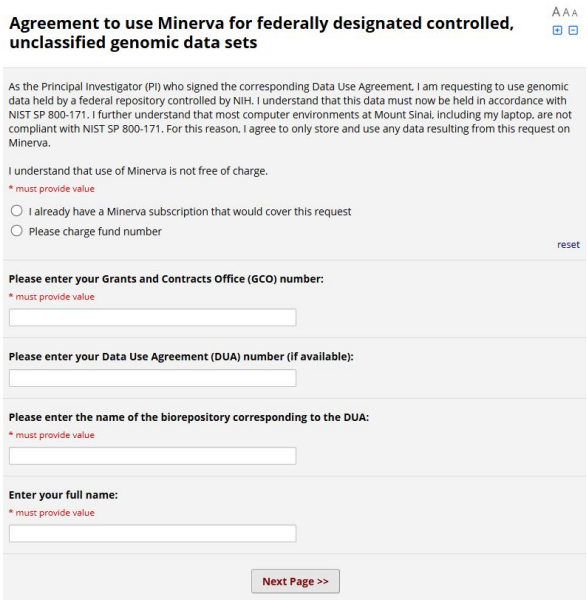
This process is in alignment with NIH Notice NOT-OD-24-157 *Implementation Update for Data Management and Access Practices Under the Genomic Data Sharing Policy*, which mandates that all data accessed from NIH-controlled data repositories, including dbGaP, must be supported within a NIST SP 800-171 compliant environment. At ISMMS, the designated NIST SP 800-171 environment is Minerva.

This guidance document outlines the steps needed for institutional approval of the Agreements and provides additional information on key areas of compliance. The document is organized in the following sections:

I. REDCap Form Instructions

Please complete prior to or at the same time as submitting/routing the Agreement to ensure the fastest processing. Any locally downloaded data must be stored, processed and analyzed only using the Minerva environment. Users must either have a Minerva account or obtain one. The process is as follows:

- Complete and sign an attestation form in REDCap, using the REDCap survey link. Below is partial snapshot of the form:



Agreement to use Minerva for federally designated controlled, unclassified genomic data sets

As the Principal Investigator (PI) who signed the corresponding Data Use Agreement, I am requesting to use genomic data held by a federal repository controlled by NIH. I understand that this data must now be held in accordance with NIST SP 800-171. I further understand that most computer environments at Mount Sinai, including my laptop, are not compliant with NIST SP 800-171. For this reason, I agree to only store and use any data resulting from this request on Minerva.

I understand that use of Minerva is not free of charge.

* must provide value

- I already have a Minerva subscription that would cover this request
- Please charge fund number

reset

Please enter your Grants and Contracts Office (GCO) number:

* must provide value

Please enter your Data Use Agreement (DUA) number (if available):

Please enter the name of the biorepository corresponding to the DUA:

* must provide value

Enter your full name:

* must provide value

Next Page >>

- Scientific Computing electronically cosigns the form.
- Your designated AOR access the approved form.

II. Updating the eDMS Conflict of Interest (COI) Triggering Event (TE) for New Individuals Meeting the COI Regulatory Definition of Investigator

If there are ISMMS colleagues on the data access request who meet the definition of an Investigator for Conflict of Interest purposes and they are not already on the eDMS Triggering Event (TE), please add them and request that they answer the TE questions. Click here for information from the Faculty Handbook on covered persons for conflict of interest purposes.

III. InfoEd Submission if the Data Sharing Is Not In Support of An Already Existing Project Submitted to the GCO

If the data sharing is not in support of an already existing project submitted to the GCO, you will need to submit an InfoEd application for this research. If this is an "ISMMS" supported project, click here for application submission instructions.

IV. Information Required by Your Designated Authorized Organization Representative (AOR) Prior to Signing/Certifying the Agreement

Please email your designated AOR the following information:

- Confirmation that you have completed the REDcap form requesting storage access in Minerva.
- Include a GCO # for the project that will utilize the data.
- Confirmation that all individuals for which you are requesting data access request are ISMMS employees.
- List any individuals for whom you are requesting data access and are not on the eDMS Triggering Event (TE). Confirm that these individuals are not responsible for the design, conduct or reporting of the research.
- In the Agreement, if there is required language for the plan on how you will destroy the data, please include that language in the e-mail. If this statement is missing from the Agreement, it will be returned to you.

V. Unauthorized Sharing of and Access to Data

Unless explicitly stated otherwise, data providers and repositories restrict data access to the individuals listed in the Agreement. Your access to data does not automatically grant permission to share it with others in your lab.

It is a serious violation with potential financial and legal consequences if you share data with unauthorized individuals. Likewise, do not transfer, store or otherwise access data using a personal email account or computing device that is not managed by Mount Sinai.

VI. Adding Individuals to an Agreement

To add ISMMS individuals, follow the steps in accordance with the requirements of the data repository and the terms of your Agreement.

The PI is responsible for ensuring that all individuals with access to the data are aware of the Agreement terms, especially any restrictions on further data access and sharing.

VII. External Collaborators and Investigators with Multiple Research Appointments

External collaborators need to request access to the data repository through their own institution. The external collaborator within their institution needs to establish the Agreement.

If you have a multiple research appointment, the data access is for you at ISMMS only.

VIII. Data Storage and End of Usage Data Destruction or Return Terms

If required by the repository as part of the Data Access Request (DAR), the Data Use Statement should:

- Included a sentence that says if the data will or will not be downloaded and stored locally.
- If data will be stored locally, indicate where. (Minerva, since that is the only compliant environment at Mount Sinai at this time)

- If data will be stored locally, include a statement about how and when the data will be destroyed.

  Sample Data Use and Destruction Statement:

  The data will be accessed by downloading from [depository name] to the Minerva supercomputing cluster at Mount Sinai (https://labs.icahn.mssm.edu/minervalab/scientific-computing-and-data/).

  The recipient agrees that data that has been downloaded from the [depository name] will be permanently deleted from the Minerva cluster when research is completed or this [Agreement (e.g., (DUC)] is expired, whichever comes first.

It is a serious violation if you do not follow and document compliance with the end of usage data destruction or return policy, which may result in loss of future data access and other legal or financial consequences.

IX. Procedure to Access Genomic Data from Federal Data Repositories

Below is the typical process for an investigator to access genomic data from a federal data repository, and includes information about the procedural differences across select NIH data repositories.

1. **Identify the Repository and Data Collections**
   - Determine which repository hosts the data you need.
   - Review the repository's data dictionary (i.e., variable catalog) and access policies.

2. **Create an Account**
   - Register for an account on the repository's portal.
   - Provide institutional affiliation and contact details.
   - For the NIMH Data repository, go to the NDA portal at nda.nih.gov and register for an account. You'll need to provide your name, email, institutional affiliation, and other details.

3. **Submit a Data Access Request (DAR)**
   - Complete the repository-specific DAR form.
   - Specify:
     - Data collections or datasets you need
     - Research purpose and project description
     - Individuals at ISMMS who will access the data (as required by the repository)

4. **Complete and Sign the Agreement**
   - Most repositories require an institutional signature on the Agreement. The Agreement will outline the terms and conditions for responsible use of human subjects data.
   - It must be signed by:
     - You (the investigator)
     - Your institution's authorized official (AOR)
   - All team members who will access the data generally must also be listed as "Recipients" and agree to the Agreement terms. It is the PI's responsibility to ensure all collaborators and

Recipients who will use the data have been made aware of the Agreement terms and conditions.

5. **Institutional Review Board (IRB) Compliance**
   - Upload proof of IRB approval, if required by the repository.

6. **Review and Approval**
   - Repository staff review your data access request and Agreement documents, as applicable.
   - Approval timelines vary by repository (often 1 - 3 weeks)
   - Once approved, you'll receive access to the requested data collections.
   - If denied, you will need to revise the request to address the denial reason and resubmit.

7. **Accessing Data**
   - You can download data packages or use in-platform tools.
   - Some repositories offer APIs or cloud-based workspaces for analysis.

8. **Maintain Compliance**
   - Follow all confidentiality and security requirements.
   - Renew access annually or as required. You must renew before expiration if you need continued access.

Key Procedural Differences Across Select NIH Repositories:

- dbGaP (Database of Genotypes and Phenotypes): Requires eRA Commons credentials and PI status.
- NIMH Data Archive (NDA) : Uses a DUC and lists all recipients.
- NICHD DASH (Data and Specimen Hub): Requires a Data Use Agreement
- NHLBI BioData Catalyst: Often integrates with cloud workspaces and requires DUAs.

Important Notes:

- Only Principal Investigators (PIs) or equivalent can submit the DAR; students and postdocs must work with their faculty mentor/PI.
- Even when data are de-identified they are still considered sensitive; confidentiality rules apply.

X. Resources

Please refer to these resources for additional information and guidance.

ISMMS

- Minerva Account Request
- Minerva Environment
- REDCap Survey Form
- Faculty Handbook: Definition of Investigator for Conflict of Interest Purposes

- GCO Submission Steps for an ISMMS Sponsored Project
- InfoEd Login
- eDMS Login

Federal

- NIST SP 800-171 r3 (May 2024) Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations
- NOT-OD-24-157 Implementation Update for Data Management and Access Practices Under the Genomic Data Sharing Policy
- NIH Scientific Data Sharing: Policies and Access to Data
- NIMH Data Archive: Accessing Shared Data Tutorial
- NIMH Data Archive Data Use Certification

NIH Genomic Data Repositories

Visit these websites below to find information on NIH genomic data repositories.

- NIH Controlled-Access Data Repositories (CADR)
  NIH has established detailed security and operational standards for NIH Controlled-Access Data Repositories (NIH CADRs). These standards harmonize submission and access processes, standardize user terms of access, establish specific security requirements, ensure transparency, and align with national security directives.

- Trans-NIH Genomic Data Repositories
  NCBI hosts repositories that contain genomic data from humans as well as many other organisms. The table below lists several frequently used repositories along with the type of data hosted at the repository, how the repository manages access, and a link to the repository's access portal.

- NIH Institute and Center Supported Repositories
  Some individual NIH Institutes and Centers (ICs) support repositories that contain human genomic as well as other types of data that are relevant to their specific area of interest.