

NIH Genomic Data Sharing Policy

NIH Genomic Data Sharing (GDS) Policy and NIH Applications

The NIH Genomic Data Sharing Policy ensures the broad and responsible sharing of genomic research data and applies to all NIH-funded research that generates or uses large-scale human or non-human genomic data as well as these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data.

Resources:

- NIH Website: Genomic Data Sharing Policy, Supplemental Information
- UCSF IRB Website: NIH Genomic Data Sharing (GDS Policy and the Genome- Wide Association Studies (GWAS))

PI Responsibilities:

- **Inform your RSC that you intent to submit a proposal that falls under the NIH Genomic Data Sharing Policy**
- **Follow the guidance in the NIH Notice (NOT-OD-15-083 NIH Grant Applications and the NIH Genomic Data Sharing Policy):**

Applicants preparing applications that involve the generation or use of large-scale genomic data should:

1. State in the application cover letter that the studies proposed will generate large-scale human and/or non-human genomic data.
2. Include in a genomic data sharing plan in the application.
3. If sharing of human data is not possible, provide an explanation why and an alternate data sharing plan.

Applicants that plan to use controlled-access human genomic data from NIH-designated data repositories (e.g. dbGaP) as a secondary user should:

1. Briefly address plans for requesting access to the data.
2. State their intent to abide by the NIH Genomic Data User Code of Conduct in the Research Plan.

NOTE: Instructions in individual Funding Opportunity Announcements (FOA) supersede this guidance.

- **If the FOA specifies that the Institutional Certification letter is required prior to submission of the application the PI must inform his/her RSC as soon as possible.**

- The RSC will request a waiver of the Institutional Certification letter at the application stage from the Genomic Program Administrator (GPA).
- If the GPA does require the **Institutional Certification** letter:
 - The RSC will forward the **Institutional Certification letter** to be completed and signed.
 - Work with the UCSF IRB to obtain the GDS Data Submission Certification (this is an internal letter signed by the IRB director that verifies the proposed consent form)
 - Submit the completed, signed **Institutional Certification letter and GDS Data Submission Certification** to your RSC no later than 10 business days prior to the internal application review due date.

At the JIT stage: The Grants Management Specialist will require the Institutional Certification letter regardless of whether the GPA issued a waiver at the time of application submission

- ○ Submit your IRB application
- Work with UCSF IRB to obtain the GDS Data Submission Certification (this is an internal letter signed by the IRB director that verifies the proposed consent form)
- Your RSC will forward NIH Institutional Certification; complete and sign the letter
- Provide your RSC with:
 - The GDS Data Submission Certification signed by the IRB director
 - The NIH Institutional Certification signed by the PI
 - Copy of the IRB approval letter

- **When Submitting Data to dbGaP:** The dbGaP Submission Process guides the PI to discuss the project, data sharing plans, and the Institutional Certification letter with their IRB prior to registration of their study in dbGaP. They are then instructed to provide the Institutional Certification letter to the funding NIH Institute. This letter should be submitted to the funding NIH IC through the Office of Sponsored Research (OSR) and is required prior to submitting all large-scale human data to the NIH Database of Genotypes and Phenotypes (dbGaP).
 - If the consent form has not changed since the JIT stage:
 - Submit current IRB approval and Institutional Certification (from the JIT stage) to RSC.
 - If the consent form has changed since the JIT stage:
 - Work with UCSF IRB to obtain the GDS Data Submission Certification (this is an internal letter signed by the IRB director that verifies the proposed consent form)
 - Your RSC will forward NIH Institutional Certification; complete and sign the letter
 - Provide your RSC with:
 - The GDS Data Submission Certification signed by the IRB director
 - The NIH Institutional Certification signed by the PI
 - Copy of the IRB approval letter

RSC Responsibilities:

- **Instruct the PI to follow the guidance in the NIH Notice (NOT-OD-15-083 NIH Grant Applications and the NIH Genomic Data Sharing Policy):**
- If the FOA specifies that the Institutional Certification letter is required prior to submission of the application, contact the Genomic Program Administrator (GPA) for the NIH IC administering the program:
 - Get clarification of the required documentation ? the Institutional Certification letter on the NIH GDS website is intended for use at Just-In-Time.
 - Normally, the consent form is not available until JIT. The process to verify this letter may take several days and may hinder the application process. Request a waiver of this requirement at the application stage.
 - Maintain documentation of the clarification/waiver as an addendum to the FOA.
 - Follow GPAs direction.
- If the GPA does require the Institutional Certification letter prior to submission of the application, direct the PI to work with the UCSF IRB, to obtain the GDS Data Submission Certification (see above under the PI Responsibilities section)
- Generate the Institutional Certification letter Fill-in sponsor and institution information, project title, salutation and signature blocks and forward to the PI for completion and signature.
- Have the PI return the completed, signed **Institutional Certification** letter with the GDS Data Submission Certification signed by the IRB Director.
- Upon receipt execute the **Institutional Certification** letter and include in the application as specified in the FOA.

- **At JIT Stage:** The Grants Management Specialist will require the Institutional Certification letter regardless of whether the GPA issued a waiver at the time of application submission.
 - Direct your PI to submit their IRB application.
 - Have your PI work with the UCSF IRB, to obtain the GDS Data Submission Certification letter (internal IRB approval that verifies the consent form meets GDS policy criteria.
 - Generate the Institutional Certification letter from the NIH GDS website by clicking on the link That Have Consent and complete the following:
 - ■ Fill-in sponsor and institution contact information, project title, salutation and signature blocks
 - Forward the letter to the PI for completion and PI's signature.
 - Have the PI return the completed and signed letter with a copy of the IRB approval letter for the human subject protocol and the internal GDS Data Submission Certification letter signed by the IRB Director.
 - Both documents are needed before the Institutional Certification letter can be signed by an Institutional Officer (OSR Officer). Only this letter should be sent to NIH with the JIT package.
 - Complete JIT procedures.

- **When Submitting Data to dbGaP:**
 - Confirm with the PI or their delegate if there have been changes to the consent form since the JIT Stage

- If there are no changes to the consent form:
 - Maintain the confirmation as back-up for the submission
 - Use the Institutional Certification Letter submitted at JIT
 - If there have been changes to the consent form:
 - Have the PI work with IRB to obtain the GDS Data Submission Certification Letter
 - Download the download the Institutional Certification letter
 - Fill-in sponsor and institution contact information, project title, salutation and signature blocks.
 - Have the PI for complete, sign and return the letter.
 - A Certified Officer can then forward the Institutional Certification letter to Grants Management Specialist of the funding NIH Institute with the PI's request to submit large-scale human data to dbGaP.
 - Copy the PI, their delegate (if appropriate), the NIH IC Program Official.
 - Complete a CACTAS Correspondence record

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