NIH Genomic Data Sharing (GDS) Policy and the Genome-Wide Association Studies (GWAS)

Overview

This guidance applies to the Genomic Data Sharing (GDS) Policy. Additional information can be found at the NIH Genomic Data Sharing (GDS) website [1].

NIH has strict standards for IRB review and informed consent for the data they will accept for inclusion in GDS data repositories.

The IRB is now required to review investigators' requests to submit data to the NIH data repositories and must also certify that the informed consent that was obtained from subjects was consistent with NIH requirements for sharing genomic data. In addition, virtually all NEW

grant applications that request NIH funding for genomic research must incorporate, as part of the NIH application, a genomic data sharing plan that is consistent with GDS policy. Because of the additional time required for IRB review, as well as the need to incorporate specific sharing language in their consent forms, contact the IRB [2] as early as possible.

When does the GDS Policy apply?

Effective 1/25/15, the GDS Policy applies to the following:

- NIH-funded research that generates human or non-human genomic data (e.g. SNP arrays, genome sequencing, RNA sequencing, transcriptomic, metagenomics, epigenomic and gene expression data, GWAS studies) from more than 100 individuals.
- Studies that are not NIH-supported but plan to submit genotype/phenotype data to one of the following NIH Supported repositories:
    - Database of Genotypes and Phenotypes (dbGaP)
    - Gene Expression Omnibus (GEO)
    - Sequence Read Archive (SRA)
    - Cancer Genomics Hub (CaHUB)

When does the GDS Policy not apply?

- When the genomic data is generated without NIH funds (unless the researcher voluntarily requests submission to one of NIH-supported repositories)
- When NIH-funded projects involve instrument calibration exercises, statistical or technical methods development, or the use of genomic data for control purposes, such as for assay development
- When the following funding is requested: Institutional Training Grants (T32s, T34s, T35s, and TL2s), Career Development Awards (Ks), Individual Fellowships (Fs), Resource Grants and Contracts (Ss), linked awards derived from previously reviewed applications, or facilities or coordinating centers funded through related initiatives to provide genotyping, sequencing, or other core services in support of GDS.

Submitting an NIH Proposal and Just-In-Time (JIT) Materials

1. Work with your Research Service Coordinator if the Funding Opportunity Announcement requires IRB review and approval of the consent form content prior to application submission. Work with your study coordinator to provide a basic plan for following the GDS policy, located in the Resource Sharing Plan section of funding applications.

- Genomic Data Sharing Plans Guidance [3] (also see the Genomic Data Sharing FAQs [4])
- Genome-Wide Association Studies Data-Sharing Guidance [5]
- Genome-Wide Association Studies Data-Sharing Example [6]
- If broad sharing of genomic data is not possible, include an explanation

2. Work with your Research Service Coordinator to complete documentation in response to a Just-In-Time request from NIH:

- An IRB approval letter for your human subjects protocol

- An Institutional GDS Data Submission Certification letter signed by the HRPP Director, which verifies that the consent form meets the GDS criteria

Submit these documents to your RMS Research Services Coordinator, who will generate the Institutional Certification[7]. Include the signed Institutional Certification with your JIT submission.

IRB Application Requirements

Include the following information in these sections of the IRB Application (either as part of a new study or to modify an approved study to GDS):

"Scientific Considerations" section, specific aims question

- State explicitly that data will be sent to NIH for GDS, and describe the genotype and phenotype data to be sent
- Indicate whether data will be collected PROSPECTIVELY or, if the PI is submitting a modification to an ongoing study, whether the investigator wishes to submit data that has ALREADY been collected. NIH expects that ALL data collected after 1/25/15 was consented according to the GDS-required criteria (see consent form template)
- Specify if data shared with the NIH for GDS Policy will be for broad use or limited to specific diseases or conditions

"Procedures" section

Studies that plan to contribute to NIH GDS repositories should have IRB approval for **specimen collection for future research and/or specimen repository/bank administration.** In the "Procedures" section, check "Yes" when asked if the study involves these activities and fill out the applicable section(s) regarding specimen collection and banking that follow.

"Confidentiality and Privacy" section

- **Plans for maintaining privacy in the research setting:** Specify that a random, unique code will be assigned to the data sent to NIH to protect participant privacy and confidentiality, and that identifiers will not be sent to the NIH.
- **Possible consequences to subjects resulting from loss of privacy:** Describe risks of broad sharing, risks to individuals, families and groups.

Consent Form Requirements and GDS Consent Form Checklist

The IRB has developed a **NIH GDS Policy Consent Checklist** [8] that specifies the informed consent elements for studies to meet GDS Policy data submission requirements. For multi-center research, submit a copy of this checklist for each consent form and also submit a copy of the consent form from the other sites. Submit this checklist to IRB at the time of your request for a GDS data submission certification letter if your study does not include the IRB recommended language (below).

For new studies and prospective collection for existing studies that plan to send data to NIH under the GDS Policy

There are two options:

1. Use the existing consent templates [9] that include the GDS required language, or
2. Develop your own verbiage and upload the NIH GDS consent checklist [8] to document that all of the required elements are included.

For existing studies where the data have already been collected

Submit the NIH GDS consent checklist [8] to document that all of the required elements are included to meet GDS Policy data submission requirements.

Recommended consent language

Genetic information (also known as genotype data) and the medical record data (also known as phenotype data) may be shared broadly in a coded form for future genetic research or analysis. We may give certain medical information about you (for example, diagnosis, blood pressure, age if less than 85) to other scientists or companies not at UCSF, including to a *(public or controlled access)* government health research database, but we will not give them your name, address, phone number, or any other identifiable information. Research results from these studies will not be returned to you *(describe any rare instances that this may occur)* .

Donating data may involve a loss of privacy, but information about you will be handled as confidentially as possible. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your health. Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. It is possible that future research could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.

There will be no direct benefit to you from allowing your data to be kept and used for future research. However, we hope we will learn something that will contribute to the advancement

of science and understanding of health and disease . If the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits. If you decide later that you do not want your information to be used for future research, you can notify the investigator in writing at [*insert address or contact information*], and any remaining data will be destroyed. However, we cannot retract any data has been shared with other researchers.

IRB will review for restrictions on the following

The IRB will review the study and the consent document for restrictions on:

- The types of research using the participant?s phenotype and genotype data
- The location of such research
- The types of medical conditions or diseases studied
- The duration of storage and use of phenotype and genotype data
- Who will be allowed to use the participant?s phenotype and genotype data
- The commercial use subject?s phenotypic and genotypic data

If any of the required consent elements are missing, the **NIH may not accept the data, or may place limitations on subsequent use of the submitted data.** Furthermore, **NIH will not accept GDS Policy data from studies that did not obtain consent from the participants (after 1/25/2015),** including studies where the local IRB granted a waiver of consent to collect this data.

For previously approved research, if the approved consent form omitted several of the required GDS Policy elements, the IRB may have to conclude that the original consent is not adequate for submission to the GDS Policy data repository and subsequent sharing for research. It may become necessary for the investigator to seek explicit re-consent participants.

Certification Letter for NIH

When you have received IRB approval for the GDS data submission and are ready to submit data to NIH under the GDS Policy, the IRB will provide a signed data submission certification letter to the investigator.

Resources

If you have questions, contact the HRPP office at 415-476-1814.

- UCSF Office of Sponsored Research [10]
- UCSF CTSI RKS: Regulatory Knowledge and Support Service [11]
- NIH website for Genomic Data Sharing (GDS Policy) [1]
- GWAS and GDS - Frequently Asked Questions [4]

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Links
[1] https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/
[2] https://irb.ucsf.edu/contact-us
[3] https://osp.od.nih.gov/wp-content/uploads/NIH_Guidance_Developing-GDS_Plans.pdf
[4] https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing-faqs/
[5] http://gds.nih.gov/pdf/gwas_data_sharing_plan.pdf
[6] http://grants.nih.gov/grants/sharing_example_data_sharing_plan.doc
[7] http://gds.nih.gov/Institutional_certifications.html
[8] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/gds-checklist.pdf
[9] https://irb.ucsf.edu/consent-and-assent-form-templates
[10] http://osr.ucsf.edu/
[11] http://ctsi.ucsf.edu/about-us/programs/regulatory-knowledge-support