Overview

The Institutional Review Board (IRB) requires investigators to provide a plan to ensure the privacy and confidentiality of participants, minimize the risks associated with genetic research, and provide adequate disclosure of genetic results that may be clinically relevant to the participant.

Types of Genomic Studies

Genomic studies usually fall into one of the following general categories:

1. Anonymous donors, who are untraceable by any means. This would include samples that have been collected or will be collected solely for non-research purposes, such as pathology samples, where only the samples, and not any identifying information linking the samples to individuals, will be provided to the researcher.
2. Donors whose identity is known or traceable, but the investigator does not plan to track the individual. An example would be a study where specimens are obtained, banked, and coded by the investigator, or the investigator obtains samples and associated data from a public, private or commercial repository (and there may be a key linking these to the subject's name/identifying information), but no subject-related genomic analysis is planned at this time. (However, the investigator retains identifying information or ability to identify individual subjects should plans change in the future.)
3. Donors whose identity is known or traceable, where the investigator plans to link genomic analyses to other study data from the specific individual, but will not inform subjects of the results of the analyses. An example would be a study about whether impulse control is hereditary, where the investigator would compare individual DNA data to behavioral assessment data, but would not inform the subject of these results.

Genome-Wide Association Studies (GWAS) Policy

In 2008, NIH implemented the Genome-Wide Association Studies (GWAS) Policy. A genome-wide association study is an approach used in genetics research to associate specific genetic variations with particular diseases. This policy requires data from NIH-funded GWAS to be shared with the research community in a central data repository maintained by NIH (i.e., the database of Genotypes and Phenotypes (dbGaP), Gene Expression Omnibus (GEO), Sequence Read Archive (SRA), and Cancer Genomics Hub (CaHUB).

NIH Genomic Data Sharing (GDS) Policy

To protect research subjects' privacy, access to sensitive data in the Database of Genotypes and Phenotypes (dbGaP), is through a controlled access policy. To further expand genomic data sharing of all types, NIH released a Genomic Data Sharing (GDS) Policy that went into effect on **January 25, 2015**. This policy applies to all NIH-funded research that generates large-scale human or non-human genomic data for ***more than one hundred*** individuals, regardless of the funding level, as well as the use of these data for subsequent research. Additional information can be found at the NIH Genomic Data Sharing (GDS) website.

NIH has strict standards for IRB review and informed consent for the data they will accept for inclusion in GDS data repositories. For more detailed information see: NIH Points to Consider for IRBs and

Institutions in Their Review of Data Submission Plans for Institutional Certifications under NIH's Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS).

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, investigators should contact the ORI 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. For more examples of studies under the GDS policy please see: Supplemental Information to the NIH Genomic Data Sharing Policy
- 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 the 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.

IRB Application Requirements

If your study meets the definition of human subject's research, you must submit a General IRB application to the Office of Research Integrity (ORI) including the following information in these

sections of the application (either as part of a new study or to modify an approved study to GDS):

"Study Summary" section

- Indicate if data will be collected *PROSPECTIVELY* or if the PI is submitting a modification to an ongoing study, or, 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 below "**Consent Form Requirements**" section).

"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, please provide the specific procedures regarding specimen collection and banking.

Please note: Not all studies that must comply with the NIH GDS policy require an IRB application. To determine whether or not your study meets the definition of human subjects research, please contact the ORI as early as possible, or complete and submit the *Determination of Activity* form found on our Forms Page. This form will assist us in determining whether your activity meets the definition of 'research involving human subjects' and requires IRB review/approval.

"Privacy, Confidentiality & Data" 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.
- State explicitly that data will be sent to NIH for GDS, and describe the genotype and phenotype data to be sent.
- Specify if data shared with the NIH for GDS Policy will be for broad use or limited to specific diseases or conditions.

Consent Form Requirements

For new studies and prospective collection for existing studies that plan to send data to NIH under the GDS Policy, use the IRB-Clin Informed Consent Template and ensure that the GDS required language is included.

For existing studies where the data have already been collected submit the consent form to IRB, whom will review the document to ensure that all of the required elements were included to meet GDS Policy data submission requirements.

GDS required consent language

In order to meet the expectations for future research use and broad sharing under the GDS Policy, the

consent form, whether for existing studies data or prospective data collection, should capture and convey in language understandable to prospective participants information along the following lines:

- Genomic and phenotypic data, and any other data relevant for the study (such as exposure or disease status) will be generated and may be used for future research on any topic and shared broadly in a manner consistent with the consent and all applicable federal and state laws and regulations.
- Prior to submitting the data to an NIH-designated data repository, data will be stripped of identifiers such as name, address, account and other identification numbers and will be de-identified by standards consistent with the Common Rule. Safeguards to protect the data according to Federal standards for information protection will be implemented.
- Access to de-identified participant data will be controlled, unless participants explicitly consent to allow unrestricted access to and use of their data for any purpose.
- Because it may be possible to re-identify de-identified genomic data, even if access to data is controlled and data security standards are met, confidentiality cannot be guaranteed, and re-identified data could potentially be used to discriminate against or stigmatize participants, their families, or groups. In addition, there may be unknown risks.
- No direct benefits to participants are expected from any secondary research that may be conducted.
- Participants may withdraw consent for research use of genomic or phenotypic data at any time without penalty or loss of benefits to which the participant is otherwise entitled. In this event, data will be withdrawn from any repository, if possible, but data already distributed for research use will not be retrieved.
- The name and contact information of an individual who is affiliated with the institution and familiar with the research and will be available to address participant questions.

IRB Review for Restrictions

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 subjects 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.

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

If the funding solicitation requires IRB review and/or approval of the consent form content prior to application submission, investigators should either work with the Sponsored Programs Administration (SPA) Officer assigned to your award, or contact the ORI directly to either submit a Determination of Activity form, or a General IRB application, in order to obtain the relevant IRB letter and the signed GDS data submission certification letter.

Resources

If you have questions, please contact the ORI office at irb@ucr.edu or *951-827-4802*.

Links

1. Office of Research Integrity website, https://research.ucr.edu/or-home.aspx
2. NIH Genomic Data Sharing, https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/
3. NIH Genomic Data Sharing Policies, https://osp.od.nih.gov/scientific-sharing/policies/
4. NIH Guidance for Investigators in Developing Genomic Data Sharing Plans, https://osp.od.nih.gov/wp-content/uploads/NIH_Guidance_Developing-GDS_Plans.pdf
5. NIH Key Elements for a Data Sharing Plan, http://grants.nih.gov/grants/sharing_example_data_sharing_plan.doc
6. NIH Institutional Certifications, https://osp.od.nih.gov/scientific-sharing/institutional-certifications/
7. NIH GDS IRB guidance, https://osp.od.nih.gov/wp-content/uploads/GDS_Points_to_Consider_for_Institutions_and_IRBs.pdf
8. National Institutes of Health Points to Consider in Developing Effective Data Use Limitation Statements, https://osp.od.nih.gov/wp-content/uploads/NIH_PTC_in_Developing_DUL_Statements.pdf
9. Supplemental Information to the NIH GDS Policy, https://osp.od.nih.gov/wp-content/uploads/Supplemental_Info_GDS_Policy.pdf
10. NIH GWAS FAQs, https://osp.od.nih.gov/wp-content/uploads/Genome-Wide-Association-Studies-GWAS-Policy-Frequently-Asked-Questions.pdf