FRED HUTCH
Institutional Review Office

Policy/Procedure

Title:	IRB Review of Genomic Data Sharing Studies
Policy:	2.27
Version:	1.00
Effective Date:	August 1, 2016
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director Karen Hansen 8/1/16 *Signature/date*

POLICY STATEMENT

The Institutional Review Board (IRB) is responsible for overseeing research activities in accordance with the federal regulations which govern human subjects. As part of the IRB's oversight, it will review all requests to allow sharing of genomic data, which may be required in support of institutional sign-off and/or certification for the genomic data sharing.

DEFINITIONS

Coded: any identifying information (such as name) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code) and a key to decipher the code exists, enabling linkage of the identifying to the private information or specimens.

Controlled-access: Data are available to an investigator for a specific project only if certain stipulations are met.

dbGaP (database of Genotypes and Phenotypes): A central data repository at the National Center for Biotechnology Information (NCBI), a branch of the National Library of Medicine.

De-identified Data: Note that this definition is specific to NIH's Genomic Data Sharing policy. Data that has been de-identified according to the following criteria: the identifiers of data subjects cannot be readily ascertained or otherwise associated with the data by the repository staff or secondary data users (45 CFR46.102(f)); the 18 identifiers enumerated at 45 CFR 164.514(b)(2) (the HIPAA Privacy Rule) are removed; and the submitting institution has no actual knowledge that the remaining information could be used alone or in combination with other information to identify the subject of the data.

Large-scale genomic data: The GDS Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data as well as use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomics, epigenomic, and gene expression data. Examples are included below. See Supplemental Information to the NIH Genomic Data Sharing Policy for more examples.

- Sequence data from more than one gene or region or comparable size in the genomes of more than 1,000 human research participants.

- Sequence data from more than one gene or region or comparable size in the genomes of more than 1,000 human research participants.
- Sequence data from more than 100 genes or region of comparable size in the genomes of more than 100 human research participants.
- Sequence data from more than 100 isolates from infectious organisms.

NIH GWAS Data Repository: Also known as the "Database of Genotype and Phenotype (dbGaP)", the NIH GWAS Data Repository is a database developed by the National Center for Biotechnology Information (a division of the National Library of Medicine) to archive and distribute the results of studies that have been investigated.

NIH-designated repository: Any data repository maintained or supported by NIH either directly or through collaborative.

Unrestricted-access: Data are accessible to anyone via public website (previously referred to as "open access").

Fred Hutch IO: A Senior Official at the institution who is credentialed through NIH eRA Commons system and is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who has submitted data or a data access request to NIH. The Fred Hutch Institutional Official who has the authority to provide institutional certification for data sharing under GWAS and GDS Policies is the Fred Hutch Director of the Office of Sponsored Research.

REFERENCES

45 CFR 46.109(a)
NIH Genome-Wide Association Studies (GWAS) website
NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies
NIH Genome-Wide Association Studies (GWAS) Points to Consider (11/12/07)
NIH Genome-Wide Association Studies (GWAS) Frequently Asked Questions
NIH Genomic Data Sharing Plans (NIH Policy, January 25, 2015)

PRINCIPLES/OVERVIEW

The Institutional Review Board (IRB) will review proposed genome wide association studies, including those accessing genomic data and those generating genomic data, in accordance with the applicable regulations governing human subjects research. When applicable, broad sharing of study data will be reviewed against the foundational consent along with the Genomic Data Sharing Supplement to determine if the data sharing plan is appropriate.

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, Principal Investigators and the research team.

PROCEDURES

1. **Studies with no requirements or provisions for broad sharing of studies generating genetic data.**

   a. **Submission to the IRB**: If no broad sharing of genetic results is planned or required, the IRB will follow regular review processes outlined in IRB Policy 2.1 *New Application,* or IRB Policy 2.5 *Modification of Ongoing Activities*. Investigators complete the *Application for Review Interventional Research, Application for Review Observational Research, or Application for Review Human Specimen or Data Research,* as appropriate. No additional review or actions are required.

2. **Studies that will create genomic data that will be shared with the wider research community:**

   a. **Submission to the IRB**: Requests for broad sharing of genomic data may be submitted to the IRB at initial review (for new studies) or via modification (for ongoing studies). Investigators complete an *Application for Review Interventional Research, Application for Review Observational Research, or Application for Review Human Specimen or Data Research;* or *Research Modification Form* for IRB review as appropriate. In addition, the Investigator will provide the IRB with the following information:

      i. *Genomic Data Sharing Supplement*;

      ii. Data Sharing Plan for the dataset to be shared;

      iii. All applicable Foundational Consent Form(s); and

      iv. Any documentation or certifications required to share the genetic data.

   b. **IRB Review Process**:

      i. Genomic studies submitting data to databases/repositories intended for broad access (e.g., dbGaP, caBIG, TGEN, etc.).

         1. The IRB will only review requests for genomic data sharing when the FHCRC is the IRB of record for the study that generates the genetic data to be posted into the database.

         2. In order to ensure risks are minimized, the IRB will consider the extent to which the dataset is de-identified. It will also consider the repository or mechanism through which the genetic/genomic data will be shared.

         3. The IRB will review any foundational consent forms and assess the extent to which participants were informed of broad sharing of their genetic data. In reviewing the foundational consent forms, the IRB will consider any restrictions outlined in the consent form, including opt-in / opt-out decisions.

         4. <u>For studies deriving genomic data from specimens collected before January 25, 2015:</u> The IRB will review the *Genomic Data Sharing Supplement* including any foundational consent forms to determine if the consent documents are silent or if the data was collected without informed consent; the IRB may consider whether broad sharing of the dataset is <u>not</u> inconsistent with any consent provisions; whether broad sharing requires re-consent of participants; and/or or any other findings in accordance with governing regulations and policies of the database.

            <u>For studies deriving genomic data from specimens collected on or after January 25, 2015:</u> The IRB will require copies of the foundational consent which must discuss broad sharing of genomic data or controlled access of data that is shared.

5. If the IRB determines foundational consent(s) described in the *Genomic Data Sharing Supplement* is not consistent with the foundational consent forms and/or governing regulations and policies, the IRB can disapprove the request or require restrictions on the future use of the datasets.

ii. **Additional requirements for submissions to dbGaP** In accordance with NIH requirements, the Committee will review and verify that:

1. The submission of data to the NIH GWAS data repository and subsequent sharing for research purposes are not inconsistent with the informed consent of study participants from whom the data were obtained;
2. The investigator's plan for de-identifying datasets is consistent with the standards outlined in the policy;
3. It has considered the risks to individuals, their families, and groups or populations associated with data submitted to the NIH GWAS data repository; and
4. The genotypic and phenotypic data to be submitted were collected in a manner consistent with 45 CFR Part 46.

3. Research study that will access a repository with genomic data:

a. Submission to the IRB: Studies that will conduct research using data taken from a genomic data repository must submit the appropriate Application paperwork to the Institutional Review Office (see Policy 2.1 *New Application*). The Application should disclose the source of data.

b. IRB Review Process: Review of these types of studies will be done in accordance with Policy 2.1 *New Application*.

4. **Other Responsibilities: Preparation of Data Use or other Institutional Certifications that permit sharing of genomic data**: After IRB review and approval of these activities, researchers may be required to satisfy other requirements of the sponsor or institution including, but not limited to Institutional Certifications, Data Use Certifications, etc. These shall be completed in accordance with the database/repository requirements.

4.1. The Institutional Certification should state whether the data wil be submitted to an unrestricted or controlled-access database.

4.2. The Institutional Certification should assure that:

4.2.1. The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies;

4.2.2. Any limitations on research use of the data, as expressed in the informed consent documents are delineated.

4.2.3. The identities of research participants will not be disclosed to NIH-designated repositories; and

4.2.4. An IRB, privacy board, and /or equivalent body, as applicable, has reviewed the investigator's proposal for data submission and assures that:

4.2.4.1. The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR 46;

4.2.4.2. Data submission and subsequent data sharing for research purposes are consistent with informed consent of the study participants from whom the data were obtained;

4.2.4.3. Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing;

4.2.4.4. To the extent possible, consideration was given to risks to groups or populations associated with submitting data to NIH designated repositories and subsequent sharing; and

4.2.4.5. The investigator's plan for de-identifying datasets is consistent with standards outlined in the NIH GDS Policy.

FHCRC will only issue Institutional Certifications for data posted to the repository/database directly from FHCRC generated genomic data where the FHCRC is the IRB of record for the project generating the data. If an Institutional Certification is required by the database / repository, the FHCRC IRB staff will prepare the Institutional Certification document for review by FHCRC Office of General Counsel prior to signature by the Director of the Office of Sponsored Research. Data Use Certifications for (accessing) the NIH dbGaP database are signed by the FHCRC Director of Sponsored Research. Other certifications are signed by the appropriate party per the requirements of the specific database / repository.

SUPPORTING DOCUMENTS

IRB Policy 2.1 New Application
IRB Policy 2.11 Informed Consent
IRB Policy 2.5 Modifications to Ongoing Activities
Application for Review Interventional Research
Application for Review Observational Research
Application for Review Human Specimen or Data Research
Research Modification Form
Genomic Data Sharing Supplement
Model Consent for Clinical Research
Model Consent Form for Minimal Risk Studies
Model Consent Minimal Risk PHS
Model Consent PHS
Model Consent R
IRO Form Institutional Certification Letter