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Boston Children's Hospital

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Department Research

Applicability Boston Children's Hospital- Policies & Procedures

NIH Genomic Data Sharing Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

This policy provides guidance for investigators who wish to conduct Genome-Wide Association Studies with National Institute of Health (NIH) funds. It also provides information on compliance with the NIH Genomic Data Sharing (GDS) Policy that became effective on January 25, 2015.

Policy Statements

The National Institute of Health (NIH) Genomic Data Sharing Policy promotes sharing for research purposes, large-scale human and non-human genomic data generated from NIH-funded research.

It sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports the NIH mission and is essential to facilitate the translation of research results into knowledge, products, and procedures that improve human health. NIH has longstanding policies to make a broad range of research data, in addition to genomic data, publicly available in a timely manner from the research activities that it funds.

The GDS policy applies to new projects with a research component that involve the generation of large-scale, human and/or non-human genomic data. If NIH funding supports the generation of the genomic data, the genomic data sharing policy (GDS) applies.

Large-scale data is described as genomic-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, transcriptomic, metagenomic, epigenomic, and gene expression data.

Information about the policy may be found at ***https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/***

Procedures

IRB Review and Informed Consent

For studies initiated after the effective date of the GDS policy, NIH expects investigators to obtain participants' consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly. This also includes specimens used to generate a cell line as well.

This informed consent requirement includes collection of clinical specimens used for research as well as specimens obtained specifically for research – both identifiable as well as de-identified.

It is important to note that under this new policy, de-identified excess clinical specimens can no longer be considered non-human subject research. Also, a waiver of informed consent can longer be allowed.

This is a major change and requires that investigators obtain consent in cases where previously was not necessary. In addition, it will be required to specify that samples and data may be used for unspecified and broad research topics not limited to the condition for which a subject is receiving care. Obtaining informed consent and specifying broad use will give investigators the greatest amount of flexibility in the future.

Template Consent Language

An example of consent language that may be considered is as follows:

In order to allow researchers to share results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) "banks" that collect the results and analyze data from genetic studies. These central banks may also analyze, and store samples and health information form research conducted by Boston Children's Hospital. These central banks will store your genetic and health information and/or samples and give them to other qualified and approved researchers to do more studies on diseases related to your condition and many other types of diseases or conditions. We do not think that there will be further risks to your privacy and confidentiality by sharing your health information, samples and/or genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your study code number attached. Your name or other directly identifiable information will not be given to these central banks. There are many safeguards in place to protect your privacy.

Data Collected Before the GDS Policy

For studies using data from specimens collected before the effective date of the GDS Policy, **there may be considerable variation in the extent to which future genomic research and broad sharing were addressed in the informed consent materials for the primary research**.

In these cases, an assessment by the IRB will be made to ensure that data submission is not inconsistent with the informed consent. NIH will accept data derived from de-identified cell lines or

clinical specimens lacking consent for research use that were created or collected before the GDS Policy effective date.

In some circumstances, broad sharing may not be consistent with the informed consent of the research participants whose data are included in the dataset. In such circumstances, institutions planning to submit aggregate or individual-level data to NIH for controlled access should note any data use limitations in the data sharing plan as part of the funding request. These data use limitations will be specified in the Institutional Certification submitted to NIH prior to the award.

For studies involving human subjects that were initiated before the policy's effective date and used consent forms that do not meet the expectations of the GDS policy, NIH anticipates that investigators will plan a transition to a consent for future research uses and broad sharing. If possible, particularly for new or additional collections of specimens.

Grant Application Submissions

The GDS policy applies to the following grant application mechanisms:

- Research projects (R)
- Program projects (P) and SCORs (S)
- Cooperative agreements (U)
- Individual career development awards (K)
- All other activities that include a research component

Unlike the Data Sharing policy, which applies to submissions with annual direct costs of $500,000 or more, there is no direct cost threshold associated with the GDS policy.

Application Components:

1. **Cover Letter**: If the GDS policy applies to the proposed research project, a cover letter should be included as part of the submission which states that the studies proposed will generate large-scale human and/or non-human genomic data.

2. **Budget**: Applicants may request appropriate resources needed to prepare data for submission to repositories.

3. **Resource Sharing Attachment**: Applicants should briefly describe the data, their plans for sharing, and provide assurance that it conforms to NIH policy. If the sharing of human data is not possible, applicants should provide a justification explaining why they cannot share these data and provide an alternative data sharing plan.

4. **Research Strategy Attachment**: Applicants planning to access human genomic data from NIH-designates repositories (dbGaP) to achieve the specific aims of the proposed research should briefly describe their plans and state their intentions to abide by the NIH Genomic Data User Code of Conduct.

NIH Just-In-Time Stage (JIT):

As part of the JIT request, an Institutional Certification will be required to assure that the proposal for data submission and sharing is consistent applicable laws and regulations and to describe the appropriate research uses of the data.

Research Administration, including the Office of Sponsored Programs and the IRB, will coordinate efforts to provide these certifications and will request the following information from BCH research teams:

- A brief description of the samples/data to be shared
- The date range of when the samples/data were used
- The applicable IRB protocol number(s)
- The applicable informed consent form(s)
- Is the submission to an Unrestricted or Controlled-Access Database?

NIH Awards:

If the grant is funded, the resource sharing plan including the genomic data sharing plan, will be referenced as a *Special Term and Condition* in the Notice of Award. BCH investigators will be required to provide updated genomic data sharing plans as part of their annual progress report (RPPR) submissions.

Related Content

Federal Resources

Guidance for Investigators in Developing Genomic Data Sharing Plans

Implementation of Genomic Data Sharing Policy: *NOT-OD-14-111*

NIH Data Sharing: *FAQs*

NIH Genomic Data User Code of Conduct

NIH Program Officials Genomic Data Sharing Policy: *NOT-OD-14-124*

Points to Consider in Developing Effective Data Use Limitation Statements

Points to Consider for IRBs and Institutions in their review of Data Submission Plans for Institutional Certifications

Approval Signatures

Step Description	Approver	Date

Applicability

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