Icahn School of Medicine at Mount Sinai (ISMMS) Program for the Protection of Human Subjects (PPHS) National Institutes of Health (NIH) Human Genomic Data Sharing (GDS) Policy and Guidelines

1. When did the policy go into effect? The NIH GDS Policy became effective for competing grant applications submitted for the January 25, 2015 receipt date.

2. What is the purpose of the policy? To ensure the broad and responsible sharing of genomic research data generated from NIH-funded research.

3. What research is covered by the policy? The NIH GDS Policy applies to all NIH-funded research (e.g., grants, contracts, and intramural research) that generates large-scale* human or non-human genomic data, regardless of the funding level, as well as the use of these data for subsequent research.

(*Large-scale genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data).

4. What are the principal investigator (PI) responsibilities when preparing a proposal for NIH funding and before award?

(a) NIH application:

* PIs seeking NIH funding should contact their NIH Institute or Center Program Officer (PO) to discuss the project, data sharing plan and data certification process.
* Basic plans for following this policy should be included in the "Genomic Data Sharing Plan" located in the Resources Sharing Plan section of the grant application. Data sharing plans should be prepared to be consistent with the grant requirements but should not include activities that are proscribed by the applicable consent and protocol. PPHS will be happy to provide assistance.
* Resources needed to support the Genomic Data Sharing Plan should be included in the budget.

(b) Just-in-Time:

* A more detailed Genomic Data Sharing Plan must be provided to the funding PO *prior* to award.
* A GDS Institutional Certification for Sharing Human Data must be provided to the funding PO *prior* to award. The GDS Institutional Certification will include IRB approval, limitations or restrictions to data sharing, and state that data are being submitted to a controlled-access database.

For further guidance see the Grants and Contracts SOP:: GCO's NIH Genomic Data Sharing (GDS) Policy: Grant Application Instructions

5. What is a GDS Institutional Certification?

* There are two kinds of Institutional Certifications:
  o GDS Extramural Institutional Certification
  o GDS Provisional Institutional Certification
* ISMMS's Institutional Official (IO) is required to provide a certification to the PO prior to award consistent with the genomic data sharing plan submitted with the funding request. The IRB will coordinate the completion of this certification. Generally, the institution which is the primary awardee will prepare the certification on behalf of all sites. If you are not the primary awardee, please contact the primary site to see what they will need from ISMMS in order for them to process the project wide certification.

- A request for a GDS Institutional Certification must be submitted to the PPHS office via the IRB In-box (see below for instructions).
- The PPHS must review the data submission proposal and assure:
  - The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46.
  - Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained.
  - Consideration was given by the IRB to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing;
  - To the extent relevant and possible, consideration was given by the IRB to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing; and
  - The PI's plan for de-identifying datasets is consistent with the standards outlined in the Policy
- Note the ISMMS IRB will not allow for uploaded materials to be used for "general research use" unless consent language specifically supports that use. If not further specified in the consent, the PPHS interprets "unrelated uses" to be limited to the areas of Health/Medical/Biomedical (HMB) research.

6. What is the process for obtaining a GDS Institutional Certification? (Expected review time takes up to two weeks)

- If the study has not already been submitted to and approved by the ISMMS IRB, an application must be submitted when the PI has received a score that is in the fundable range.
- A planning phase application is acceptable if the complete study documents and details have not been developed; a Genomic Data Sharing Plan must be included.
- Regardless of whether the study is being reviewed under a Request to Rely process (an IRB other than ISMMS), the GDS Institutional Certification must be reviewed and approved through the ISMMS PPHS office.
- A request for review and approval of the GDS Certification must be submitted through the IRB Inbox process at IRB@mssm.edu.
- The email message must include the following: Please answer the questions and attach the needed documents.
  - Subject line of the message should read: GDS Institutional Certification Request for Approval.
  - Attach a completed GDS Institutional Certification form signed by the PI.
  - Attach a copy of the Data Sharing Plan.
  - If the study providing the specimens or genomic data is approved at ISMMS, attach all consent forms approved for that project(s) related to uses of biospecimens and/or genetic sequences.
  - Will the samples/data to be uploaded, all have the same future use parameters?
    - If not, provide the PPHS with a plan to assure that the varied restrictions will be transmitted to, and honored by, the repository.
  - Confirm that only biospecimens/sequences of participants who have consented to sharing data/samples will be sent to the repository.
  - Provide a list of all sites the samples have been/will be obtained (both internal and external sites).
  - Which site will upload the samples into the large repository, as it is not always the lead site?
  - If biospecimens/sequences are received by an ISMMS PI from outside sources, the following request for a Data Use Limitation Record (DULR) form must be completed by each site's IRB office/IO.
    - Data Use Limitation record for biospecimens collected *before* January 25, 2015
    - Data Use Limitation record for biospecimens collected on or *after* January 25, 2015
    - Cover letter to request DULR