**NIH Genomic Data Sharing (GDS) requirements**

The US Department of Health & Human Services instituted a policy, effective January 25, 2015, regarding genomic data sharing (GDS) found at www.gds.nih.gov. The policy applies to:

- All NIH-funded research that generates large scale (> than 1000 individuals) human or non-human genomic data (e.g., SNP arrays, genome sequencing, RNA sequencing, transcriptomic, metagenomic, epigenomic and gene expression data), as well as the use of these data for subsequent research sharing in NIH-supported repositories;
- All competing NIH grant applications or contract proposals submitted to NIH for the January 25, 2015 due date; and
- All research involving genotype/phenotype data that will be submitted to one of the NIH-supported repositories, even if the research itself is not NIH-supported:
  - Database of Genotypes and Phenotypes (dbGaP),
  - Gene Expression Omnibus (GEO),
  - Sequence Read Archive (SRA), or
  - Cancer Genomics Hub

If the project is subject to the NIH GDS requirements, then the IRB protocol should include a description of:

- Type of data that will be shared (i.e., the type of genomic data, relevant associated data, and information necessary to interpret the data)
- The data repository to which the data will be submitted
- The timeline for the data to be shared
- Any limitations on the secondary research uses of the data, if the study involved human data acknowledgement that the Institutional Certification will be submitted and assurance by the Institutional Review Board (IRB) that the data can be shared through NIH-designated data repositories, consistent with data sharing under the NIH GDS Policy

This information must also be in the informed consent, if applicable, so that subjects can reasonably understand where their information will be stored.

**When does the 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 research for 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), K12 Career Awards (KL2s), 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.

What if the consent was silent on data sharing, or was not consistent with submission of data?

• For data from specimens collected before 1/25/2015, the IRB will assess whether the data submission is consistent with the informed consent given by the participant. NIH will accept data derived from de-identified cell lines or clinical specimens lacking consent for research that were created or collected before 1/25/15.

• For studies initiated after 1/25/15, NIH expects researchers to obtain participants’ consent for their data to be shared broadly for future research.

• For studies that prohibit sharing by using statements such as “Your data will never be shared outside of Stanford,” re-consenting may be possible. Any plan to re-consent should be submitted to the IRB as a modification to the protocol along with the modified consent form prior to implementation.

Certification Requirements

Certification from an Organizational Official is required to submit materials through the GDS policy. The certification should assure that:

• The data submission is consistent with all applicable laws and regulations as well as institutional policies;
• The appropriate research uses of the data and the uses that are specifically excluded by the informed consent documents are delineated;
• The identities of research participants will not be disclosed to the NIH GWAS data repository; and
• An IRB and/or Privacy Board, as applicable, reviewed and verified that:
  o The submission of data to the NIH GWAS data repository and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
  o The investigator’s plan for de-identifying datasets is consistent with the standards outlined in the policy; o It has considered the risks to individuals, their families, and groups or populations associated with data submitted to the NIH GWAS data repository; and
  o The genotype and phenotype data to be submitted were collected in a manner consistent with 45 C.F.R. Part 46.
An Institutional Certification can be obtained in two ways:
1) Complete and submit to HRPP the 'Determination of Human Research' form, AND complete and submit the 'Institutional Certification for GDS'.
2) Complete and submit to HRPP a proposal for human research, AND complete and submit the 'Institutional Certification for GDS'.