The NIH’s GDS (Genomic Data Sharing) policy became effective January 25, 2015 and applies to:

- All NIH-funded research that generates and uses large scale human or non-human genomic data, as well as the 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, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism (e.g., grant, contract, cooperative agreement, or intramural support).
  - Examples include, but are not limited to, sequence data from more than one gene or region of comparable size in the genomes of more than 1000 human research participants; sequence data from more than 100 genes in the genomes of more than 100 human research participants; comparisons of differentially methylated sites genome-wide at single-base resolution within a given sample (e.g. within the same subjects over time or across cell types). Additional examples are available in the Supplemental Information to the NIH GDS Policy.

When does the policy NOT apply?

Examples of NIH-funded research or research-related activities that are outside the Policy’s scope include, but are not limited to, projects that do not meet the criteria above such as:

- instrument calibration exercises
- statistical or technical methods development, or
- the use of genomic data for control purposes, such as for assay development.

In addition, the following types of funding generally do not fall under the GDS Policy: Institutional Training Grants, K12 Career Awards, Individual Fellowships (Fs) such as the Ruth L. Kirschstein National Research Service Award, Resource Grants and Contracts (Ss), or Facilities and coordinating centers funded to provide genotyping, sequencing, or other core services in support of GDS.

When NIH funding is requested for a grant proposal:

Work with your Research Process Manager at RMG to submit a basic genomic data sharing plan in the Resource Sharing Plan section of funding applications.

What is required for Just-In-Time (JIT) awards notification?

- A Stanford Institutional Official-signed Extramural Institutional Certification
- If no IRB-approved consents exist at JIT, a Provisional Institutional Certification can be used until the consent(s) is/are IRB-approved.
Extramural Institutional Certification

Extramural Institutional Certification is required prior to depositing human genomic data into one of the NIH-supported repositories, even if the research itself is not NIH-supported. NIH-supported repositories include, but are not limited to Database of Genotypes and Phenotypes (dbGaP), Gene Expression Omnibus (GEO), or the Sequence Read Archive (SRA).

To request Extramural Institutional Certification, submit the following to the IRB:

- A blank copy of each consent form used to collect samples from which data were/will be generated.
  - If the dataset includes data from samples obtained at another institution, including commercial vendors such as ATCC, the Stanford IRB will review each of those consents as well.
  - Submit “each consent,” version across studies, and across time. Essentially EACH IRB-approved consent document used to collect samples represented in the dataset.
- A completed Genomic Data Sharing Checklist for each consent.
- A completed PD-signed Extramural Institutional Certification form that correlates with the dates samples were collected from participants.

Once the IRB confirms the data can be submitted to an NIH-supported genomic data repository, the IRB will obtain the Authorized Institutional Official’s signature and return the signed form to whomever requested the extramural certification.

Note: sample consent language for Genomic Data Sharing is included in the informed consent templates available on the Medical Research: Forms & Consent Templates webpage.

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