NIH's GDS (Genomic Data Sharing) policy is effective January 25, 2015 and applies to:

- All NIH-funded research that generates large scale (> than 100 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 the
    - Cancer Genomics Hub.

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.

When NIH funding is requested for a grant proposal, what does the researcher need to do?

- Work with your RPM to provide a basic plan for following the GDS policy, located in the Resource Sharing Plan section of funding applications.
  See Genomic Data Sharing Plan template
- If broad sharing of genomic data is not possible, include an explanation.

What will be required for Just-In-Time awards?

- NIH will require the following documentation at Just-In-Time:
    - An **IRB approval letter** for your human subjects protocol
    - An Institutional Certification to be completed and signed by the researcher, and then submitted to the RPM for an authorizing signature

What is required when genomic data needs to be submitted to an NIH-supported data repository, but NIH is not the funder and/or a funding request is not involved?

- The IRB will be responsible for the authorizing signature on the **Institutional Certification**. See FAQs.

Sample informed consent language to use when genetic data will be deposited in NIH-supported repositories:

Information from analyses of your coded samples and your coded medical information will be put into one of the National Institutes of Health (NIH) databases along with information from the other research participants and will be used for future research. These databases will be accessible by the Internet.   Only anonymous information from the analyses will be put in a completely public database, available to anyone on the Internet.

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be put into the public database. While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

However, your privacy is very important to us and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

General Information/Background

- NIH established the GWAS Repository for Genome Wide Association Studies on January 25, 2008. Previous to this date, data sharing was required for funding over a threshold of $500,000. After 2008, the GWAS policy had no threshold, and was required for any amount of NIH funding.

- On August 27, 2014, the NIH announced the final Genomic Data Sharing (GDS) Policy. The policy sets forth NIH expectations "that ensure the broad and responsible sharing of genomic research data."   The GDS policy expands upon previous GWAS policy, and highlights the necessity for gaining the informed consent of study participants for broadly sharing data for future research.

See the following NIH documents for complete details and related policies:

Resources	
NIH	- The Genomic Data Sharing Policy effective 1/25/2015 - Implementation of the NIH Genomic Data Sharing Policy for NIH Grant Applications and Awards – Instructions for implementation of the GDS policy for grant applications - Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS) – 2007-2008 – GWAS policy prior to 1/25/2015 - Genome-Wide Association Studies (GWAS): NIH Points to Consider - NIH Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications under NIH's Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS) - Key Elements to Consider in Preparing a Data Sharing Plan Under NIH Extramural Support
Stanford resources	- Genomic Data Sharing Plan template - Institutional Certification - FAQs - RMG resources: Institutional Certification Genetic/Genomic Data Sharing - Memorandum from Vice Provost and Dean of Research, and Senior Associate Dean for Research, SoM