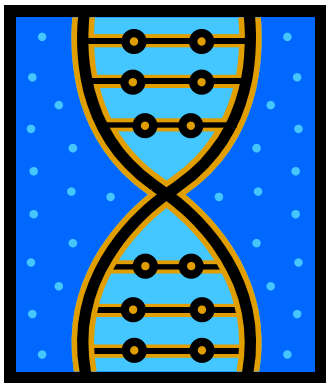
NIH Genomic Data Sharing (GDS) Policy

What YOU Need to Know:



What is the purpose of the GDS policy?

To promote robust sharing of human and non-human data from a wide range of genomic research and to provide appropriate protections for research involving human data, the National Institutes of Health (NIH) issued the *NIH Genomic Data Sharing Policy* (GDS Policy) on August 27, 2014 in the *NIH Guide Grants and Contracts* (available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html and in the *Federal Register* (available at https://federalregister.gov/a/2014-20385) on August 28, 2014.

Who does it apply to?

All NIH-funded research (e.g., grants, contracts, intramural research) that generate large-scale human or non-human genomic data, regardless of the funding level, as well as the use of these data for subsequent research.

The GDS Policy does not apply to: Institutional training grants (T32s, T34s, T35s, and TL2s); K12 career development awards (KL2s); Individual fellowships (Fs); Resource grants and contracts (Ss); Linked awards derived from previously reviewed applications (KL1, KL2, RL1, RL2, RL5, RL9, TL1, UL1); Facilities or coordinating centers funded through related initiatives to provide genotyping, sequencing, or other core services in support of GDS.

"Large-scale data" include:

- genome-wide association studies (GWAS),
- single nucleotide polymorphism (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).

When does it go into effect?

Compliance with this Policy will become a special term and condition in the Notice of Award or the Contract Award for applications for grants and contracts submitted on or after January 25, 2015.

Research that was initiated prior to the effective date of the GDS Policy will continue to operate under the terms of the policies that were in effect when the research began, such as the 2008 *NIH Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies* (the GWAS Policy), the 2004 *NIH Policy on Sharing of Model Organisms for Biomedical Research*, or the 2003 *NIH Data Sharing Policy*, however, NIH strongly encourages investigators to comply with the expectations outlined in the Policy.

For studies initiated before the Policy's effective date that involved human specimens and did not use consents that meet the expectations of the GDS Policy, investigators should plan to transition to a consent for future research uses and broad sharing, if possible.

What are the Investigator responsibilities?

- Contact Project Officer to discuss data sharing expectations and timelines
- Provide basic Genomic Data Sharing Plan with application, and a more detailed plan prior to award
- Include costs of Genomic Data Sharing Plan in the proposed application budget
- Abide by the NIH Genomic Data User Code of Conduct through their agreement to the Data Use Certification when downloading controlled-access data from NIH-designated data repositories and their institutions
- Investigators should register all studies with human genomic data that fall within the scope of the GDS Policy in dbGaP by the time that data cleaning and quality control measures begin, regardless of which NIH-designated data repository will receive the data. After registration in dbGaP, investigators should submit the data to the relevant NIH-designated data repository (e.g., dbGaP, GEO, SRA, the Cancer Genomics Hub32)
- Investigators should ensure that appropriate data security measures are in place and that confidentiality, privacy, and data use measures are consistent with the GDS Policy

Human Research Protections: 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.
    - The consent should include an explanation about whether participants' individual-level data will be shared through unrestricted- or controlled-access repositories.
- For studies proposing to use genomic data from cell lines or clinical specimens that were created or collected after the effective date of the Policy, NIH expects that informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified.
    - If there are compelling scientific reasons that necessitate the use of genomic data from cell lines or clinical specimens that were created or collected after the effective date of this Policy and that lack consent for research use and data sharing, investigators should provide a justification in the funding request for their use. NIH will review the justification and decide whether to make an exception to the consent expectation.
- 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 is needed to ensure that data submission is not inconsistent with the informed consent provided by the research participant.

What are the Institutional responsibilities?

- With implementation of the GDS Policy, submission of the Institutional Certification for human genomic data will become part of the NIH grant application process. The authorized Institutional Official of the institution submitting the application should provide the Institutional Certification to assure that the proposal for data submission and sharing is consistent with appropriate laws and regulations, and to delineate the appropriate research uses of the data. Following initial peer review and prior to award, potential grantee institutions will be asked to submit an Institutional Certification through the standard Just-in-Time process.
- For research that falls within the scope of the GDS Policy, submitting institutions, through their IRB, are to review the informed consent materials to determine whether it is appropriate for data to be shared for secondary research use.

Additional Information:

- Guidance for Developing Data-Sharing Plans (http://gds.nih.gov/pdf/gwas_data_sharing_plan.pdf)
- Points to Consider in Drafting Effective Data Use Limitation Statements (http://gds.nih.gov/pdf/NIH_PTC_in_Drafting_DUL_Statements.pdf)
- Points to Consider for IRBs and Institutions in their Review of Data Submission Plans for Institutional Certifications (http://gds.nih.gov/pdf/PTC_for_IRBs_and_Institutions.pdf)
- FAQs for Genomic Data Sharing (http://gds.nih.gov/13faqs.html)