NIH Genomic Data Sharing (GDS) Policy

On August 27, 2014, the National Institutes of Health (NIH) announced its final Genomic Data Sharing (GDS) Policy. This policy is designed to promote sharing, for research purposes, of large-scale human and non-human genomic data generated from NIH-funded research. The GDS Policy applies to all competing NIH grant applications and contracts submitted after January, 2015 if the proposed research will generate large-scale human or non-human genomic data or will use these data for subsequent research. In such cases, the GDS Policy applies regardless of the funding level.

The following guidance is to assist Principal Investigators at the application stage only. PIs should review additional genomic data sharing requirements at the Just-in-Time (JIT)/post-award stages provided by NIH.

What Research Projects are affected by this Policy?
Examples of large scale genomic research projects that are subject to the GDS Policy are available in Supplemental Information to the NIH GDS.

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 Genome Data Sharing
- Smaller studies (e.g., sequencing the genomes of fewer than 100 human research participants) are generally not subject to this Policy.

Application Requirements
Unless the Funding Opportunity Announcement states otherwise, applicants preparing grant applications are expected to:

- Contact the appropriate NIH Institute or Center (IC) Program Official or Project Officer as early as possible to discuss Genome Data Sharing expectations and timelines that would apply to their proposed research.
- State in the cover letter with the application that the research proposed will generate large-scale human and/or non-human genomic data.
- Include a Genomic Data Sharing plan in the Resource Sharing Plan section of the funding application or proposal. (A more detailed genomic data sharing plan will need to be provided to the funding IC prior to award.)

- Include costs of genomic data sharing (including the costs of stripping the identifiers from the data) in the proposal application budget. These costs may be significant.

In situations in which the sharing of human data is not possible, applicants should provide a justification explaining why they cannot share these data and provide an alternative data sharing plan. Exceptions to NIH expectations for data submission to an NIH-designated data repository will be considered on a case-by-case basis by the NIH. Applicants who wish to use controlled-access human genomic data from NIH-designated data repositories (e.g., dbGaP) as a secondary user to achieve the specific aim(s) of the research proposed in the grant application should briefly address their plans for requesting access to the data and state their intention to abide by the NIH Genomic Data User Code of Conduct in the Research Plan of the application.

Researchers should be aware that access to these data is dependent on an approval process that involves the relevant NIH Data Access Committee(s). Researchers may wish to secure access to the data prior to submitting their application for NIH support.

GDS Policy Questions

Investigators with questions about whether the Policy applies to their proposed research should consult the relevant Program Official or Program Officer or the IC's Genomic Program Administrator (GPA). Names and contact information for GPAs are available through the NIH GDS website. General questions regarding the policy can be directed to Chris Green, Director of the Office of Sponsored Programs at greenc@uthscsa.edu or via phone at 210.567.4938.