

## **Important Notice**

The NIH has released its Genomic Data Sharing (GDS) Policy, which is effective beginning with proposals submitted for the January 25, 2015 due date. The Policy expands the data-sharing expectation from the NIH-funded genome-wide association studies (GWAS) to all large-scale genomic data collection. The GDS Policy applies to all grant types, with few exceptions (T-types, K12s, and Fs, for instance), and to contracts. Implementation details provided by NIH also address expectations for the transition of research submitted prior to the Policy's effective date.

### **What is defined as large-scale?**

“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).

### **What will be required in the application?**

Applicants subject to the new policy are expected to state in their cover letter if their proposed research will generate large-scale human or non-human genomic data. If so, applicants are required to include a basic genomic data sharing plan with the application and a more detailed plan prior to award. NIH will ask peer reviewers to comment on this plan, though it will not factor into the overall impact score for the project (unless specified otherwise in the funding opportunity announcement).

### **What should investigators do prior to submitting the application?**

- Contact the appropriate NIH Program Officer as early as possible to discuss data sharing expectations and timelines for the proposed study.
- Include costs of genomic data sharing (including the costs of stripping the identifiers from the data) in the proposed application budget. These costs could be significant.
- Consider how you will obtain human samples for the proposed research. This is a critical aspect of the data sharing plan.
  - Will you collect prospectively...ensure that consent documents include language about sharing and the risk of sharing genomic data. This is a critical aspect of the data sharing plan.

- Are you using stored samples that were collected under another research study...what did the research consent from other study say about sharing?
- Are you using stored samples that were collected for clinical purposes?

If you are planning to submit an NIH application subject to the GDS Policy for the January 25 deadline, please contact Kelley O'Donoghue or Gunta Liders as soon as possible.