Icahn School of Medicine at Mount Sinai

Procedures for NIH Grant Applications that Propose to Generate or Use Large-Scale Genomic Data

The NIH issued a series of notices and posted additional resources to assist researchers who propose to generate or use large scale genomic data in complying with the Genomic Data Sharing (GDS) policy. The NIH's GDS policy has been effective with all competitive grants applications submitted on or after January 25, 2015. The NIH defines large scale genomic data in the "Scope and Applicability" section of the GDS policy document. The NIH provides examples in a supplemental information document.

Below are instructions for applicants to use in their NIH grant applications organized by research type.

You must include a basic genomic data sharing plan in the in the Resources Sharing Plan section of the grant application. During the Just in Time process prior to award, the NIH will request a more detailed plan. In addition to the guidance provided in this document, you are encouraged to contact the PPHS office for assistance. Click here for additional policy information and guidance from Mount Sinai's Program for the Protection of Human Subjects (PPHS) office.

Do factor in any associated costs to support the plan in your budget.

I. Primary Users: Research Generating <u>Human and/or Non-Human</u> Genomic Data
   A. General
      1. State that the studies proposed will generate large-scale <u>human and/or non-human genomic data</u> in an application cover letter.
      2. Include a genomic data sharing plan in the "Resource Sharing Plan" section of the Research Plan.
      3. Once a grant is awarded, PIs should note NIH requirements that could jeopardize their ability to publish the results of his/her research first, before anyone else.

         <u>For Research Generating Human Genomic Data:</u>
         The NIH reserves the right to release human genomic data six months after the data have been submitted to NIH-designated data repositories, regardless of whether the data has been published.

         <u>For Research Generating Non-Human Genomic Data:</u>
         While generally this data must be made publicly available no later than the date of initial publication, the NIH reserves the right to request the pre-publication of certain data, including "projects with broad utility as a resource for the scientific community such as microbial population-based genomic studies."

      GCO recommends that the PI contact his/her Program Officer to determine how the GDS policy will affect his/her right to first publish.

   B. Specific to Research Generating Human Genomic Data

1. If 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.
2. Use of NIH's Sample Data Sharing Plan
NIH's [Guidance for Investigators in Developing Data-Sharing Plans](#) includes sample data sharing plans. While you are welcome to use the sample, if your project includes human genomic data, GCO encourages you to <u>not</u> incorporate the term "the IRB advised" in your data sharing plan unless you have already obtained IRB prior approval prior to submission of your NIH application. GCO <u>does</u> recommend replacing the "IRB advised" term with "Consistent with similar projects, I anticipate that the IRB will advise that…."

Please do contact the IRB at IRB@mssm.edu if have any questions or need assistance in developing a plan.

II. Secondary Users: Research Using (e.g., analyzing) Controlled-Access <u>Human</u> Genomic Data from NIH-Designated Data Repositories
A. Briefly address plans for requesting access to the data. Since the NIH notices do not specify the placement, we requested and received clarifying information from the NIH Policy Office that the plan can be placed in the "Research Strategy" section under any of the subheadings as appropriate. Note that the "Approach" sub-section does include instructions for methodology and data collection so that this may an appropriate place for the information.

B. State intention to abide by the NIH Genomic Data User Code of Conduct, in the Research Plan. See section above for placement in the grant application.

III. Primary Users: Research Generating <u>Human and/or Non-Human</u> Genomic Data Initially Funded Prior to the NIH Policy's Effective Date
The NIH recommends the following:
A. Researchers should make every effort to include a data sharing plan in the application that outlines plans to comply with the expectations outlined in the GDS Policy, and

B. Researchers should plan to transition to a consent for future research uses and broad sharing, if possible, if the studies involve human participants and were initiated before the Policy's effective date and used consents that do not meet the expectations of the GDS Policy.

NIH's [Guidance for Investigators in Developing Data-Sharing Plans](#) includes sample data sharing plans.

Additional Resources
[PPHS Genomic Data Sharing Guidance and Resources](#)

NIH [Genomic Data Sharing Website](#) and Policy Resource**s**
Notices
- [Implementation of the NIH Genomic Data Sharing Policy for NIH Grant Applications and Awards (NOT-OD-14-111)](#)
- [NIH Genomic Data Sharing Policy (NOT-OD-14-124)](#)

- Reminder: Implementation of the Genomic Data Sharing Policy Begins January 25, 2015 (NOT-OD-15-027)
- Reminder: NIH Grant Applications and the NIH Genomic Data Sharing Policy (NOT-15-083)
- Notice of Information: Alignment Among the Disease Definitions Utilized to Govern Genetic and Genomic Data Sharing for Studies Involving Alzheimer's Disease (NOT-AG-17-007)

Guidance
- Policy
- Supplemental Information
- FAQs
- Guidance for Investigators in Developing Data-Sharing Plans
- Points to Consider in Drafting Effective Data Use Limitation Statements