

September 22, 2014

Dear Colleagues,

Effective January 25, 2015, all NIH-supported research that generates large-scale genomic data, defined as >100 individual participants, must include the following:

NIH applications:

- Data Sharing Plan must be included to describe
  - how data will be de-identified
  - how consent will be obtained
  - consent language specifying broad data sharing

Just-in-Time:

- Institutional Certification will be required including
  - IRB approval
  - limitations or restrictions to data sharing
  - whether data submission is to an unrestricted- or controlled-access repository

NOTE: Large-scale genomic data is defined as including genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data.

The School of Medicine Research Management Group and the Research Compliance Office (IRB) are preparing guidance for you to use in addressing these requirements. They will provide examples of data sharing plans, informed consent templates and requirements for Institutional Certification. Guidance and instructions will be posted soon on the IRB and RMG websites.

Please contact [Celia.Molvin@stanford.edu](mailto:Celia.Molvin@stanford.edu) (IRB) or [Sonia.Barragan@stanford.edu](mailto:Sonia.Barragan@stanford.edu) (RMG) if you have questions or need assistance.

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