

NIH Genomic Data Sharing Policy

Summary:

- **NIH requires an Institutional Certification for data to be shared with dbGaP.**
- **DF/HCC research involving sharing of data must be described in the protocol and the research consent form signed by each participant in order for data to be shared. This is required for Institutional Certification.**
- **Institutional Certifications are submitted to OHRS as an amendment that will then be reviewed and signed by the IRB Director or designee.**
- **Sharing may be required with other scientific databases. Your institutions Grants Administration office can help determine what sharing is required.**

The NIH released an updated **Genome Data-Sharing Policy**, effective January 25, 2015 which applies to all NIH-funded research that generates large-scale human or non-human genomic data as well as the use of the data for subsequent research initiated after the effective date. This applies to all informed consent documents for studies obtaining samples that will be used for future NIH-funded research and for submission to NIH-funded repositories such as dbGaP, GEO, SRA, or Cancer Genomics Hub.

The full text of the policy is linked here: http://gds.nih.gov/PDF/NIH_GDS_Policy.pdf

Institutional Certification: Journals and databases such as dbGaP require that IRBs confirm that the protocol includes language that permits sharing with scientific databases and that specific consent for data sharing is present in the informed consent document.

Please note that samples collected with informed consent prior to January 25, 2015 will be subject to the old policy. Those that were collected after January 25, 2015 will be governed by the new. Study teams must keep track of sample collection dates

SUGGESTED LANGUAGE FOR "What about Confidentiality?" SECTION OF THE INFORMED CONSENT DOCUMENT:

As part of this study, your de-identified specimens or genetic data may be placed into one or more publicly-accessible scientific databases, such as the National Institutes of Health's Database for Genotypes and Phenotypes (dbGaP). Through such databases, researchers from around the world will have access to de-identified samples or data for future research.

NIHGRI guidance here: <http://www.genome.gov/informedconsent/>