NIH GENOMIC DATA SHARING	SOP 5.1.06

1. Purpose & Policy

This SOP provides guidance on the process for the management and sharing requirements for genomic data. IRB Policy *Section 5.1*.

2. General Information

Our federal sponsors, particularly, the National Science Foundation (NSF) and the National Institutes of Health (NIH) have requirements for the dissemination of research results. In general, investigators are expected to share data with other researchers and are also expected to provide a Data Management Plan (DMP) or Data Management Sharing Plan (DMSP).

The expectations of sharing genomic data generated with federal funding are outlined in the NIH's Genomic Sharing (GDS) Policy: NOT-OD-14-124: NIH Genomic Data Sharing Policy. Plans for sharing genomic data under the GDS Policy are to be described in the DMSP submitted at the time of application, not in a separate GDS Plan or at Just-In-Time.

3. Training Requirements

In addition to the normally required and study specific training for all human subjects research, investigators must complete the CITI module *Genomic Research in Human Populations – BIO*, along with carefully reading and following this guidance.

4. Procedure

A. Institutional Certification

Institutional Certifications are expected for the submission of large-scale human genomic data under the NIH Genomic Data Sharing Policy. The Institutional Certification for sharing human data should be provided to the funding NIH Institute or Center prior to award, along with any other Just-In-Time information.

NIH provides different versions of the Institutional Certification based on:

1. Source of NIH funding,
2. Whether samples were collected before or on/after the effective date of the GDS policy, and
3. Consent status for samples collected before the effective date.

Type of Institutional Certification Form	Downloadable Forms
Sample collected ON OR AFTER Jan 25, 2015	Extramural Institutional Certification
Sample collected BEFORE Jan 25, 2015	Certification With Consent Certification Without Consent
Provisional (IRB or equivalent body has not yet completed review)	Provisional Institutional Certification

Investigators should complete the appropriate Institutional Certification and email the completed form (including with PI signature) to IRB@caltech.edu.

In addition to the completed form, the PI must complete and submit an Initial Query or Full Application in the IRB Protocol Application System (PAS). The IRB will review the protocol and assure: that the collection of genomic and phenotypic data are consistent with 45 CFR 46; data submission and sharing are consistent with the informed consent; risks of data sharing to participants and their families were considered; risks of data sharing to groups or populations associated with the data were considered; the investigator's plan for de-identification meets HIPAA and DHHS standards.

If a study is not yet fully developed and an IRB protocol application is not submitted, a Provisional Certification may be submitted to IRB@caltech.edu for review and signature.

In tandem with protocol review, the IRB Administrator will review the Institutional Certification and work with the submitting PI on any areas of concern. The IRB Administrator will obtain signature from the Institutional Official and return to the PI.

B. Cybersecurity Requirements

When investigators want to access covered data (e.g., de-identified phenotypes or genotypes for individual study participants) for research (including the creation of analytical tools for research), they will need to attest that the Caltech IT systems that are used to access and/or store this data meet the cybersecurity standard at NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations. Investigators should contact IMSS to confirm all NIH GDS cybersecurity requirements have been met. Developer requirements apply to individuals that receive NIH funding for management/development of NIH controlled access repositories.

The expectations for Caltech/PIs are as follows:

1. Perform self-assessment against NIST 800-171 criteria
2. Identify gaps
3. If there are gaps, develop a Plan of Action with Milestones under (POAM) which Caltech/PI use "best efforts" to resolve gaps and mitigate risk in a "timely manner without undue delay", with timeline based on risk.

4. POAM does not need to be provided to NIH unless requested