

PI GENOMIC DATA SHARING CERTIFICATION: JUST-IN-TIME STAGE

This form is designed to comply with the requirements of the National Institutes of Health Genomic Data Sharing Policy: <http://gds.nih.gov/>.

Following initial peer review and prior to award, potential grantee institutions will be asked to submit an Institutional Certification through the standard Just-in-Time (JIT) process. The responsible Institutional Signing Official in SPO will provide an Institutional Certification to the NIH funding Institute or Center after the Principal Investigator (PI) provides SPO with this signed PI Genomic Data Sharing Certification.

Note: If the research protocol involves generation of large-scale human genomic data as well as the use of these data for subsequent research, it will be necessary for the PI to obtain UC Berkeley's Institutional Review Board (IRB) approval of the research protocol before the Institutional Certification will be provided to NIH by SPO. See <http://cphs.berkeley.edu> for more information.

For information on the preparation of Informed Consent materials for new studies involving human genomic research as well as studies initiated prior to the effective date of the NIH GDS Policy, see <http://cphs.berkeley.edu/informedconsent.html>.

For further guidance, see <http://rac.berkeley.edu/gds.html>.

Principal Investigator Certification for:

Title of Study: _____

Phoebe Proposal Number: _____

I certify that:

1. This research will involve the generation of large-scale:
 - Human Genomic Data
 - Non-Human Genomic Data

2. Data produced by this research will be submitted to (please check all that apply):
 - An unrestricted access database
 - A controlled access database

3. I agree to all of the following Institutional Criteria:
 - Yes
 - No
 - a. The identities of research participants will not be disclosed to NIH-designated data repositories.
 - b. Data submission and subsequent data sharing for research purposes will be consistent with the informed consent of study participants from whom the data were obtained.
 - c. Any limitations on the research use of the data will be expressed in the informed consent documents I provide to human subjects, if applicable.
 - d. I will give consideration to the risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing;
 - e. I will give consideration to the risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing; and
 - f. I will de-identify datasets in a manner consistent with the standards outlined in the NIH Genomic Data Sharing Policy as described in NOT-OD-14-124.
 - g. If applicable, I will comply with the human subjects' protocol approved by Berkeley's Committee for Protection of Human Subjects in a manner consistent with 45 C.F.R. Part 46.
 - h. I will require no data use limitations

If you answered "No" above, please attach a justification for any data submission exceptions you will require.

PI Name: _____ Title: _____

PI Signature: _____ Date: _____