

Institutional Certification for Single Site Studies

Date: [MM/DD/YYYY]

Name of GPA

Genomic Program Administrator

_____, NIH, HHS

9000 Rockville Pike

Bethesda, MD 20892-7395

Re: Institutional Certification of _____ [NAME OF INSTITUTION] to Accompany
Submission of the Dataset from _____ [ORIGINAL STUDY NAME¹] for
_____ [PROJECT TITLE FOR DATA TO BE SUBMITTED] to an NIH-designated data repository.

Dear

The _____ hereby assures that submission of data from the study
entitled _____ to an NIH-designated data
repository meets the following expectations, as defined in the [Genomic Data Sharing Policy](#):

- The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.²
- Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 3.³
- The identities of research participants will not be disclosed to NIH-designated data repositories.
- An Institutional Review Board and/or Privacy Board, and/or equivalent body, as applicable, has reviewed the investigator's proposal for data submission and assures that:
 - The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46.⁴
 - Data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;⁵
 - Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing;
 - To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing; and
 - The investigator's plan for de-identifying datasets is consistent with the standards outlined in this Policy (see section IV.C.1.).

The data are to be made available through unrestricted⁶ or controlled-access⁷ (If unrestricted access is marked, the data use limitation table on page 2 does not need to be completed.)

The National Center for Biotechnology Information is authorized to upload the display of variant alleles and/or frequencies from this study in public variation archives (i.e., dbSNP and dbVar)⁸. Yes No

Sincerely,

Authorized Institutional Official:⁹

Name: _____ Title: _____

Signature: _____ Date: _____

Investigator:

Name: _____ Title: _____

Signature: _____ Date: _____

¹ Original Study Name should reflect the name of the original IRB-approved study (e.g. cohort or case-control study, clinical trial) under which participants provided informed consent and biospecimens were collected (e.g., Nurses' Health Study, Framingham Heart Study).

² For the submission of data derived from cell lines or clinical specimens lacking research consent that were created or collected before the effective date of this Policy, the Institutional Certification needs to address only this item.

³ For guidance on clearly communicating inappropriate data uses, see NIH Points to Consider in Drafting Effective Data Use Limitation Statements, http://gwas.nih.gov/pdf/NIH_PTC_in_Drafting_DUL_Statements.pdf

⁴ 45 CFR Part 46. Protection of Human Subjects. See <http://www.gpo.gov/fdsys/pkg/CFR-2013-title45-vol1/xml/CFR-2013-title45-vol1-part46.xml>

⁵ As noted earlier, for studies using data or specimens collected before the effective date of this Policy, the IRB, privacy board, or equivalent body should review informed consent materials to ensure that data submission is not inconsistent with the informed consent provided by the research participants.

⁶ Data made publicly available to anyone

⁷ Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.

⁸ The Single Nucleotide Polymorphism Database (dbSNP) is a public archive for genetic variation (apparently neutral polymorphisms, polymorphisms corresponding to known phenotypes, and regions of no variation) within and across species. The Database of Genomic Structural Variants (dbVar) is a collection of genomic structural variation data, typically 50 nucleotides in length or longer, for different organisms. For more information, see: http://www.ncbi.nlm.nih.gov/variation/dbSNP_dbVar_FAQ/.

⁹ A senior official at an institution who is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who plans to submit data to NIH, e.g., Dean, Vice President for Research.