



Intramural Submission Certification

For data generated from cell lines created or clinical specimens collected before August 31, 2015, that lack consent

Date: [MM/DD/YYYY]

To:
Genomic Program Administrator,

From:
Scientific Director,

Subject: 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.

The submission of data to the NIH-designated data repository is being made with institutional approval from _____, along with appropriate institutional approvals from collaborating sites, as listed here:

[IF APPLICABLE ENTER COLLABORATING SITE NAMES HERE AND CLICK 'ADD TO LIST'] **LIST OF COLLABORATING SITES**

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

Unless otherwise specified by _____ on page 2 of this certification, the data from this study may be made available for general research purposes without any further limitations on secondary research use.

The data are to be made available through unrestricted² or controlled-access³ (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)⁴.

¹ Certification must be provided for all sites contributing samples. If more than one site is contributing samples, the primary site may submit one Institutional Certification indicating that they are providing certification on behalf of all collaborating sites. Alternatively, each site providing samples may provide their own Institutional Certification.

Sincerely,

Investigator:

Name: _____ Title: _____

Signature: _____ Date: _____

Authorized Institutional Official:⁵

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 Data made publicly available to anyone

³ Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.

⁴ 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/.

⁵ 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.