Extramural Institutional Certification*

For studies using data generated from cell lines created or clinical specimens collected after January 25, 2015

Date: [MM/DD/YYYY]
Name of GPA Jonathan Pollock
Genomic Program Administrator
NIDA [, 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 NAME[1]] for _____ [PROJECT TITLE FOR DATA TO BE SUBMITTED] to an NIH-designated data repository.

Dear Jonathan Pollock,
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']

Add to list >>

LIST OF COLLABORATING SITES

Clear list

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;
  - 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 ☐ unrestricted[5] or ☒ controlled-access[6] (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)[7].

*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.

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For guidance on drafting data use limitations, please refer to the NIH Points to Consider in Drafting Effective Data Use Limitation Statements found at: http://gds.nih.gov/pdf/nih_ptc_in_drafting_dul_statements.pdf. Data use limitations are developed based on the original informed consent from the participant.

Data Use Limitations (will be used in dbGaP to create Consent Groups)

General Research Use	GRU	Use of the data is limited only by the terms of the Data Use Certification:these data will be added to the dbGaP Collection.
Health/Medical/Biomedical	HMB	Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Disease-specific [list disease]	DS	Use of the data must be related to the specified disease.
Other		[ENTER CUSTOMIZED TEXT, IF APPLICABLE]

Data Use Limitation Modifiers

IRB approval required	IRB	Requestor must provide documentation of local IRB approval.
Publication required	PUB	Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration required	COL	Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit use only	NPU	Use of the data is limited to not-for-profit organizations.
Methods	MDS	Use of the data includes methods development research (e.g., development of software or algorithms)
Genetic studies only	GSO	Use of the data is limited to genetic studies only.

Using the tables above, please indicate in the form below the consent group(s) for each collaborating study site. Use one row per consent group.

Collaborating Site Name	**Data Use Limitation**	**Data Use Limitation Modifiers**
Eg: Cold Cohort Study	*Health/Medical/Biomedical*	IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS ☐ GSO ☐
Eg: Cold Cohort Study	*Disease Specific Research* [*Lung Cancer*]	IRB ☒ PUB ☐ COL ☐ NPU ☒ MDS ☐ GSO ☐
	Select consent group title	IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS GSO
	Select consent group title	IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS GSO
	Select consent group title	IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS GSO
	Select consent group title	IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS GSO
	Select consent group title	IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS GSO
	Select consent group title	IRB ☐ PUB ☐ COL ☐ NPU ☐ MDS GSO

Sincerely,

Investigator:

Name: _____ Title:_____

Signature: _____ Date:_____

Authorized Institutional Official:[8]

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] Data made publicly available to anyone.

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

[7] 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 Varian (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/.

[8] 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.