

Intramural Institutional Certification*

For studies using data generated from cell lines created or clinical specimens before August 31, 2015

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 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 [NIH 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.
- Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table on page 3.
- The identities of research participants will not be disclosed to NIH-designated data repositories.
- An Institutional Review Board (IRB), 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](#);²
 - Data submission and subsequent data sharing for research purposes are not inconsistent 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, including unrestricted access to genomic summary results;
 - 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, including unrestricted access to genomic summary results; and
 - The investigator's plan for de-identifying datasets is consistent with the standards outlined in the [NIH Genomic Data Sharing Policy](#) (See section IV.C.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 its own Institutional Certification.

The individual-level data are to be made available through (check one)

controlled-access ³

unrestricted access ⁴

If **unrestricted access** is marked, the data use limitations table on the following page(s) does not need to be completed.

NIH provides genomic summary results⁵ (GSR) from most studies submitted to NIH-designated data repositories through unrestricted access. However, data from data sets considered to have particular ‘sensitivities’ related to individual privacy or potential for group harm (e.g., those with populations from isolated geographic regions, or with rare or potentially stigmatizing traits) may be designated as “sensitive” by

In such cases, “controlled-access” should be checked below and a brief explanation for the sensitive designation should be provided. GSR from any such data sets will only be available through controlled-access.

The genomic summary results (GSR) from this study are only to be made available through controlled-access.

Explanation if controlled-access was selected for GSR.

Institutional Certification

NIH expects the submitting institution(s) to select one of the three standard [Data Use Limitations](#) (DULs) for appropriate secondary use, or, if necessary, create a customized DUL. DULs are developed based on the original informed consent of the participant(s).

Data Use Limitations

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]

Additional modifiers to the standard DULs (e.g., Not-for-profit Use Only) can be indicated, if appropriate. Use of the modifiers should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population.

Data Use Limitation Modifiers (Optional)

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 and testing 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 table 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 (optional)					
<i>Eg: Cold Cohort Study</i>	<i>Health/Medical/Biomedical</i>	IRB <input type="checkbox"/>	PUB <input type="checkbox"/>	COL <input type="checkbox"/>	NPU <input type="checkbox"/>	MDS <input type="checkbox"/>	GSO <input type="checkbox"/>
<i>Eg: Cold Cohort Study</i>	<i>Disease Specific Research [_____]</i>	IRB <input type="checkbox"/>	PUB <input type="checkbox"/>	COL <input type="checkbox"/>	NPU <input checked="" type="checkbox"/>	MDS <input type="checkbox"/>	GSO <input type="checkbox"/>
		IRB <input type="checkbox"/>	PUB <input type="checkbox"/>	COL <input type="checkbox"/>	NPU <input type="checkbox"/>	MDS <input type="checkbox"/>	GSO <input type="checkbox"/>
		IRB <input type="checkbox"/>	PUB <input type="checkbox"/>	COL <input type="checkbox"/>	NPU <input type="checkbox"/>	MDS <input type="checkbox"/>	GSO <input type="checkbox"/>
		IRB <input type="checkbox"/>	PUB <input type="checkbox"/>	COL <input type="checkbox"/>	NPU <input type="checkbox"/>	MDS <input type="checkbox"/>	GSO <input type="checkbox"/>
		IRB <input type="checkbox"/>	PUB <input type="checkbox"/>	COL <input type="checkbox"/>	NPU <input type="checkbox"/>	MDS <input type="checkbox"/>	GSO <input type="checkbox"/>

Sincerely,

Investigator:

Name: _____ Title: _____

Signature: _____ Date: _____

Scientific Director/Designee:

Name: _____ Title: _____

Signature: _____ Date: _____

References

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. 45 CFR Part 46. Protection of Human Subjects. See <https://www.gpo.gov/fdsys/pkg/CFR-2013-title45-vol1/xml/CFR-2013-title45-vol1-part46.xml>.
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. Data made publicly available to anyone.
5. Genomic summary results are results from primary analyses of genomic research that convey information relevant to genomic associations with traits or diseases across datasets rather than data specific to any one individual research participant (e.g., genotype counts and frequencies; allele counts and frequencies; effect size estimates and standard errors; likelihoods; and p-values).