Extramural Institutional Certification*

OMB Control Number: 0925-0670
Expiration Date: July 2019

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

Date: [MM/DD/YYYY] Today's Date
Name of GPA: Find the name of your Genomic Program Administrator
Genomic Program Administrator
Select IC [, NIH, HHS Typically this is "NCI", but it is referenced in JIT request
9000 Rockville Pike
Bethesda, MD 20892-7395

Re: Institutional Certification of Your institution name [NAME OF INSTITUTION] to Accompany Submission of the Dataset from DF/HCC protocol number under which you are enrolling patients [ORIGINAL STUDY NAME[1]] for Enter grant title [PROJECT TITLE FOR DATA TO BE SUBMITTED] to an NIH-designated data repository.

Dear , *Your Name of GPA will auto-populate*
The submission of data to the NIH-designated data repository is being made with institutional approval from *Your Institution name will auto-populate*, 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*

Add any protocol numbers or collaborating institutions associated with your study (will auto-populate Table on page 2)

Add to list >> Clear list

The *Your Institution name will auto-populate* hereby assures that submission of data from the study entitled *Your grant title will auto-populate* 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 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, 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] ← *DFCI and NCI strongly recommend selecting "controlled access". Therefore, you must fill out Table on page 2*
- ( ) **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 results[5] (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.**

If you have a sensitive population (for example: Pediatric, HIV positive, or other identifiable cohort) you may want to select "controlled-access"

Explanation if controlled-access was selected for GSR.

Write justification here.

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.

It is highly recommended to work with your GPA to determine which of these needs to be dictated

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)**
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☐
Populated from page 1	Select consent group title OHRS will determine this	IRB☐ OHRS will determine this 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: *List the Principal Investigator's name* Title: *Principal Investigator*

Signature: **Validate and sign...** Date: *Date signed by PI*

PIs signs this once returned by OHRS

Institutional Signing Official:[6]

By signing below, I certify on behalf of
that, in addition to myself, an IRB or Privacy Board or equivalent body, as applicable, and other relevant senior-level institutional staff (e.g., Dean, Vice President/Provost for Research, Chief Science Officer) have reviewed the requirements in this certification and agree that the submission meets them.

Name: *Institutional Signing Official (ISO)* 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).

6. Under the NIH Genomic Data Sharing Policy, an Institutional Signing Official is generally a senior official at an institution who is credentialed through the NIH eRA Common system and is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who has submitted data or a data access request to NIH.