

# EXTRAMURAL INSTITUTIONAL CERTIFICATION\*

*Institutional Certification for studies using data generated from cell lines created or clinical specimens collected BEFORE January 25, 2015, that LACK CONSENT*

Date: [MM/DD/YYYY]

Name of GPA: \_\_\_\_\_

Genomic Program Administrator(GPA)

\_\_\_\_\_, National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS)

RE: Institutional Certification of \_\_\_\_\_ [NAME OF INSTITUTION] to Accompany  
Submission of the Dataset from \_\_\_\_\_ [ORIGINAL STUDY NAME<sup>1</sup>] for  
\_\_\_\_\_ [PROJECT TITLE FOR DATA TO BE SUBMITTED] to  
an NIH-designated repository.

To the National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS):

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". IF MORE THAN FOUR (4) COLLABORATING SITES ARE INVOLVED, COMPLETELY FILL OUT AVAILABLE ENTRIES AND FORM WILL THEN CREATE ENTRIES FOR ADDITIONAL SITES]

COLLABORATING SITE NAME

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 \(GDS\) Policy](#) (NIH Guide  
Notice Number NOT-OD-14-124):

- The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.

\* 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.

## Availability of Individual-Level Human Data

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

Controlled-access<sup>2</sup>

Unrestricted access<sup>3</sup>

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

**Is the individual-level, human genomic data to be submitted** funded in whole or in part by NIH?

YES

NO

IMPORTANT: If your research involves the generation of individual-level, human genomic data and is funded in whole or in part by NIH, your research is automatically deemed to be issued a Certificate of Confidentiality (CoC). For more information, see [the NIH Certificates of Confidentiality webpage](#).

**Is the individual-level, human genomic data to be submitted covered by a CoC?**

YES

NO

## Availability of Genomic Summary Results (GSR)

NIH provides genomic summary results<sup>4</sup> (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 \_\_\_\_\_ and public posting would be prohibited.

In such cases, “controlled access” should be checked below and a brief explanation for the sensitive designation should be provided. GSR from any such study will only be available through controlled access and public posting would be prohibited.

Controlled access

**If “controlled access” is checked, include a brief explanation for the sensitive designation.**

**If GSR are designated as sensitive and “controlled access” is checked above, are the GSR covered under (or have been issued) a CoC?**

YES

NO

Note: If GSR are designated as sensitive and available only via controlled access, they may be subject to the [NIH Certificates of Confidentiality Policy](#) if there is at least a very small risk the individuals included in the summary results may be re-identified.

## Institutional Certification Data Use Limitations (DUL)

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 <a href="#">dbGaP Collection</a> .
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"/>

**SIGNATURE PAGE FOR THIS INSTITUTIONAL CERTIFICATION**

**SUBMITTED AND AGREED TO BY:**

**Investigator:**

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Institutional Signing Official:<sup>5</sup>**

By signing below, I certify on behalf of that, in addition to myself, an IRB or Privacy Board or equivalent body, 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: \_\_\_\_\_ Title: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Certification are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).**

## 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. Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.
3. Data made publicly available to anyone.
4. For the purposes of the NIH Genomic Data Sharing (GDS) Policy, genomic summary results (GSR) are defined to include those provided by a study's investigator, if any, as well as summary statistics that may be computed by relevant NIH-designated data repository across all non-"sensitive" studies with data included in that repository. GSR include systematically computed statistics such as, but not limited to: 1) frequency information (e.g., genotype counts and frequencies, or allele counts and frequencies); and 2) association information (e.g., effect size estimates and standard errors, and p-values) ([NIH Guide Notice NOT-OD-19-023](#)).
5. Under the NIH Genomic Data Sharing (GDS) Policy, an Institutional Signing Official is generally a senior official at an institution who is credentialed through the NIH eRA Commons system and is authorized to enter the institution into a legally binding contract and sign on behalf of the institution and the investigator who has submitted data or a data access request (DAR) to NIH.

**OMB Control Number: 0925-0670**

**Expiration Date: May 31, 2029**

Public reporting burden for this collection of information is estimated to vary from 15 to 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925- 0670). Do not return the completed form to this address.