EXTRAMURAL INSTITUTIONAL CERTIFICATION*

OMB Control Number: 0925-0670
Expiration Date: March 31, 2026

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

Date: [MM/DD/YYYY] 03/27/2023
Name of GPA: _____
Genomic Program Administrator(GPA)
Select IC [, 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[1]] 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

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 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.
- Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated in the table for Institutional Certification Data Use Limitations (DUL) in this document.
- 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. (45 CFR Part 46. Protection of Human Subjects);
    - 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 (GDS) 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.

Availability of Individual-Level Human Data

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

- (●) Controlled-access[2]
- ( ) Unrestricted access[3]

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[4] (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 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)**
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

SIGNATURE PAGE FOR THIS INSTITUTIONAL CERTIFICATION

SUBMITTED AND AGREED TO BY:

Investigator:

Name: _____ Title:_____

Signature: Validate and sign... Date: 03/27/2023

Institutional Signing Official:[5]

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: Validate and sign... Date: 03/27/2023

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.

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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.