Data Submission Certification

INTRODUCTION

The Data Submission Certification describes terms and conditions of data submission to NIH controlled-access data repositories for data not subject to the NIH Genomic Data Sharing (GDS) Policy. Studies subject to the NIH GDS Policy should submit an Institutional Certification for submission of large-scale human genomic data to a NIH-designated repository. This Data Submission Certification cannot be used for the submission of Limited Data Sets.

DATA SUBMISSION CERTIFICATION TERMS AND CONDITIONS

Data submission to the NIH controlled-access data repository is being made with institutional approval from the primary institution, [Name of Institution], for the study or project entitled [study or project name], funded by [insert funder name and grant number]. Non-NIH funded submissions are not expected to provide funding information.

If additional data are expected to be submitted to [study or project name] from other institutions, the primary institution may submit one Data Submission Certification on behalf of all institutions. Alternatively, each institution may submit a Data Submission Certification using the same study or project name and funding information, if applicable.

[Name of Primary Institution] (hereby referred to as "Submitting Institution"), and any other collaborating institution involved in the submission of data, hereby assures that submission of data from the study entitled [name of study] to the NIH controlled-access data repository meets the following expectations:

- That the data was collected in a manner consistent with all applicable national, Tribal, and state laws and regulations as well as relevant institutional policies.
- That submission of the data is consistent with applicable national, Tribal, and state laws and regulations as well as relevant institutional policies.
- That expectations with explicit limitations on subsequent use, such as those imposed by laws, regulations, policies, informed consent, and agreements, as applicable, or as otherwise determined by the Submitting Institution, will be delineated in the table for Data Use Limitations (DUL) in this document.
- That metadata and supporting information, materials, and documentation to adequately describe and facilitate interpretation will be submitted to NIH controlled-access data repositories at submission.
- That different offices or components of an institution with appropriate roles and expertise (such as an Institutional Review Board (IRB), Privacy Board, or equivalent body) has reviewed the investigator's proposal for data submission and assures that:
    - That submission for subsequent sharing and use of the data for research purposes is consistent with explicit limitations on subsequent use, such as those imposed by laws, regulations, policies, informed consent, and agreements, or as otherwise determined by the Submitting Institution.".

- That the submitted data has been de-identified to the extent required by the NIH controlled-access data repository, applicable laws, regulations, and NIH policies.
- That consideration has been given to risks to individual participants and their families associated with data submitted to NIH controlled-access data repositories and subsequent sharing.
- That consideration has been given to risks to groups or populations associated with submitting datasets to NIH controlled-access data repositories and subsequent sharing.

Does the information to be submitted include **identifiable, sensitive information**?

☐Yes ☐No

IMPORTANT: Research in which identifiable, sensitive information is collected or used includes research that:

- Meets the definition of human subjects' research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46)), including exempt research in which participant information cannot be identified or their identity cannot readily be ascertained, directly or through identifiers;
- Is collecting or using human biospecimens that are identifiable or that have at least a very small risk of being used to deduce the identity of an individual;
- Involves the generation or use of individual level human genomic data from biospecimens, regardless of identifiability; or
- Involves any other information where there is at least a very small risk that a person could be identified.

Is the identifiable, sensitive information to be submitted covered by a CoC?

☐Yes ☐No

IMPORTANT: Note that research subject to the NIH Certificates of Confidentiality Policy that involves the generation, collection, or use of identifiable, sensitive information that is funded in whole or in part by NIH is automatically deemed to be issued a Certificate of Confidentiality (CoC). For more information, see the NIH Certificates of Confidentiality webpage.

Data Submission Certification Data Use Limitations (DULs)

NIH expects the Submitting Institution and any other collaborating institution involved in the submission of data, through those with appropriate expertise and institutional role to select one of the three standard Data Use Limitations (DULs) for appropriate secondary use, or, if necessary, create a customized DUL.

Data Use Limitations

General Research Use	GRU	Use of the data is limited only by the terms of the Data Use Agreement
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, indicate in the table below the consent group(s) for each Submitting Institution. Use one row per consent group.

Collaborating Submitting Institution Name	Data Use Limitation (GRU, HMB, DS, Other)	Data Use Limitation Modifiers (optional)					
		IRB □	PUB □	COL □	NPU □	MDS □	GSO □
		IRB □	PUB □	COL □	NPU □	MDS □	GSO □
		IRB □	PUB □	COL □	NPU □	MDS □	GSO □
		IRB □	PUB □	COL □	NPU □	MDS □	GSO □

Data Submission Certification Signature Page

Submitted and Agreed to By:

Investigator:

Name: _____

Title: _____

Signature: _____

Date: _____

Institutional Signing Official:

By signing below, I certify on behalf of (Name of Submitting Institution) that I have reviewed the terms and conditions in this certification and agree that the submission meets them.

Name: _____

Title: _____

Signature: _____

Date: _____

OMB control Number: 0925-0670

Expiration Date: March 31, 2026