Attachment 2: Documentation of the Institutional Certification form, including changes since 2019 PRA approval

Submitting Investigator

OMB Control Number: 0925-0670
Expiration Date: November 30, 2022

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.

EXTRAMURAL INSTITUTIONAL CERTIFICATION*

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

Date: [MM/DD/YYYY] _____
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] [LIST OF COLLABORATING SITES]
ADD TO LIST 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 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

Form is now addressed to NIH/HHS instead of a GPA

Submitting Investigator

Availability of Individual-Level Human Data

The individual-level human 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.

[_____EXPLANATION_____]

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.

2 new questions added related to Certificates of Confidentiality and individual-level data

New language added prohibiting public posting in certain instances

Added new question & note regarding Certificates of Confidentiality for sensitive genomic summary results

Submitting Investigator

SIGNATURE PAGE FOR THIS INSTITUTIONAL CERTIFICATION

SUBMITTED AND AGREED TO BY:

Investigator:

Name: _____

Title: _____

Signature: _____

Date: _____

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: _____

Date: _____

Added a warning against making false or misleading statements

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.

Reference #4 has been rewritten for clarity, but no content changed

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Submitting Investigator

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New form created for submitting investigators who are waiting for IRB approval

PROVISIONAL INSTITUTIONAL CERTIFICATION

Date: [MM/DD/YYYY] _____
Name of GPA: _____
Genomic Program Administrator (GPA)
_____ [Select IC], National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS)

RE: Provisional Institutional Certification of _____ [Name of Institution] for _____ [NAME OF STUDY/TITLE OF GRANT, GRANT OR PROPOSAL NUMBER] as part of an expectation of the NIH Genomic Data Sharing (GDS) Policy.

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

This Provisional Certification is being provided pending submission of the Institutional Certification and is to accompany the Just-in-Time (JIT) information submitted for the above-referenced _____, [NAME OF STUDY] from _____ [NAME OF PI], as part of an expectation of the NIH Genomic Data Sharing (GDS) Policy (NIH Guide Notice Number NOT-OD-14-124) because _____ [REASON(S) WHY CERTIFICATION ELEMENTS CANNOT BE MET, E.G., IRB HAS NOT YET GRANTED FINAL APPROVAL][i]

This document serves as an assurance from _____ that future data sharing outlined in the data management and sharing plan addressing genomic data sharing submitted by _____ for _____ will be consistent with the elements delineated in an Institutional Certification that will be submitted to the NIH by _____ [MM/DD/YYYY].[ii]

Form continues on next slide

Submitting Investigator

SIGNATURE PAGE FOR THIS PROVISIONAL INSTITUTIONAL CERTIFICATION

SUBMITTED AND AGREED TO BY:

Investigator:

Name: _____

Title: _____

Signature: _____

Date: _____

Institutional Signing Official[iii]

By signing below, I certify on behalf of _____ that the investigator and our institution are unable to provide assurances to the criteria of the Institutional Certification at Just-in-Time and will follow-up with a completed Institutional Certification at the appropriate time.

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).

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[i] This document is intended to be used as needed on a case-by-case basis where the submitting institution, at the time of Just-in-Time, is unable to provide assurance to the elements of the formal Institutional Certification. An example of when a provisional Institutional Certification would be used would be for a prospective study where the Institutional Review Board

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Form continues on next slide

Submitting Investigator

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(IRB) has not completed its review of the protocol and therefore the institution cannot attest to all of the elements of the formal Institutional Certification. In such situations, this provisional Institutional Certification will be submitted until a formal Institutional Certification can be provided.

[ii] https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/about-institutional-certifications

[iii] 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.