# NICHD DATA AND SPECIMEN HUB (DASH)

# INSTITUTIONAL CERTIFICATION (IC) FORM

## For Data and/or Biospecimen Catalog Submission

**OMB Control Number:** 0925-0744
**Expiration Date:** 07/31/2027

*All data and biospecimen catalog submissions to NICHD DASH must be accompanied by an Institutional Certification from the submitting institution.*

STUDY NAME:

GRANT/AWARD NUMBER:

STUDY PRINCIPAL INVESTIGATOR/S:

DATA AND/OR BIOSPECIMEN CATALOG SUBMITTING INSTITUTION INVESTIGATOR:

DATA AND/OR BIOSPECIMEN CATALOG SUBMITTING INSTITUTION:

This Institutional Certification assures that:

1. The data and/or biospecimen catalog was or will be collected in a manner consistent with all applicable national, Tribal, and state laws and regulations as well as relevant institutional policies.
2. Submission of the data and/or biospecimen catalog is consistent with applicable national, Tribal, and state laws and regulations as well as relevant institutional policies.
3. 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 at submission.
4. Metadata and supporting information, materials, and documentation to adequately describe and facilitate interpretation will be submitted to NICHD DASH at submission.
5. Different offices or components of an institution with appropriate roles and expertise (such as an Institutional Review Board (IRB), Privacy Board, Human Research Protection Program (HRPP), or equivalent body) has reviewed the investigator's proposal for data and/or biospecimen catalog submission and assures that:
    a. Submission for subsequent sharing and use of the data and/or biospecimens 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, such as an IRB determination of exemption or waiver of consent.
    b. The submitted data and/or biospecimen catalog has been or will be de-identified to the de-identification standards outlined in the NICHD DASH Policy, applicable laws, regulations, and NIH policies.
    c. Consideration has been given to risks to individual participants and their families associated with data and/or biospecimens submitted to NICHD DASH and subsequent sharing.
    d. Consideration has been given to risks to groups or populations associated with submitting datasets and/or biospecimen catalog to NICHD DASH and subsequent sharing.
6. The identities of research participants will not be disclosed to NICHD DASH.
7. The Data and/or Biospecimen Catalog Submitting Institution will be responsible for informing the NICHD DASH Administrator if they become aware that data or biospecimen/s will need to be removed from NICHD DASH for any reason, such as change in informed consent.
8. The Data and/or Biospecimen Catalog Submitting Institution will not be responsible if research participant identities are inadvertently revealed after submission to NICHD DASH.
9. The Data and/or Biospecimen Catalog Submitting Institution approves, if applicable, to share with NICHD DASH the cross-walk file linking de-identified participant codes in the data and biospecimen catalog submission

**Are there any limitations on secondary use of the data or biospecimens based on the original informed consent of the participant or other legal requirements?**

☐ **Yes** ☐ **No**

**If yes, please specify limitations:**

**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 except for human subjects 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 Certificate of Confidentiality?**

☐ **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.

☐ **I certify to the best of my knowledge that the information submitted here is accurate.**

**Signature of Investigator: _____**
(Data and/or Biospecimen Catalog Submitting Institution)

Name: _____

Title: _____

Date: _____

**Signature of Authorized Organizational Representative (AOR)/ Signing Official (SO): _____**
(Data and/or Biospecimen Catalog Submitting Institution)

Name: _____

Title: _____

Date: _____