Attachment A.2-3 – Institutional Certification Template (Approved OMB Number: 0925-0744)

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

NICHD DATA AND SPECIMEN HUB (DASH) INSTITUTIONAL CERTIFICATION

For Data and/or Biospecimen Catalog Submission

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

STUDY NAME:

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 to be submitted to NICHD DASH were collected in a manner consistent with 45 CFR 46.
2. ☐ The data and/or biospecimen catalog submission to NICHD DASH are consistent with all relevant institutional policies and applicable local, state, tribal, and Federal laws and regulations[i].
3. ☐ The study was conducted and the study data and/or biospecimen catalog will be prepared for submission in alignment with NICHD DASH submission policies.
4. ☐ The plan to de-identify the study data and/or biospecimen catalog is consistent with the de-identification standards outlined in the NICHD DASH Policy.
5. ☐ The identities of research participants will not be disclosed to NICHD DASH.
6. ☐ Any limitations to the use of data and biospecimens submitted to NICHD DASH are consistent with the informed consent and will be delineated during the data and/or biospecimen catalog submission process.
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 has considered the risks to individuals, their families and groups or populations associated with the data and/or biospecimen catalog that will be submitted to NICHD DASH.
10. ☐ 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 submissions.
11. Based on your study, select the option/s below that are applicable:
    a. ☐ The study was conducted under an IRB determination of exemption or waiver of consent.
    b. ☐ There is specific language describing sharing in the original consent AND/OR an IRB, Privacy Board, and/or equivalent body, as applicable, has reviewed the consent and determined that the data and/or biospecimens can be shared for research purposes[ii].

☐ **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)

Date :

Name:

Title:

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

Date :

Name:

Title:

[i] Applicable Federal regulations may include HHS human subjects regulations (45 CFR Part 46), FDA human subjects regulations (21 CFR Parts 50 and 56), and the Health Insurance Portability and Accountability Act Privacy Rule (45 CFR Part 160 and Part 164, Subparts A and E) and any laws applicable to the Institution.
[ii] For retrospective (older) studies where the participant consent form does not explicitly state broad data or biospecimen sharing, an IRB, Privacy Board, and/or equivalent body, as applicable, must determine whether the data and/or biospecimen catalog can be submitted to NICHD DASH.