OMB Control No: 0925-0744
Expiration Date: xx/xx/xxxx

0925-0744-NEW_DASH_ATTACHMENTA.2-3_INSTITUTIONAL CERTIFICATION TEMPLATE

NICHD DATA AND SPECIMEN HUB (DASH) INSTITUTIONAL CERTIFICATION TEMPLATE

For Data and Biospecimen Inventory Submission

All data and biospecimen inventory submissions to NICHD DASH should be accompanied by a completed Institutional Certification from responsible Institutional Official(s) of the submitting institution.

STUDY NAME:

STUDY PERFORMANCE SITE PRINCIPAL INVESTIGATOR/S: Name

DATA AND BIOSPECIMEN INVENTORY SUBMITTING INSTITUTION PRINCIPAL INVESTIGATOR: Name

DATA AND BIOSPECIMEN INVENTORY SUBMITTING INSTITUTION: Name and address

This Institutional Certification assures that:

1. ☐ The named Study Performance Site Investigator(s) and any co-investigator/s conducted the study and cooperated with NICHD DASH submission policies.
2. ☐ Data and biospecimen inventory submitted to NICHD DASH is consistent with all applicable Federal and state laws and regulations[i], as well as relevant institutional and study policies of the Data Submitting Institution.
3. ☐ The data and biospecimens to be shared were collected in a manner consistent with

   45 CFR 46.
4. ☐ The Data and Biospecimen Inventory Submitting Institution's Principal Investigator has de-identified the study data and the biospecimen inventory consistent with the 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 documents have been delineated during the

Public reporting burden for this collection of information is estimated to average five 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- 0744). Do not return the completed from to this address.

data and biospecimen inventory submission process.

7. ☐ The Study Performance Site Investigator(s) will be responsible for informing the NICHD DASH Administrator if the investigator becomes 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 Biospecimen Inventory Submitting Institution and Investigator will not be responsible if research participant identities are inadvertently revealed after submission to NICHD DASH.

9. ☐ The Data and Biospecimen Inventory Submitting Institution has considered the risks to individuals, their families and groups or populations associated with data and biospecimen inventory submitted to NICHD DASH.

10. ☐ The Data and Biospecimen Inventory Submitting Institution approves, if applicable, to share the cross-walk file linking the de-identified codes to the original participant codes with NICHD DASH.

11. Based on your study, select the option/s below that are applicable:

    a. ☐ The study was conducted under a waiver of consent ruling from the study IRB.

    b. ☐ An IRB and/or Privacy Board, as applicable, reviewed and verified that sharing of the data and biospecimens for research purposes is consistent with the informed consent of study participants from whom the data and biospecimens were obtained[ii].

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

Signature of Principal Investigator **Date**
(Data and Biospecimen Inventory Submitting Institution)

Name:

Title:

Signature of Authorized Organizational Representative/ Institutional Representative **Date**
(Data and Biospecimen Inventory Submitting Institution)

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 State laws applicable to the Data Submitting Site.

[ii] For retrospective (older) studies where the participant consent form does not explicitly state broad data sharing, the IRB will determine whether the data can be submitted to NICHD DASH.