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THE CUSTOMIZED MTA FOR EXECUTION WILL BE GENERATED DURING THE BIOSPECIMEN REQUEST PROCESS

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

DATA AND SPECIMEN HUB (DASH)

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement (the "MTA") is by and between

The *Eunice Kennedy Shriver* National Institute of

Child Health and Human Development ("NICHD"),

(NICHD Division Director/Designee)

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and

(The "Recipient Institution," which is signing on behalf of its employee, the "Recipient"),

and is effective as of the date of the last signature affixed hereto (the "MTA Effective Date").

This MTA refers to the transfer of biological specimens from the study listed below stored in the NICHD Contracted Biorepository, heretofore referred to as the NICHD Biorepository (currently, held under contract by Fisher BioServices [Contractor]), to approved institutions for research purposes as further defined below.

Biospecimens requested from the NICHD DASH Study: [*Name will be automatically added by NICHD DASH system during the request process***]**

I. INTRODUCTION

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) established the NICHD Data and Specimen Hub (DASH) as a data sharing mechanism that enables investigators to organize, store, and access de-identified data from NICHD-funded research studies for secondary research use. Many of these studies also involved collection of biospecimens that have been stored in the NICHD Biorepository. To facilitate access to biospecimens stored in the NICHD Biorepository, NICHD DASH will store and provide the biospecimen catalog for studies that have associated research data in NICHD DASH.

Biospecimens made available through NICHD DASH are stripped of individually identifiable information as defined by the Department of Health and Human Services (HHS) Regulations for the Protection of Human Subjects[1] and in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule[2]. All biospecimens accessible through NICHD DASH have been assigned the same random, unique code as the associated data stored in NICHD DASH.

NICHD has established policies and processes designed to make these biospecimens available through NICHD DASH under appropriate terms and conditions to qualified investigators. NICHD requires the Recipient to read and understand and sign this Material Transfer Agreement (MTA) and their institutions to acknowledge and agree to abide by the terms and conditions of this NICHD DASH MTA as a condition of access. A requester who is granted access to biospecimens must adhere to the specifications of this MTA as executed in its final form. Failure to do so shall result in denial of further access by the Recipient Institution to biospecimens available through NICHD DASH.

II. DEFINITIONS

The following definitions apply for purposes of this MTA:

"Affiliates" are individuals within the same institution as the Recipient, for whom access to Biospecimens is required to carry out the Research Plan. They must read and understand the terms and conditions executed by the Recipient Institution who is the subject of this MTA and are not required to submit a separate Biospecimen Request Form or sign a separate MTA with NICHD. Please see Section III below for roles and responsibilities of an Affiliate.

"Biospecimens" refer to biological specimens and/or derivatives collected from participants in research studies that are available through NICHD DASH. Biospecimens are subject to release to the Recipient, according to the criteria laid out in the NICHD DASH Policy, which includes the execution of a NICHD DASH MTA, approval by the NICHD DASH Biospecimen Access Committee, and, if applicable, by study-specific entities.

"Biospecimen Request Form" is the online form completed by the Requester during the Biospecimen request process in NICHD DASH.

"NICHD DASH Administrator" is the NICHD representative who interfaces with NICHD DASH users and manages Biospecimen requests.

"Recipient" is the lead individual who receives access to the Biospecimens on behalf of the Recipient Institution. The Recipient may share access to the Biospecimens only with individuals who are listed in *Appendix A* as Requester and Affiliates. Please see Section III below for roles and responsibilities of a Recipient.

"Recipient Institution" is an institution, e.g., a non-profit or for-profit organization or corporation, which is the employer of the Recipient. The Recipient Institution must comply with applicable human subjects protection rules and regulations, as detailed under Section 8.

"Requester" may or may not be the same individual as the Recipient of the Biospecimens. If not the same individual as the Recipient, the Requester must be from the same institution as the Recipient and must be delegated by the Recipient to submit the Biospecimen request online in the NICHD DASH system. The Requester is permitted to obtain Biospecimens on behalf of the Recipient from NICHD DASH. The Requester is identified in *Appendix A*. Please see Section III below for roles and responsibilities of a Requester.

"Research Plan" is a description of the proposed research that serves as the basis for the Biospecimen access request. The Research Plan must include the title of the Research Project, description of the research need (study aims/goals, hypothesis that will be tested, study design, methodology to be used, and an analytic plan with the expected outcomes).

"Study" is the research study that collected the Biospecimens described in this MTA.

"Submitter" is an investigator who has deposited the Biospecimens in the NICHD Biorepository for sharing via NICHD DASH.

[1] 45 CFR 46.102(e): https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr46_main_02.tpl

[2] 45 CFR 164.514(b)(2). The list of HIPAA identifiers that must be removed is available at: https://www.ecfr.gov/cgi-bin/text-idx? SID=e5b0f4d4196a2ff12cb6eff228d36ffb&mc=true&node=se45.1.164_1514&rgn=div8

III. ROLES AND RESPONSIBILITIES

Below is a list of general responsibilities based on the roles specified in this MTA. Additional responsibilities pertaining to the terms and conditions of the MTA are incorporated directly into the MTA.

Roles	Responsibilities
Affiliates	• Are from the same institution as the Recipient • Can access Biospecimens from the Recipient • Must use the Biospecimens for the same Research Plan as the Recipient who is the subject of this MTA • Must read and understand the terms of this MTA executed by the Recipient Institution
NICHD	• Execute the NICHD DASH MTA with the Recipient Institution • Provide access to the Biospecimens in the NICHD Biorepository upon the Recipient Institution executing the NICHD DASH MTA
NICHD DASH Administrator	• Communicates with the Recipient regarding any applicable terms and conditions pertinent to the MTA
Recipient	• Must read and understand and sign the MTA executed by the Recipient Institution • Share the Biospecimens only with individuals who are included as the Requester (if not the same individual as the Recipient) in *Appendix A* and with Affiliates • Must not share Biospecimens received from the NICHD Repository based on this MTA with anyone outside the Recipient Institution • Oversee the Requester (if not the same individual as the Recipient) and Affiliates who are provided access to the Biospecimens • Maintain compliance with the human subjects protection requirements, if applicable, under 45 CFR 46 and local rules • Contribute to the analytic effort and public disclosure of study results • Delegate authority, as needed, to an individual identified as Requester from the same institution to perform administrative functions within the DASH system (complete request process and submit biospecimen use annual report) • Must be registered in DASH
Recipient Institution	• Execute the MTA with NICHD • Acknowledge and agree to abide by the terms of the executed MTA • Assume responsibility for the compliance of the Recipient, Requester (if not the same individual as the Recipient), and Affiliates with the terms and conditions of this MTA • Maintain compliance with the human subjects protection requirements, if applicable, under 45 CFR 46 and local rules

Roles	Responsibilities
Requester (if not the same individual as the Recipient)	• May or may not be the same individual as the Recipient of the Biospecimens • Must be from the same institution as the Recipient and must be delegated by the Recipient to submit the Biospecimen request online in the NICHD DASH system • Allowed to perform administrative functions within the DASH system (complete request process and submit biospecimen use annual report) • Can access Biospecimens from the Recipient. • Must use the Biospecimens for the same Research Plan as the Recipient who is the subject of this MTA • Must read and understand the terms of the MTA executed by the Recipient Institution • Must register in NICHD DASH

IV. TERMS AND CONDITIONS

The Recipient Institution requests approval for the Recipient to obtain the Biospecimens listed in Appendix B from the study listed below, stored in the NICHD Biorepository, for purposes of the Research Plan, which is specified in the NICHD DASH online Biospecimen Request Form and incorporated herein by reference.

Biospecimens requested from the NICHD DASH Study: [*Name will be automatically added by NICHD DASH system during the request process***]**

The Recipient Institution agrees to the following terms:

1. Non-Transferability of Agreement

This MTA is not transferable. There are no third-party beneficiaries to this MTA. Any other individual that wishes to receive Biospecimens from the NICHD Biorepository is required to execute a separate MTA.

The following situations are examples of when the execution and approval of a new MTA is required:

a. Any substantive change to the scope of the Research Plan.

b. The appointment of another Recipient to complete the Research Plan.

c. Change to the Recipient Institution.
Note: If the Recipient wishes to retain access to the Biospecimens but has changed the institution under which this MTA was executed, a new MTA in which the new institution acknowledges and agrees to comply with the provisions of the MTA is necessary. The Recipient must notify the NICHD DASH Administrator about a change of institution within 30 days of starting at the new institution.

2. Approved Parties for Access to Biospecimens

The NICHD authorizes the Recipient and the Requester (if not the same individual as the Recipient) identified in *Appendix A*, and Affiliates (if any) to access the Biospecimens. The Recipient Institution must ensure that the Recipient and the Requester (if not the same individual as the Recipient), listed in *Appendix A* and all Affiliates read and understand the terms of this MTA.

3. Non-Distribution of Biospecimens

The Recipient Institution will retain control over the Biospecimens, and further, will not sell the Biospecimens, in any form, to any entity or individual and will not distribute the Biospecimens to anyone except those authorized under this MTA to access the Biospecimens. For clarity, the Recipient will not transfer any Biospecimens obtained or accessed under this MTA to individuals or organizations not specified in this MTA, except as required by law.

4. Research Use of the Biospecimens

Biospecimens obtained from the NICHD Biorepository listed in *Appendix B* will be used by the Recipient, the Requester (if not the same individual as the Recipient), and Affiliates for studies and analysis specifically indicated and described in the Research Plan specified in the NICHD DASH Biospecimen Request Form and incorporated herein by reference, in accordance with the following:

a. The Recipient agrees that Biospecimens will not be used in any research that is not approved by the NICHD DASH Biospecimen Access Committee as part of the Research Plan.

b. The Recipient Institution must submit a separate and completed MTA for each Research Plan for which Biospecimens are requested.

5. IRB Approval for Biospecimen Use

The Recipient Institution and Recipient are responsible for obtaining, or have obtained and provided documentation of, all necessary Institutional Review Board (IRB) research approvals or exemptions, if required by the Biospecimen Submitter, to use the Biospecimens at the Recipient Institution. The Biospecimens will be used by the Recipient Institution in compliance with all applicable Federal, state, and local statutes and regulations. Access to Biospecimens from some studies requires compliance with other limitations, as indicated in the Biospecimen Request Form, and the Recipient Institution agrees to ensure compliance with all such conditions and limitations.

6. Prohibition on Identification of Subjects

Anyone using or accessing the Biospecimens or their associated data must not attempt to establish the individual identities of any of the individuals from whom Biospecimens were obtained. In the event anyone discovers, or is able to deduce, the identity of a specific individual, the Recipient Institution or Recipient must immediately notify the NICHD DASH Administrator and suspend the use of the Biospecimens until further approval can be obtained. The notification must be in writing and within five (5) business days of the discovery of any unauthorized use or disclosure of identifying information related to the Biospecimens of which the Recipient, the Requester (if not the same individual as the Recipient), and/or the Affiliates become aware. The Recipient Institution shall take (i) prompt corrective action to cure any deficiencies or (ii) any action pertaining to such unauthorized disclosure required by applicable federal law.

In the event anyone discovers, or is able to deduce, the identity of a specific individual, or any associated information (such as clinically significant information), that person shall not reveal the individual's identifying information, or any associated information, to any person or attempt to contact the individual. However, it is acknowledged that the Recipient Institution and Recipient may already possess or will obtain from another source, identifying information related to the Biospecimens, and so the Recipient Institution may be subject to additional restrictions or obligations or even alternative permissions under separate agreements.

7. Certificate of Confidentiality

Biospecimen related information residing in NICHD DASH are protected by a Certificate of Confidentiality pursuant to section 301(d) of the Public Health Service Act. The Certificate of Confidentiality prohibits disclosure of identifiable, sensitive information collected or compiled during research unless disclosure is made pursuant to a statutory exception. The Certificate of Confidentiality also protects all copies of identifiable, sensitive information. The Recipient Institution will comply with the requirements of the Certificate of Confidentiality as explained in the NIH Policy for Issuing Certificates of Confidentiality[3].

8. Compliance with the Recipient's Institutional Requirements

The Recipient Institution will comply with all applicable rules for the protection of human subjects, which may include HHS regulations at 45 CFR Part 46, the U.S. Food and Drug Administration regulations at 21 CFR Parts 50 and 56, the current International Conference on Harmonization E-6 Guidelines for Good Clinical Practice, the current Council for International Organizations of Medical Sciences International Ethical Guidelines for Biomedical Research Involving Human Subjects, and any other Federal and State laws or local policy pertaining to use of the Biospecimens. The Recipient will report any proposed change in the Research Plan promptly to the NICHD. This MTA is made in addition to, and does not supersede, any of the Recipient Institution's policies or any applicable local, State, and/or Federal laws and regulations that provide additional protections for human subjects.

9. Biospecimen Disclaimers

a. THE BIOSPECIMENS ARE NOT FOR USE IN HUMAN SUBJECTS OR FOR THE TREATMENT OR DIAGNOSIS OF HUMAN SUBJECTS.

b. Any Biospecimens delivered pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. THE NICHD MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. To the extent allowed by law, the Recipient Institution assumes liability for claims for damages against it by third parties which may arise from its use, storage, processing, distribution, or disposal of the Biospecimens.

c. The Recipient Institution acknowledges that all biospecimens distributed under this MTA may be potentially biohazardous even when they are not specifically designated as such. The Recipient understands, along with the Recipient Institution, that the requested biospecimens may pose health risks to persons handling or in the vicinity of the biospecimens, the environment, and the community.

[3] NIH Policy for Issuing Certificates of Confidentiality available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

d. The Recipient Institution certifies that the Recipient, Requester (if not the same individual as the Recipient) and all Affiliates:
   i. Are cognizant of and will employ good laboratory practices and appropriate biosafety standards including special practices, equipment, and facilities.
   ii. Will comply with all applicable Institution and Government health and safety regulations and the guidelines detailed in: Biosafety *in Microbiological and Biomedical Laboratories, 5th Edition, HHS Publication No. (CDC) 21-1112, Dec 2009*[4], or the most recent revision of these guidelines.

10. Return of New Datasets

The Recipient Institution agrees to submit to NICHD DASH any new datasets generated from the use of the Biospecimens, by either the date of acceptance of publication of the main/primary findings or one year after the analysis of the data for the Research Plan is completed, whichever is the first to occur. If the submission contains genomic data, the Recipient will archive and distribute the data and results from the study to the database of Genotypes and Phenotypes (dbGap)[5].

11. Intellectual Property

The Biospecimens are made available to the research community for their use to further the research and development of ideas that will benefit and improve public health. NICHD encourages the development of new diagnostics, therapeutics, or other interventions building on basic discoveries enabled through Biospecimens obtained through NICHD DASH. The Recipient and Recipient Institution may be free to pursue patent protection on any inventions or discoveries developed through their use of the Biospecimens.

12. Security Requirements

The Recipient Institution shall ensure compliance by the Recipient of the security requirements listed below to protect the Biospecimens obtained from the NICHD Biorepository:

a. Maintenance of, and access to, Biospecimens: The Recipient shall keep the Biospecimens secure at all times and adhere to the Recipient Institution's security best practices in all aspects of specimen management to assure that only the Recipient, Requester (if different from the Recipient) and Affiliates have access to the Biospecimens obtained through this MTA.

b. Retention of Biospecimens: Upon research termination or the termination of this MTA, the Recipient and all Affiliates shall destroy all Biospecimens in compliance with all applicable statutes and regulations; or return Biospecimens to the NICHD Biorepository, if requested by NICHD.

13. Acknowledgements

The Recipient Institution and Recipient will acknowledge the contribution of the Principal Investigator(s) who conducted the original study that collected the Biospecimens, the funding organization(s) that supported the original study, the grant or contract number(s) of the original study, and NICHD DASH in all resulting oral or written presentations, disclosures, or publications of the analyses, and patents or inventions originating from the Biospecimens.

Any manuscript resulting from the Biospecimens must also include an acknowledgement, as specified by the Submitter(s), which can be obtained from NICHD DASH when processing the request online.

14. Annual Report

As a means to determine the effectiveness of NICHD DASH, the Recipient will submit to NICHD DASH an Annual Report with the following:

a. Summary of research accomplishments, including a list of oral or written presentations, disclosures, abstracts, or publications, patents or inventions resulting from the use of the Biospecimens

b. Publication number (or a copy) of any published patent application for newly discovered or developed technologies

c. Any updates to the list of Affiliates

15. Permission to Post Information Publicly

The Recipient Institution permits NICHD to post the Recipient's research use of NICHD DASH along with the Recipient's name and the name of the Recipient Institution on the NICHD DASH website.

[4] Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, HHS Publication No. (CDC) 21-1112, Dec 2009: https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF

[5] Database of Genotypes and Phenotypes (dbGaP): https://www.ncbi.nlm.nih.gov/gap/

16. Biospecimen Use Reporting

When requested by the NICHD, the Recipient Institution and Recipient will respond to requests for information on the effectiveness of the NICHD DASH Biospecimen request process, workflows, and procedures (e.g., ease of access and use, utility of Biospecimens, policy compliance, and suggestions for improving biospecimen access or the program).

17. Biospecimen Cost and Shipping

The Biospecimens are provided at no cost to the Recipient beyond necessary costs to process and ship the materials. While the NICHD will not participate in selling any of the Biospecimens, there are costs associated with pulling the Biospecimens from the NICHD Biorepository and to ship the specimens. The NICHD Biorepository will notify the Recipient when the Biospecimens are ready for shipment. The Recipient will provide the biorepository with the address and other information for shipment of the Biospecimens and will cover all costs associated with shipments.

The Recipient Institution and Recipient will provide a FedEx® (or other carrier) shipping account number and make arrangements for prepaid shipments. The Recipient Institution will confirm that the carrier is certified to ship dangerous goods (biohazardous material and dry ice) and can pick up shipments from the NICHD Biorepository. No shipments will be made until the proposed shipping arrangements are accepted by the NICHD Biorepository.

18. Privacy Act Notification

The Recipient Institution agrees that information collected from the Recipient, such as name, contact, funding, and biospecimen use information may be used in part, or in whole, for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. The authority for the collection of the information requested from the Recipient comes from the authorities regarding the establishment of the National Institutes of Health (NIH), its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and Sections 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0156 https://www.govinfo.gov/content/pkg/FR-2002-09-26/pdf/02-23965.pdf covering "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service (PHS), HHS/PHS/NIH/OD."

The primary uses of this information are to document, track, monitor, and evaluate the use of Biospecimens requested through NICHD DASH.

19. Penalties for Violation of the MTA

The Recipient Institution agrees that should NICHD determine, or have a reasonable belief, that the Recipient or any authorized user of the Biospecimens has violated any terms of this MTA, the NICHD will provide the Recipient Institution with a 30-day notice to remedy the violation. If the Recipient Institution does not rectify the violation, the NICHD, at its sole discretion, will terminate the MTA and close the NICHD DASH account of the Recipient, Requester (if different from the Recipient) listed in Appendix A, and Affiliates (if any). Accounts that have been closed due to a violation of this MTA may be reactivated upon the submission of evidence of remediation that is acceptable to the NICHD, a revised Biospecimen Request Form, and a new MTA.

If the Recipient Institution or the Recipient commits a material breach of this MTA, the NICHD may, in its sole discretion, terminate this MTA with 10 days written notice and require that the Recipient destroy the Biospecimens as instructed by the NICHD, or return Biospecimens to the NICHD Biorepository if requested by NICHD. The following situations are examples of material breaches:

a. Unauthorized distribution of Biospecimens (see Clause 3)

b. Intentional Identification of individuals from whom the Biospecimens were collected (see Clause 6)

c. Retention of Biospecimens after the MTA expiration date (see Clause 12.b.)

The Recipient Institution understands that as a result of this determination, or reasonable belief that a material breach of this MTA has occurred, the NICHD may also refuse to release new Biospecimens to the Recipient Institution.

The Recipient Institution also agrees to immediately report violations of the NICHD DASH Policy by the Requester (if not the same individual as the Recipient), and/or Affiliates who are subject to this MTA to the NICHD DASH Administrator.

20. Termination and Disposal

Either the NICHD or the Recipient Institution may terminate this MTA without cause by providing 30 days written notice to the other party. This MTA may also be terminated by mutual written agreement between the NICHD and the Recipient Institution. When the Research Project is completed, or the MTA is terminated or expires, whichever comes first, any unused Biospecimens will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the NICHD Biorepository, if requested by NICHD.

21. Term of the MTA

This MTA will remain in effect for a period of three (3) years from the MTA Effective Date and will automatically expire at the end of this period unless terminated earlier or renewed. The Recipient Institution may request that the MTA be renewed three (3) months prior to the expiration date by submitting an application to the NICHD DASH Administrator for renewal of the MTA.

22. Survival

Provision 1,3,4,5,6,7,8,9,10,11,12,13,15,16,17,19 and 20 of this MTA will survive the expiration or termination of this MTA.

23. Amendments

Amendments to this MTA must be made in writing and signed by the Recipient Institution and the NICHD. Any amendment must be submitted and approved. The MTA becomes effective only following the date of approval.

V. PROCESSING OF THIS MATERIAL TRANSFER AGREEMENT

The Recipient Institution will ensure compliance with all terms included in this MTA and expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

See the next page for Signatures.

AMENDMENT 1

This Material Transfer Agreement (MTA) is amended to include the following clause:

24. Environmental Samples

a. The definition of "Biospecimens" in this MTA shall include "Environmental Samples", which are samples of any material that is collected from an environmental source.

b. All terms and conditions under Section IV in this MTA also pertain to Environmental Samples.

By signing this Agreement on the following page, the Recipient Institution agrees to the terms of this Amendment.

VI. FOR THE RECIPIENT INSTITUTION:

Signature of the Authorized Organization Representative **Date**

Name of the Authorized Organization Representative:

Title of the Authorized Organization Representative:

I have read and understand the terms of this MTA:

Signature of the Recipient **Date**

Name of the Recipient:

Title of the Recipient:

VII. FOR THE NICHD:

Signature of the Division Director or Designee **Date**

Name of the Division Director or Designee:

Title of the Division Director or Designee:

VIII.APPENDIX A: LIST OF USERS WITH ACCESS TO BIOSPECIMENS

This MTA authorizes the Recipient and the Requester (if not the same individual as the Recipient) whose names are listed below, and any Affiliates, to access the Biospecimens obtained from the NICHD Biorepository.

Name of the Recipient:

Title:

Name of the Requester:

Title:

IX. APPENDIX B: LIST OF BIOSPECIMENS TO BE OBTAINED FROM THE NICHD BIOREPOSITORY

Name of the Study that the biospecimens are requested from: **[***Name will be automatically added by NICHD DASH system during the request process***]**

Specimen Type	Number of Samples