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THE CUSTOMIZED DUA FOR EXECUTION WILL BE GENERATED DURING THE DATA REQUEST PROCESS

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

DATA AND SPECIMEN HUB (DASH)

NICHD DASH DATA USE AGREEMENT

This Data Use Agreement (the "DUA") is by and between

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development ("NICHD"),

_____

(NICHD Division Director/Designee),

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 "DUA Effective Date").

Requested 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 share and access de-identified data from NICHD-funded studies for secondary use. To take full advantage of the research data already collected by NICHD-funded investigators and maximize its value for public health, NICHD has established policies and processes designed to make such data available through NICHD DASH, under appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner. The full NICHD DASH Policy statement is available on the NICHD DASH website.

Data deposited in NICHD DASH by the submitters (defined below) have been stripped of all individually identifying information according to both (a) the standards set forth in the Department of Health and Human Services (HHS) Regulations for the Protection of Human Subjects[1] and related guidance (which covers individually identifiable private information), and (b) the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule[2] (which covers protected health information), and have been assigned random, unique codes to ensure that data are not identifiable.

[1] 45 CFR 46.102(e) at: 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

However, the potential for deducing the identity of an individual from data stripped of identifiers is constantly evolving, due to the large number of individual data points and the advancement of computational tools.

Therefore, to protect and promote the confidentiality and privacy of the individuals whose data have been deposited into NICHD DASH, NICHD is requiring the Recipient of such data to read and understand and sign this Data Use Agreement (DUA) and their institution to acknowledge and agree to abide by the terms of this DUA as a condition of access. A Recipient who is granted access to NICHD DASH data is expected to adhere to the specifications of this DUA, as executed in its final form. Failure to do so could result in denial of further access by the Recipient's institution to NICHD DASH data.

Submitters of data to NICHD DASH make a substantial long-term contribution to public health by sharing data more widely through NICHD DASH. NICHD encourages investigators who request and receive access to the data in NICHD DASH to adhere to appropriate and reasonable conditions for data use, collaborative relationships with the submitters, and to ensure proper acknowledgement of the submitters' contribution to their research, as well as NICHD and NICHD DASH.

II. DEFINITIONS

The following definitions apply for the purposes of this DUA:

"Affiliates" are individuals within the same institution as the Recipient, for whom access to Data is required to carry out the Research Plan or Non-research Use. They must read and understand the terms and conditions executed by the Recipient Institution who is the subject of this DUA and are not required to submit a separate Data Request Form or sign a separate DUA with NICHD. Affiliates are permitted to access and download Data directly from NICHD DASH. Affiliates of the Recipient, if any, are listed in *Appendix A*. Please see Section III below for roles and responsibilities of an Affiliate.

"Associates" are individuals from a different institution than the Recipient and working on the same Research Plan or Non-research Use as the Recipient, for whom access to Data is required to carry out the Research Plan or Non-research Use. They must read and understand the terms and conditions executed by the Recipient Institution who is the subject of this DUA and are not required to submit a separate Data Request Form or sign a separate DUA with NICHD. They will not be permitted by the NICHD DASH system to access or download Data directly; instead, they must access Data only within the Recipient Institution's data platform and must not download Data from the Recipient Institution's data platform to their own local data platform or devices. Associates of the Recipient, if any, are listed in *Appendix A*. Please see Section III below for roles and responsibilities of an Associate.

"Data" refers to data and information collected and recorded from participants in research studies that are available through NICHD DASH. For the purposes of this DUA, any associated study documentation provided along with the Data are included in this definition of Data. This Data is subject to release to the Recipient, according to the criteria laid out in the NICHD DASH Policy, which includes the execution of an NICHD DASH DUA, approval by the NICHD DASH Data Access Committee, and, if applicable, by study-specific entities.

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

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

"Recipient" is the lead individual who receives access to the Data on behalf of the Recipient Institution. The Recipient may share access to the Data only with individuals who are included under the Requester, Affiliates and/or Associates as listed in *Appendix A*. 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 10.

"Requester" may or may not be the same individual as the Recipient of the Data. 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 data request online in the NICHD DASH system. The Requester is permitted to access and download Data directly 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 Data 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, methodology to be used, and the expected outcomes), and, if required by the Submitter, a design and analysis plan.

"Non-research Use" is a description of the proposed practical application of the Data that serves as the basis for the Data access request. For the purpose of this DUA, practical application means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system. The Non-research Use must include the title and purpose of the project and identify the intended benefits of the project for the health community or the participant community

"Study" is the research study that collected the Data described in this DUA.

"Submitter" is an investigator who has submitted Data to NICHD DASH, according to the criteria laid out in the NICHD DASH Policy.

III. ROLES AND RESPONSIBILITIES

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

Roles	Responsibilities
Affiliate/s	• Are from the same institution as the Recipient • Can access Data directly from NICHD DASH or from the Recipient • Must use the data for the same Research Plan or Non-research Use as the Recipient who is leading the research • Must register in NICHD DASH • Must read and understand the terms of this DUA executed by the Recipient Institution
Associate/s	• Are from a different institution than the Recipient • Must read and understand the terms and conditions of this DUA executed by the Recipient Institution who is the subject of this DUA and are not required to submit a separate Data Request Form or sign a separate DUA with NICHD • Must access Data only within the Recipient Institution's data platform • Must not download Data from the Recipient Institution's data platform to local data platform or devices • Must not download Data directly from NICHD DASH • Must use the data for the same Research Plan or Non-research Use as the Recipient who is leading the research • Not required to register in NICHD DASH

Roles	Responsibilities
NICHD DASH Administrator	• Communicates with the Recipient regarding any applicable terms and conditions pertinent to the DUA
Recipient	• Must read, understand, and sign the DUA executed by the Recipient Institution • Share access to the Data only with individuals who are included as Requester (if not the same individual as the Recipient), Affiliates, and/or Associates listed in *Appendix A* • Must not share Data received from NICHD DASH with anyone outside the Recipient Institution except with Associates who must access the data within the Recipient Institution's data platform • Oversee the Requester (if not the same individual as the Recipient), Affiliates, and /or Associates who are provided access to the Data • Maintain compliance with the human subjects protection requirements, if applicable, under 45 CFR 46 and local rules • Delegate authority, as needed, to an individual identified as Requester from the same institution to perform administrative functions within the NICHD DASH system (complete request process, add Affiliates and/or Associates, and submit data use annual report) • Must register in NICHD DASH
Recipient Institution	• Execute the DUA with NICHD • Acknowledge and agree to abide by the terms of the executed DUA • Assume responsibility for the compliance of the Recipient, Requester (if not the same individual as the Recipient), Affiliates and/or Associates with the terms and conditions of this DUA • Maintain compliance with the human subjects protection requirements, if applicable, under 45 CFR 46 and local rules
Requester (if not the same individual as the Recipient)	• May or may not be the same individual as the Recipient of the Data • Must be from the same institution as the Recipient and must be delegated by the Recipient to submit the data request online in the NICHD DASH system • Allowed to perform administrative functions within the NICHD DASH system (complete request process, add Affiliates and/or Associates, and submit data use annual report) • Must read and understand the terms of the DUA executed by the Recipient Institution • May access Data directly from NICHD DASH • Must use the data for the same Research Plan as the Recipient • Must register in NICHD DASH

IV. TERMS AND CONDITIONS

The Recipient Institution requests approval for the Recipient to access Data listed in *Appendix B* from the NICHD DASH study listed below for purposes of the Research Plan or Non-research Use, which is specified in the NICHD DASH online Data Request Form and incorporated herein by reference.

Requested 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 DUA is not transferable. There are no third-party beneficiaries to this DUA. Any other individual that wishes to receive Data from NICHD DASH is required to execute a separate DUA.

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

a. Any substantive change to the scope of the Research Plan or Non-research Use
b. The appointment of another Recipient to complete the Research Plan or Non-research Use
c. Change to the Recipient Institution. *Note, if the Recipient wishes to retain access to the Data but has changed the institution under which this DUA was executed, a new DUA in which the new institution acknowledges and agrees with the provisions of the DUA 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 Data

NICHD authorizes the Recipient, the Requester (if not the same individual as the Recipient), Affiliates and /or Associates (if any) listed in *Appendix A* to access the Data. The Recipient Institution must ensure that the Recipient, Requester (if not the same individual as the Recipient), Affiliates and/or Associates listed in *Appendix A*, read and understand the terms of this DUA.

3. Non-Distribution of Data

The Recipient Institution will retain control over the Data, and further, will not sell the Data, in any form, to any entity or individual or to otherwise distribute the Data to anyone except those authorized under this DUA to receive the Data. [*Note*: Recipients must not distribute the Data to Associates. Associates must access the Data within the Recipient Institution's data platform]. For clarity, the Recipient will not transfer any Data obtained or accessed under this DUA to individuals or organizations not specified in this DUA, except as required by law.

4. Research Use of the Data

Data obtained from the NICHD DASH study as listed in *Appendix B* will be used by the Recipient, the Requester (if not the same individual as the Recipient), Affiliates and/or Associates (if any) for the purpose indicated and described in the Research Plan or Non-research Use specified in the NICHD DASH online Data Request Form and incorporated herein by reference, in accordance with the following:

a. Data will only be used for purposes approved by the NICHD DASH Data Access Committee and /or the study-specific approving entity (such as the Study Steering Committee) as part of the Research Plan or Non-research Use.
b. A separate and completed DUA must be submitted for each Research Plan or Non-research Use for which Data are requested. A separate and fully executed DUA is also required when requesting new versions of the Data deposited later by the Submitter.
c. The Recipient, the Requester (if not the same individual as the Recipient), Affiliates and/or Associates (if any) listed in *Appendix A* will comply with all data use limitations specified by the Data Submitter and stated in the NICHD DASH Data Request Form.

5. Data Access for Research

Data in NICHD DASH are eligible for access by qualified investigators pursuant to the terms set forth in this DUA. The Recipient Institution acknowledges that other requesting investigators also have access to the same Data in NICHD DASH, and that downloading and utilization of the same Data that the Recipient received from NICHD DASH as well as the duplication of research from such Data are distinct possibilities.

6. Data Disclaimers

The Recipient Institution agrees that although all reasonable efforts have been taken to ensure the accuracy and reliability of the Data, NICHD does not and cannot warrant the results that may be obtained by using any Data included therein. NICHD disclaims all warranties as to the accuracy of the Data in NICHD DASH, or the performance or fitness of the Data for any particular purpose.

It is the specific intent of NICHD and the Recipient Institution that nothing contained in this DUA gives rise to any right or cause of action, contractual or otherwise, in or on behalf of the individuals whose Data are used or disclosed pursuant to this DUA.

The Recipient Institution understands and acknowledges that any request for access to the Data is undertaken at its sole risk and with no expense applied to any study or to NICHD.

The Recipient Institution acknowledges that certain subsets of data received from NICHD DASH may have been collected using proprietary instruments and/or coded using licensed coding standards (example, MedDRA, SNOMED), which mandates users of such data to comply with licensing and subscription requirements set forth by the owners of such instruments or standards. The Recipient Institution further agrees to comply with such requirements and release NICHD or NICHD DASH from any liability for non-compliance.

7. Certificate of Confidentiality

Data residing in NICHD DASH is 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 data from NICHD DASH. 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. Prohibition on Identification of Subjects

Anyone using or accessing the Data must not attempt to establish the individual identities of any of the individuals from whom the Data 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 Data 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 Data of which the Recipient and/or Requester and/or Affiliates and/or Associates 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 Data, and so the Recipient Institution may be subject to additional restrictions or obligations or even alternative permissions under separate agreements.

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

9. Non-Endorsement and Liability

The Recipient Institution will not claim, infer, or imply endorsement by the United States Government, the Department of Health and Human Services (HHS), the National Institutes of Health (NIH), or the NICHD of the Research Plan or Non-research Use, the entity or personnel conducting the Research Plan or Non-research Use, or any resulting commercial product(s). The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

10. 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 Data. The Recipient will report any proposed change in the Research Plan or Non-research Use promptly to NICHD. This DUA 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.

11. Data Disclosure/Breach

The Recipient Institution must notify the NICHD DASH Administrator in writing within five (5) business days upon the receipt of any legal, investigatory, or other demand for disclosure of Data. The Recipient Institution shall notify the NICHD DASH Administrator in writing within two (2) business days upon discovering any breach, or suspected breach, of any unauthorized disclosure of Data. The existence of a breach or suspected breach is not necessarily, but may be, grounds for DUA termination. NICHD may also seek injunctive relief against the Recipient Institution to prevent any disclosure of Data by the Recipient to anyone other than NICHD.

12. Intellectual Property

Data in NICHD DASH is 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 Data obtained from NICHD DASH. The Recipient Institution and the Recipient are free to pursue patent protection on any inventions or discoveries developed through their approved use of NICHD DASH Data.

13. Security Requirements

The Recipient Institution shall ensure compliance by the Recipient of the security requirements listed below:

a. Maintenance of, and access to, Data

   i. The Recipient shall retain the original version of the Data and may make no copy or extraction of the Data available to anyone other than the Requester (if not the same individual as the Recipient), Affiliates and/or Associates.
   ii. The Recipient must ensure that the Requester and/or Affiliates are registered in NICHD DASH.
   iii. The Recipient must ensure that all Associates access the Data only within the Recipient Institution's data platform and must not download Data from the Recipient Institution's data platform to their local data platform or devices.
   iv. The Recipient, the Requester (if not the same individual as the Recipient), and/or Affiliates and/or Associates must keep the Data secure and confidential at all times and adhere to the Recipient Institution's information security best practices in all aspects of data management to assure that only the Recipient, Requester (if not the same individual as the Recipient), Affiliates and/or Associates have access to the Data obtained through this DUA.

b. Retention of Data: Upon research termination or the termination of this DUA, the Recipient, the Requester (if not the same individual as the Recipient), and/or Affiliates shall destroy all copies of the Data, except as required by publication practices or law to retain them.

14. Format of Data

Data under this DUA may take many formats, depending upon the available technology.

15. Acknowledgments

The Recipient Institution and the Recipient will acknowledge the contribution of the Principal Investigator (s) who conducted the original study from which the Data were generated, the funding organization(s) that supported the original study, and NICHD DASH in all resulting oral or written presentations, disclosures, or publications, and patents, practical applications, or inventions originating from the Data.

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

16. Permission to Post Information Publicly

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

17. 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 accomplishments, including a list of oral or written presentations, disclosures, abstracts, publications, patents, practical applications, or inventions resulting from the approved use of the Data
b. For Non-research Use, a summary of the outcome from practical applications
c. Publication number (or a copy) of any published patent application for newly discovered or developed technologies
d. Any updates to the list of Affiliates and/or Associates

18. Data Use Reporting

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

19. Privacy Act Notification

The Recipient Institution agrees that information collected from the Recipient, such as name, contact, funding, and data 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, the 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[4] covering "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service (PHS), HHS/PHS/NIH/OD."

[4] Privacy Act System of Record Notice 09-25-0156 at: https://www.govinfo.gov/content/pkg/FR-2002-09-26/pdf/02-23965.pdf

The primary uses of this information are to document, track, monitor, and evaluate the use of NICHD DASH Data, as well as to notify interested parties of updates, corrections, or other changes to the Data.

20. Penalties for Violation of the DUA

The Recipient Institution agrees that should NICHD determine, or have a reasonable belief, that the Recipient or any other authorized user of the Data has violated any terms of this DUA, NICHD will provide the Recipient Institution with a 30-day notice to remedy the violation. If the Recipient Institution does not rectify the violation, NICHD, at its sole discretion, will terminate the DUA and close the NICHD DASH account of the Recipient, Requester (if not the same individual as the Recipient), Affiliates and Associates (if any) listed in *Appendix A*. Accounts that have been closed due to a violation of this DUA may be reactivated upon the submission of evidence of remediation that is acceptable to NICHD, a revised online data request, and a new DUA.

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

a. Unauthorized distribution of Data (see Clause 3)
b. Identification of subjects in the Data obtained from NICHD DASH (see Clause 8)
c. Unauthorized Data disclosure (see Clause 11)
d. Retention of Data after the DUA expiration date (see Clause 13.b.)

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

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

21. Termination of the DUA

Either NICHD or the Recipient Institution may terminate this DUA without cause by providing 30 days written notice to the other party. This DUA may also be terminated by mutual written agreement between NICHD and the Recipient Institution.

In addition to the specific circumstances whereby NICHD may terminate this DUA (as indicated under various terms and conditions of this DUA), NICHD reserves the right to terminate the DUA when the Submitter has withdrawn the Data from NICHD DASH – either permanently or to submit a redacted or revised dataset. In both cases, NICHD will terminate the DUA by providing 30 days written notice to the Recipient Institution and instruct the Recipient to destroy the Data. If and when a redacted or revised dataset is deposited by the Submitter in NICHD DASH, the Recipient may choose to execute a new DUA to obtain this new dataset.

22. Term of the DUA

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

23. Amendments

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

24. Survival

Provisions 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 15, 16, 18, 19, and 20 of this DUA will survive expiration or termination of this DUA.

V. PROCESSING OF THIS DATA USE AGREEMENT

The Recipient Institution will ensure compliance with all terms included in this DUA 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.

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 DUA:

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):

APPENDIX A: LIST OF USERS WITH ACCESS TO NICHD DASH STUDY DATA

This DUA authorizes the following individuals to access the study Data. The Data must NOT be shared with any other individuals. *Note that Associates must access the Data within the Recipient Institution's data platform.*

1. **DATA RECIPIENT**

   Name of the Recipient who is approved to access the Data from the Requester or NICHD DASH is shown below.

   Name:

   Title:

2. **DATA REQUESTER**

   Name of the Requester who is approved to access the Data from the Recipient or NICHD DASH is shown below.

   Name:

   Title:

3. **AFFILIATES**

   List of Affiliates who are approved to access the Data from the Recipient or NICHD DASH:

	First Name	Last Name	Job Title/Position
1			
2			

4. **ASSOCIATES**

   List of Associates who are approved to access the Data within the Recipient Institution's data platform:

	First Name	Last Name	Job Title/Position
1			
2			

APPENDIX B: LIST OF DATA FILES TO BE OBTAINED FROM NICHD DASH

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

Note: One of the following language options will be displayed depending on whether the study's informed consent requires IRB approval for data request. If IRB approval is required, cart level approval is dictated. Otherwise, study level approval is granted.

[OPTION A]

This study allows for "Study level approval". This means that regardless of whether entire content or only a subset of the data from this Study is requested, upon approval of this request, the Recipient, the Requester (if not the same individual as the Recipient), and/or Affiliates listed in Appendix A will have access to all Data from this study. Note that Associates, if any, must access the Data within the Recipient Institution's data platform.

[OPTION B]

This study allows for "Cart level approval". This means that, upon approval of this request, the Recipient, the Requester (if not the same individual as the Recipient), and/or Affiliates listed in Appendix A will only have access to the requested Data from this study as listed below. Note that Associates, if any, must access the Data within the Recipient Institution's data platform.