NICHD Research Materials Distribution Agreement (RMDA)

Introduction and Definitions

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the RECIPIENT Organization (RECIPIENT) and the Principal Investigator (PI) hereby enter into this Research Materials Distribution Agreement (RMDA) as of the effective date specified on the final signature page.

The Research Materials and Research Plan covered by this RMDA are:

Information will be inserted from other parts of the request process

Name of Clinical Study: < NATIONAL CHILDREN'S STUDY>

Title of Research Plan: <TITLE OF RESEARCH PLAN>

Research Materials Requested: <MATERIALS REQUESTED – DATA AND/OR BIOLOGICAL AND/OR ENVIRONMENTAL SAMPLES>

Research Plan includes a Commercial Purpose <Y/N>

Name of Principal Investigator (PI): < >

Email of Principal Investigator (PI): < >

Name of Other Approved Users at PI's Institution: < >

The Research Materials are provided through the NCS Vanguard Data and Sample Archive and Access System. The Center was established by the NICHD to develop and maintain the infrastructure necessary

to facilitate and maximize access to Research Materials from NICHD-sponsored studies in accordance with NICHD approved procedures.

The Research Materials were collected as part of the above clinical study; hereafter referred to as "STUDY." They constitute a unique scientific resource and the NICHD is committed to making them available in a timely manner, on appropriate terms and conditions, to the largest possible number of qualified investigators who wish to analyze the materials in a secondary study designed to enhance the public health benefit of the original work. The RECIPIENT and PI acknowledge responsibility for ensuring the review of and agreement to the terms within this RMDA and the appropriate research use of the Research Materials, subject to applicable laws and regulations.

The RECIPIENT and PI acknowledge that other researchers are entitled to access to the Research Materials on the same terms as RECIPIENT so that duplication of research may occur. RECIPIENT and PI also recognize that the STUDY Investigators have made a substantial long-term contribution in establishing the Research Materials and the NICHD encourages appropriate collaborative relationships by outside investigators with the STUDY Investigators and proper acknowledgement of their contributions.

The NICHD believes that the confidentiality and privacy of the STUDY participants can best be assured by requiring all who are interested in accessing the Research materials to acknowledge their review of this RMDA and agree to adhere to its provisions. Violation of its confidentiality provisions could lead to legal action on the part of STUDY participants, their families, or the U.S. Government.

Note: RECIPIENT requests access to NICHD Research Materials for its PI at its sole risk.

For the purpose of this agreement

"RECIPIENT" is any organization that is seeking access to STUDY Research Materials, and may be a:

- Public/State Controlled Institution of Higher Education;
- Private Institution of Higher Education;
- Nonprofit organization with 501(c)(3) IRS Status (Other than Institution of Higher Education)
- Nonprofit Organization without 501(c)(3) IRS Status (Other than Institution of Higher Education);
- State Government;
- Government of a U.S. Territory or Possession;
- Non-domestic (non-U.S.) Entity (Foreign Organization);
- or Eligible Agency of the U.S. Government.

"Principal Investigator (PI)" is an individual judged by the RECIPIENT to have the appropriate level of authority and responsibility to lead the scientific investigation proposed in the Research Plan using the requested materials, oversee the supporting staff who are provided access to the Research Materials and contribute to the analytic effort and public disclosure of STUDY results, and assume responsibility for all team members' compliance with the terms and conditions of this RMDA.

"APPROVED USERS" are all individuals specifically identified in the Research Plan, including the PI. Only individuals listed in the Research Plan may have access to the Research Materials.

"Research Plan" is a description of the proposed research that includes the identities of the investigators participating in the research effort. The Research Plan must include the project title, the RECIPIENT's name, the PI's name, the name of other APPROVED USERS, and the proposed research protocol with the research objectives and design. For plans including biological and/or environmental samples, the material type, number, minimum volume, and required characteristics needed to meet the objectives of the protocol must also be included.

"Research Materials" are the requested materials covered by this RMDA and may include STUDY data, defined as clinical or epidemiologic subject data, and/or STUDY biological and/or environmental samples. STUDY samples may have associated characterization data. Characterization data serve to describe STUDY samples only and are not considered to be STUDY data; they are exempt from STUDY data requirements that may be described elsewhere in this RMDA.

"STUDY" is the clinical study that collected the Research Materials described in this RMDA.

"STUDY Investigator" is a research investigator with a current or previous grant, contract, or consulting agreement from the NICHD, or one of its contractors, to work on the STUDY.

Terms of Access

1. Research Use

The RECIPIENT and APPROVED USERS agree that they will use the Research Materials solely in connection with the research project described in the Research Plan named in this RMDA. Substantive modifications to the research project will require submission of a revised RMDA.

2. Institutional and Approved User Responsibilities

RECIPIENT and APPROVED USERS acknowledge that RECIPIENT's Institutional Review Board (IRB) has reviewed the RESEARCH PLAN and either approved it or determined that it is exempt from review. RECIPIENT certifies that its IRB is operating under an Office of Human Research Protections (OHRP) - approved Assurance and in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. RECIPIENT and APPROVED USERS agree to comply fully with all such conditions.

RECIPIENT and APPROVED USERS agree to report promptly to the NICHD any proposed change in the Research Plan and any unanticipated problems involving risks to subjects or others. Changes to the Research Plan include changes in the APPROVED USERS list. This RDMA is made in addition to, and does not supersede, any of RECIPIENT's institutional policies or any local, State, and/or Federal laws and regulations that provide additional protections for human subjects.

Evidence of local IRB review and/or approval (where appropriate) from an expedited or convened review to conduct the Research Plan with the requested STUDY data must be included in a supplemental Adobe PDF document that will be uploaded during the application process and attached to the RMDA form.

Insert for biological and/or environmental samples

Evidence of local IRB approval from an expedited or convened review or a review waiver to conduct the Research Plan with the requested STUDY biological and/or environmental samples must be included in a

supplemental Adobe PDF document that will be uploaded during the application process and attached to the RMDA form.

The PI certifies, along with the RECIPIENT that NCS BIOSPECIMENS OR DERIVATIVES FROM NCS BIOSPECIMENS WILL NOT BE USED IN HUMAN SUBJECTS.

The RECIPIENT and PI agree to assume the cost of shipping biological and/or environmental samples by providing a FedEx® (or other carrier) shipping account number, or by making arrangements for prepaid shipments. The RECIPIENT will confirm that the carrier is certified to ship dangerous goods (biohazardous material and dry ice) and can pick up shipments from the NCS Repository. No shipments will be made until the proposed shipping arrangements are accepted by the NCS Repository.

Certification of Compliance with Safety Standards

The RECIPIENT and APPROVED USERS acknowledge that all biospecimens distributed under this RMDA may be potentially biohazardous even when they are not specifically designated as such. The PI understands, along with the RECIPIENT, that the requested biospecimens may pose health risks to persons handling or in the vicinity of the biospecimens, the environment, and the community.

The PI certifies that all APPROVED USERS:

- Are cognizant of and will employ good laboratory practice and the appropriate biosafety standards including special practices, equipment, and facilities.
- 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, December 2009, or the most recent revision of these guidelines.

3. Public Posting of Approved User's Research Use Statement

The RECIPIENT and PI agree that information about the proposed research use can be posted on a public web site that describes the project(s) included in the RESEARCH PLAN. The information will include the PI's name, RECIPIENT institution, project title, and a brief summary of the research. In addition, citations resulting from the use of Research Materials may be posted on the NCS Vanguard Data and Sample Archive and Access System Website.

4. Non-Identification

The PI agrees not to use the Research Materials, either alone or in concert with any other information, to identify or contact individual STUDY subjects without specific approval to contact STUDY subjects obtained from the IRB(s) responsible for the STUDY.

5. Non-Transferability of Research Materials

The RECIPIENT and PI agree to retain control over the Research Materials, and further agree not to release or distribute Research Materials in any form to any entity or individuals not specified in the Research Plan described in the Request. The RECIPIENT and PI agree to store Research Material data on a computer with adequate security controls (see Section 6), and to maintain appropriate control over the Research Materials at all times. Research Materials data containing individual-level information, in whole or in part, may not be transferred or sold to any entity or individual at any point in time for any purpose.

The PI agrees that if his or her relationship with the RECIPIENT terminates and a relationship with a different RECIPIENT is established during the period of the RMDA, a new RMDA from the second RECIPIENT will be submitted and approved before the PI resumes use of the Research Materials. Any

versions of Research Material data stored at the first RECIPIENT will be destroyed and their destruction documented. However, if advance written notice and approval by the NICHD Program Office is obtained to transfer responsibility for the approved Research Plan to a different PI with a relationship with the first RECIPIENT, the Research Material data may not need to be destroyed.

6. Security of Research Materials

The RECIPIENT and PI agree to store Research Material data on a computer with security controls adequate to protect sensitive or identifiable information, to ensure that only approved, supervised persons have access to the Research Material, and to maintain appropriate control over the Research Materials at all times. Hard copies of any Research Material or related data must similarly be stored under conditions sufficiently secure to avoid inappropriate access, and shredded prior to discarding.

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This RMDA will be in effect for a period of three (3) years from its effective date for the requested STUDY data set. At the end of the three (3) year period, the RECIPIENT and PI agree to destroy all copies of the STUDY data, and all derivatives that contain individual-level information,. Characterization data associated with the STUDY biological and/or environmental samples are exempt from this requirement.

An extension of this RMDA may be permitted by the NICHD upon submission by the PI and RECIPIENT of evidence of IRB approval for the extended period.

7. Intellectual Property (IP)

By requesting access to the STUDY Research Materials, the RECIPIENT and APPROVED USERS acknowledge the intent of the NICHD to see that anyone authorized for research access through the attached Research Plan, follow the intellectual property principles within the NIH Genomic Data Sharing Policy (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html; Notice Number: NOT-OD-14-124, Release Date: August 27, 2014)) as summarized below:

> Achieving maximum public benefit is the ultimate goal of Research Material distribution through the NICHD Biological and Data Repository Information Coordinating Center. The NIH believes that Research Materials, such as these covered by this RMDA, should be considered as pre-competitive, and urges APPROVED USERS to avoid making IP claims derived directly from the STUDY Research Materials. However, the NICHD also recognizes the importance of obtaining IP rights for downstream discoveries, especially in therapeutics, that may be necessary to support full investment in products to benefit the public.
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> It is expected that these NICHD-provided data, and conclusions derived there from, will remain freely available, without requirement for licensing. The NICHD encourages broad use of shared Research Materials coupled with a responsible approach to management of IP derived from downstream discoveries in a manner consistent with the NIH's Best Practices for the Licensing of Genomic Inventions (http://www.ott.nih.gov/policy/genomic_invention.html) and the NIH Research Tools Policy (http://grants.nih.gov/grants/intell-property_64FR72090.pdf).

8. Acknowledgement of NICHD Research Resources

RECIPIENT and APPROVED USERS agree to acknowledge the contribution of the STUDY in all oral and written presentations, disclosures, or publications resulting from any analyses conducted on the STUDY Research Materials.

APPROVED USERS will acknowledge the source of the data by including language similar to the following either in the acknowledgment or in the text of the manuscript: “This Manuscript was prepared using National Children’s Study Research Materials obtained from the NCS Vanguard Data and Sample Archive and Access System and does not necessarily reflect the opinions or views of the National Children’s Study or the NICHD.” Manuscripts and abstracts resulting from the Research Plan should not use the name of the STUDY in the title of the manuscript/abstract unless the title clearly denotes the source of the Research Materials as being from the NCS Vanguard Data and Sample Archive and Access System (e.g., “…An investigation using the National Children’s Study”).

The RECIPIENT and PI agree to ensure that all APPROVED USERS will not include in any manuscripts derived from Research Materials any case studies that describe the characteristics of individual participants, or groups of fewer than 10 participants.

9. Research Use Reporting

It is expected that any new individual level data that are produced under this research plan will be provided back to the archive for addition to study resources. This shall be completed before the expiration of the RMDA.

10. Non-Endorsement, Indemnification

The RECIPIENT and PI acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of Research Materials, the NICHD, and STUDY Investigators do not and cannot warrant the results that may be obtained by using any Research Materials included therein. The NICHD and all contributors to these Research Materials disclaim all warranties as to performance or fitness of the Research Materials for any particular purpose.

No indemnification for any loss, claim, damage or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement, except that the NIH, as an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. 2671 et seq.

11. Termination and Violations

The NICHD may terminate this agreement if RECIPIENT or APPROVED USERS are in default of any of its conditions and such default has not been remedied within 30 days after the date of written notice of such default by an authorized representative of the NICHD. Past violations will be taken into consideration by the NICHD for future requests from the RECIPIENT and APPROVED USERS to access NICHD Research Materials.

12. Amendments

Amendments to this Agreement must be made in writing and signed by authorized representatives of all parties.

Signatures Page

By submission of the RMDA, the RECIPIENT and PI attest to the APPROVED USERS qualifications for access to and use of STUDY Research Materials and certify their agreement to the NICHD principles, policies, and procedures for the use of Research Materials as articulated in this document.

This Agreement is entered into as of: _____ (effective date)

BY RECIPIENT:

Name of RECIPIENT Institution:_____

Name and Title of RECIPIENT's Authorized Institutional Business Official*:

_____

Signature and Date of RECIPIENT's Authorized Institutional Business Official*:

_____

E-Mail address of Authorized Institutional Business Official:

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*Authorized Institutional Business/Signing Official" is an individual with the authority to enter into business transactions on behalf of the RECIPIENT.

BY REQUESTING INVESTIGATOR:

Name: <NAME OF PRINCIPAL INVESTIGATOR>

Title: _____

Surface Mail Address: _____

E-Mail Address: <EMAIL OF PRINCIPAL INVESTIGATOR>

Telephone Number: _____

Fax Number: _____

Signature and Date: _____

BY NICHD Authorized Representative:

Name and Title: _____

Signature and Date: _____