NIDDK Central Repository
Material Transfer Agreement

This Material Transfer Agreement ("MTA") is made and entered into as of the last date of the signatures by the Parties, by and between National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK"), and the Contributor identified below. This MTA is intended for use when Materials are transferred to NIDDK Central Repository ("NIDDK-CR"). This MTA sets all terms and conditions to transfer Materials to NIDDK-CR.

Contributor:

Contributing Study (if applicable):

Grant Number is:

Protocol Number is:

Introduction

NIDDK has supported the collection of Materials (e.g., phenotypic data and specimens) from participants in numerous clinical studies. These Materials submitted to NIDDK-CR are taken under custodianship of NIDDK and are deemed NIDDK-CR held Resources.

To maximize the benefits and research value of NIDDK-CR held Resources, it is important that these Resources be made available to the largest possible number of qualified investigators who: submitted a request for access to NIDDK-CR held Resources; are primarily responsible for the research proposed; have been approved by the applicable NIH oversight committee; and have a fully-executed NIDDK-CR Data and Resource Use Agreement ("DUA") for the requested Resources.

Transfer of Materials to and Resources from NIDDK-CR is governed by NIH, NIDDK, and NIDDK-CR sharing policies, practices and procedures, and applicable federal regulations.

NIDDK-CR receives only Materials that do not include direct personal identifiers or codes linking to the identifiable information, and distributes these Resources via controlled access.

Definitions

"Contributing Study": An NIDDK-sponsored (or non-NIDDK sponsored) network, consortia, or study groups that deposits items generated in the conduct of clinical study protocol(s) into NIDDK-CR. Also known as Submitting Study.

"Contributor": is an individual authorized and responsible to transfer Materials to NIDDK-CR. Also known as Submitter.

"Materials": items generated by researchers and submitted to NIDDK-CR, to include but not limited to, all data, specimens, products, analytes, metadata, documentation, code, analytic tools, methods, algorithms, workflows, results, summaries, analyses, or conclusions.

"Resources": items held under the guardianship of and distributed by NIDDK-CR, to include but not limited to, data, specimens, products, analytes, metadata, documentation, code, methods, analytic tools, algorithms, workflows, results, summaries, analyses, or conclusions.

"Permitted Use": informed consent language describing the permitted research purposes and allowed use in future secondary work.

"Use Modifier": controlled vocabulary describing restrictions and requirements to the authorized terms of use within the permitted research purposes.

Terms of Agreement

1. Contributor agrees to transfer to NIDDK-CR the following Materials (check all that apply):

   ☐ Data

   ☐ Specimens

   ☐ Products or analytes

   ☐ Metadata, documentation, attributes, linkage file(s)

   ☐ Code, methods, algorithms, analytic tools

   ☐ Results, analyses, summaries, conclusions(s)

   ☐ Other, please specify:

2. The Materials listed above are being provided by the Contributor for the purpose of NIDDK-CR distributing these to qualified investigators.
3. The Contributor hereby grants NIDDK-CR explicit permission to distribute the Resources to qualified investigators as a research resource without any intellectual property assertions.
4. Terms specific to a Contributing Study:
   a. The Contributor certifies that the Materials were collected according to 45 CFR Part 46, "Protection of Human Research Participants," with the understanding that the Materials are not to be used in human research participants or for the treatment or diagnosis of human research participants.
   b. The Contributor certifies that an Institutional Review Board ("IRB") or equivalent governing body has reviewed and verified that the submission of Materials to NIDDK-CR for subsequent sharing for research purposes is consistent with the informed consent of study participants from whom the Materials were obtained.
   c. The Contributor agrees to provide NIDDK-CR, the Contributor/Contributing Study Certification attached hereto, as a clear statement identifying all Permitted Use and authorized terms for the distribution and future use of Materials, as specified in the study participants' informed consent documents, or check "None" if there are no known restrictions or limitations for future use. NIDDK-CR agrees to provide notice to qualified investigators requesting these NIDDK-CR held Resources.
5. The Contributor and NIDDK-CR acknowledge that some Materials may be limited in quantity and that their distribution for secondary research purposes will be based on the scientific merit of the proposed research. Scientific merit of all requests for NIDDK-CR-held Resources will be determined by NIDDK.

6. The Contributor acknowledges that NIDDK-CR will periodically assess the ongoing scientific utility of Resources. Options for Resource management or deaccessioning will be determined for Resources found to be of low utilization after an established amount of time per NIDDK-CR policy and established practices.
7. The Contributor may request NIDDK-CR-held Resources using the same procedures as other qualified investigators. The Contributor, who may retain the code for Materials and thus can identify their source, will be responsible for compliance with all applicable federal, state, tribal, and local laws and regulations (e.g., 45 CFR, Part 45) and all institutional policies relevant to their future research use.
8. To respect the privacy of the research participants, NIDDK-CR agrees not to contact or make any effort to identify individuals, families, communities, tribes, or populations that are or may be the source of the Materials. In addition, NIDDK-CR Data and Resources Use Agreement ("DUA") requires that qualified investigators granted access must abide by this same term of this MTA.
9. The Contributor is submitting the Materials to NIDDK-CR as a service to the research community. The Contributor makes no representation or warranties, express or implied, to NIDDK-CR with respect to the accuracy or completeness of the Materials. However, the Contributor will use reasonable efforts to ensure that the Materials are complete and accurate in all respects. Contributors will provide reasonable cooperation to NIDDK-CR to correct any failures of the Materials as requested by NIDDK-CR.

Contributor/Contributing Study Certification

1. **Name of Study (research project) that collected/generated the Materials**:

2. **Information on Materials being submitted to NIDDK-CR related to the above Study (research project):**

   a. **Materials are related to (check one):**

   ☐ Publication

   ☐ End of Study

   ☐ End of period of performance

   ☐ Other, please specify:

   b. **Terms of Use in Secondary Research based on the informed consent document:**

   Please identify all **Permitted Use**(s) of **the Materials** (as specifically stated in the participants' informed consent):

   ☐ Use is allowed for any research purpose

   ☐ Use is allowed for health, medical, or biomedical research purposes

   ☐ Use is allowed only for the specified disease(s), disorder(s), condition(s), or research area(s):

   (if additional space is necessary, consider including "health-related research")

   ☐ Not applicable, Materials being submitted are a result of secondary use of NIDDK-CR provided resources

   Please select any authorized **Use Modifier** (that aligns with the informed consent for the **Materials** or check "None" if there are not known restrictions or requirements:

   ☐ None

   ☐ Use does not allow sharing for commercial purposes

   ☐ Use does not allow sharing with for-profit organizations

☐ Use does not allow for whole genome sequencing (however, the use for genetic research purposes is allowed)

☐ Use does not allow for genetic research purposes

☐ Use does not allow for methods development research purposes, including artificial intelligence

☐ Use does not allow for sharing and further distributing as a training or educational resource

☐ Other authorized restriction or limitation than listed above, please specify:

Use does not allow for:

☐ Not applicable, Materials being submitted are a result of secondary use of NIDDK-CR provided resources

Material Transfer Agreement and Contributing Study Certification Signature Page

CONTRIBUTING STUDY ORGANIZATION:

The undersigned Contributor (and Contributing Study when applicable) expressly certifies and affirms that the contents of any statement made herein are truthful and accurate.

Certification of Contributor

The Contributor certifies that Materials described above, were collected, and are provided, in accordance with all applicable laws and assurances, IRB or other equivalent governing body approvals relating to Human Research Participants research. The Contributor also represents that the transfer of the Materials to NIDDK-CR for subsequent distribution for research purposes is consistent with all applicable federal, state, tribal, and local laws, and regulations for research participant protections.

Contributor's Institution
Authorized Representative signature:

Name of Authorized Signatory:

Title of Authorized Signatory:

Acknowledgment of Contributor
I have read and understand the terms of this Agreement.

Contributor Signature:

Name of Contributor:

Title of Contributor:

E-mail for Contributor:

NIDDK-CR INFORMATION and AUTHORIZED SIGNATURE

Organization: NIDDK

Name of Authorized Official: Rebecca M. Rodriguez, Ph.D.

Title of Authorized Official: Program Official, NIDDK Central Repository

Signature of Authorized Official:

Name of Authorized Official: Agnes Rooke, J.D. on behalf of Charles Niebylski, Ph.D., J.D.

Title of Authorized Official: Director, Technology Advancement Office

Signature of Authorized Official:

Any false or misleading statements made, presented, or submitted to the United States Federal Government, including any relevant omissions, under this MTA and during the course of negotiation of this MTA are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) (US Code Civil Liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment) (US Code Criminal Liability).