NIDDK Central Repository

Material Transfer Agreement for Biospecimen and/or Data

This Material Transfer Agreement (MTA) is intended for use when coded or unlinked biospecimens and/or study data are transferred to a biologic specimen and data repository managed by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH).

Provider:

Provider Scientist:

Recipient:

DEFINITIONS:

Biospecimen is a quantity of tissue, blood, urine, or other human-derived material.

Characterization Data is data collected as part of the Study that describes the Biospecimen

Coded Biospecimens are Biospecimens maintaining

- Identifying information (such as name or social security number) that would enable a Requestor to readily ascertain the identity of the individual from whom data or Biospecimens were derived that is replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
- A key to decipher the code, enabling linkage of the identifying information to the Study Data or Biospecimens. Each Coded Biospecimen is labeled with a unique code and does not carry any identifying information. The key to decipher the code is not be provided to a Requestor.

Provider is an organization that has the authority to transfer the Research Materials to Recipient under this MTA

Provider Scientist is an individual judged by the Provider to have the authority and responsibility to transfer the Research Materials to Recipient under this MTA

Recipient will serve as the custodian of the Research Materials and make them available to Requestors. The Recipient is the NIDDK Central Repository (or an NIDDK approved repository).

Repository is the physical entity where the Research Materials will be stored and distributed following the Recipient's approval processes and procedures

Requestor is a member of the scientific research community receiving Research Material from the Repository under a separate agreement between the Requestor and the Repository that will include all restrictions and limitations identified by Provider

Research Materials are collectively the Biospecimens, Study Data, Characterization Data and Study Documents which are transferred to the Recipient

Study is the clinical study under which the Research Materials described in this MTA were collected

Study Data is clinical or epidemiological participant data collected as part of the Study, e.g., phenotypic data

Study Documents are the documents that were used to manage the Study

Unidentified Biospecimens are Biospecimens that were collected without identifiers of any kind. Biospecimens may retain demographic or diagnostic information and still be considered unidentified if such information cannot be used to reveal the identity of the source

Unlinked Biospecimens are Biospecimens that were either initially collected without identifiers or were collected with identifiers that were then irreversibly stripped from the Biospecimens before transfer so that no one could link any individual Biospecimen to its source. However, certain clinical pathological, and/or demographic information may have been attached to Unlinked Biospecimens before participant identifiers were removed

Terms of Agreement

1. Provider agrees to transfer to Recipient the following Research Materials: **(List types of Biospecimens, i.e., DNA, serum, urine, etc. and indicate the type(s) of data being transferred)**

   , which is classified as

Biospecimens	Data
☐ **Coded**	☐ **Study Data**
☐ **Unlinked**	☐ **Characterization Data**
☐ **Unidentified**	☐ **Study Documents**

   and which was, or will be, collected as part of the

   under institutional protocol number , and NIH grant/contract number(s) .

2. The Research Materials are being provided under this MTA for the purpose of the Repository distributing the Research Materials to Requestors. The Provider hereby grants the Repository explicit permission to distribute the Research Materials to Requestors as a research resource.
3. The Provider certifies that the Research Materials were collected according to 45 CFR Part 46, "Protection of Human Subjects" at all the Study sites and the RESEARCH MATERIALS ARE NOT TO BE USED IN HUMAN SUBJECTS OR FOR THE TREATMENT OR DIAGNOSIS OF HUMAN SUBJECTS.
4. The Provider certifies that an Institutional Review Board (IRB) has reviewed and verified that submission of Research Materials to the Repository for subsequent sharing for research purposes is consistent with the informed consent of study participants from whom the Research Materials were obtained.
5. The Provider and the Recipient acknowledge that the Biospecimens may be limited in quantity and that their distribution for research purposes will be based on the scientific merit of a proposed research project. Scientific merit of all requests for Research Materials will be determined by Recipient. The Provider acknowledges that the NIDDK Central Repository will periodically assess the ongoing scientific utility of Biospecimens. Biospecimens determined to be of low scientific utility or non-viable may be discarded.
6. The Provider agrees to provide Recipient, in Appendix 1 attached hereto, a clear statement identifying all restrictions or limitations on the use or distribution of Research Materials (e.g., for diabetes research only) specified in the Study participants' informed consent documents. If no restrictions or limitations exist, Provider will write "NONE" in Appendix 1. The Recipient agrees to provide notice to Requestors

regarding restrictions or limitations described by the Provider in Appendix 1 in any distribution agreements entered into between Repository and Requestor.

7. Provider Scientist may request Research Materials from the Repository using the same procedures as other Requestors. Provider and Provider Scientists, who may retain the code for Research Materials and thus can identify their source, will be responsible for compliance with any applicable federal, state, and local laws and regulations (e.g., 45 CFR, Part 45) and any institutional policies relevant to their future research use of the Research Materials.
8. In order to respect the privacy of the human subjects, the Recipient agrees not to contact of make any effort to identify individuals, families, communities, tribes, or populations that are or may be the source of the Research Materials.
9. The Provider is submitting the Research Materials to the Recipient as a service to the research community. THEY ARE BEING SUPPLIED "AS IS" TO RECIPIENT WITH NO WARRANTIES, EXPRESSED OR IMPLIED.

The undersigned Provider expressly certifies and affirms that the contents of any statement made herein are truthful and accurate

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient 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

PROVIDER INFORMATION and AUTHORIZED SIGNATURE

Provider Organization:

Certification of Provider

The Provider certifies that the Research Materials were collected, and are provided, in accordance with all applicable laws and all assurances and Institutional Review Board or other review body approval relating to Human Subjects Research. The Provider also represents that the transfer of the Research Materials to the Recipient for subsequent distribution for research purposes is consistent with all applicable laws and regulations.

Provider Authorized Signature

Name of Authorized Signatory:

Title of Authorized Signatory:

Acknowledgement of Provider Scientist

I have read and understand the terms of this Agreement

Provider Scientist Signature

Name of Provider Scientist:

Title of Provider Scientist:

E-mail for Provider Scientist:

Provider address for documents:

E-mail for documents:

Any false or misleading statements made, present, or submitted to the Government, including any relevant omissions, under this Agreement and during the course of negotiation of this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fines(s) and/or imprisonment).

APPENDIX 1

INFORMATION ON RESEARCH MATERIALS BEING TRANSFERRED TO THE NIDDK CENTRAL REPOSITORY

Name of Study that collected the Research Materials:

Information on database of the above Study:

Please check one item below:

☐ Database was locked; Study has published results and is NOT requesting publication delay.

☐ Database was locked on ; a publication delay IS requested for studies that conflict with the Provider Scientist's primary publication(s).

☐ Databased is not currently locked; Provider IS requesting publication delay and will notify the Repository Program Official when database is locked.

Research Material Use Restrictions:

Identify all restrictions or limitations on the use or distribution of the Research Materials. Enter "NONE" if there are no restrictions: