

**NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE KIDNEY DISEASES**

MATERIAL TRANSFER AGREEMENT FOR BIOSPECIMENS

This Material Transfer Agreement (MTA) is intended for use when coded or unlinked biospecimens and associated data, are transferred to a biologic specimen and data repository managed either by the National Heart, Lung, and Blood Institute (NHLBI) or the National Institute of Diabetes and Digestive 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 a Biospecimen

Coded Biospecimens are Biospecimens maintaining

- identifying information (such as name or social Security number) that would enable an investigator to readily ascertain the identity of the individual from whom data or Biospecimens were derived. The identifying information 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 data or Biospecimens. Each Coded Biospecimen is labeled with one specific code and does not carry any identifying information. The key will not be transferred to the Recipient

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.

Repository is the physical entity where the Research Materials will be stored and distributed following the Recipient's approved 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 subject data collected as part of the Study, e.g. phenotypic data sets.

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 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 subject identifiers were removed.

Terms of Agreement

1. Provider agrees to transfer to Recipient the following Research Materials: **(Please list types of Biospecimens— i.e., DNA, serum, urine, etc. and indicate the type of data being transferred)**
_____ , which is classified as

<input type="checkbox"/> Coded	<input type="checkbox"/> Study Data
<input type="checkbox"/> Unlinked	<input type="checkbox"/> Characterization Data
<input type="checkbox"/> Unidentified	<input type="checkbox"/> Study Documents

And which was, or will be, collected as part of the _____ **(name of Study)**,
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 that 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 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.
6. The Provider agrees to provide to 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 heart 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 the Research Materials from the Repository using the same procedures as other investigators. Provider and Provider Scientists, who may retain the code for the Research Materials and thus can identify their sources, will be responsible for compliance with any applicable federal, state, and local laws and regulations (e.g., 45 CFR, Part 46) 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 or make any effort to identify individuals, families, communities, tribes, or populations that are or may be the sources 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, EXPRESS OR IMPLIED.

The Undersigned Provider expressly certifies and affirms that the contents of any statements made herein are truthful and accurate.

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Organization: [Insert IC (NIDDK or NHLBI)]

Name of Authorized Official:
Title of Authorized Official:
Address:

Signature of Authorized Official: Date: _____

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 (IRB) or other review body approvals 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 Date: _____

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 Date: _____

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, presented, 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 fine(s) and/or imprisonment).

APPENDIX 1

INFORMATION ON RESEARCH MATERIALS BEING TRANSFERRED

TO THE [Insert NIDDK or NHLBI] REPOSITORY

Name of Study that collected the Biospecimens and data:

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 _____ (date); a publication delay IS requested for studies that conflict with the Provider PI's' primary publication(s).

_____ Database is not currently locked; Provider IS requesting publication delay and will notify the Repository Representative 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: