NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

MATERIAL TRANSFER AGREEMENT FOR BIOSPECIMENS

This Material Transfer Agreement (MTA) is intended for use when coded, unlinked or unidentified Biospecimens and associated Study or Characterization Data, hereafter "Research Materials," are transferred to the Biologic Specimen Repository and Data Repository, hereafter "Repository," managed by the National Heart, Lung, and Blood Institute (NHLBI).

Provider:

Provider Scientist:

Recipient:

Name of Study:

DEFINITIONS

Research Materials are the Biospecimens, Study Data or Characterization Data collected as part of the Study and the Study documents used to manage the Study. Characterization Data describe the biospecimens only. Study Data are the clinical or epidemiology subject data collected by the Study.

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

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 is the National Heart, Lung, and Blood Institute, National Institutes of Health. The Recipient will serve as the custodian of the Research Materials and make them available to members of the scientific community under separate agreements.

Recipient Representative is an individual judged by the Recipient to have the authority to accept transfer of the Research Materials under this MTA.

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

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

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 whether phenotypic data sets or characterization data sets are being transferred)**

   _____, which is classified as

Indicate Degree of Biospecimen Deidentification	Indicate Type of Data to be Transferred
☐ Coded ☐ Unlinked ☐ Unidentified	☐ Study Data ☐ Characterization Data

   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 the research community. The Provider hereby grants the Repository explicit permission to distribute the Research Materials to the research community 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 reviewed according to the Recipient's distribution guidelines. The Research Materials will be made available by the Repository to qualified scientists, under a separate distribution agreement in accordance with all restrictions or limitations identified by Provider. The Provider acknowledges that the NHLBI will periodically assess the ongoing scientific utility of Biospecimens. Biospecimens determined to be of low scientific utility may be discarded.

6. The Provider agrees to provide to Recipient 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 should write "NONE" in Appendix 1, attached hereto. The Recipient agrees to provide notice to any third-party recipient regarding restrictions or limitations described by the Provider in Appendix 1 in any separate distribution agreements entered into by Repository.

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.

SIGNATURES BEGIN ON FOLLOWING PAGE

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Representative: _____ Recipient Organization: NHLBI

_____ Date: _____
Signature of Recipient Representative

Name of Authorized Official: _____

Title of Authorized Official: Director, Office of Technology Transfer & Development, NHLBI

Address of Authorized Official: Refer to http://www.nhlbi.nih.gov/research/tt/

_____ Date: _____
Signature of Authorized Official

PROVIDER INFORMATION and AUTHORIZED SIGNATURE

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 Organization: _____

_____ Date:_____
Provider Authorized Signature

Name of Authorized Signatory: _____

Title of Authorized Signatory: _____

Provider address for documents: _____

_____

Provider e-mail for documents: _____

Acknowledgement of Provider Scientist

I have read and understand the terms of this Agreement

_____ Date:_____
Provider Scientist Signature

Name of Provider Scientist: _____

Title of Provider Scientist: _____

Provider Scientist's address for materials: _____

_____

E-mail for Provider Scientist: _____

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).

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

MATERIAL TRANSFER AGREEMENT FOR BIOSPECIMENS - APPENDIX 1

INFORMATION ON RESEARCH MATERIALS BEING TRANSFERRED TO THE 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:

_____

_____

_____