MATERIAL TRANSFER AGREEMENT -- HUMAN

This Material Transfer Agreement ("MTA") has been adopted for use by the National Institutes of Health ("NIH"), the Food and Drug Administration ("FDA"), and the Centers for Disease Control and Prevention ("CDC"), collectively referred to herein as the United States Public Health Service ("PHS") within the Department of Health and Human Services ("DHHS"), in all transfers of research material ("Research Material") whether PHS is identified below as its Provider or Recipient.

Provider: National Institute of Diabetes and Digestive and Kidney Diseases

Provider Scientist: _____

Recipient: _____

Recipient Scientist: _____

1. Provider agrees to transfer to Recipient's Scientist the following Research Material:

_____, which is classified as:

☐ **Identifiable**: samples or data that are still attached to a readily available subject identifier such as a name, social security number, address, telephone number, medical record number, etc.

☐ **Coded**: collected samples or data that are unidentified for research purposes by use of a random or arbitrary alphanumeric code but that may still be linked to their sources through use of a key to the code available to an investigator or collaborator.

☐ **Anonymized**: human data or samples that were initially collected with identifiers but, before research use, have been irreversibly stripped of all identifiers by use of an arbitrary or random alphanumeric code and the key to the code is destroyed, thus making it impossible for anyone to link the samples to the sources. This does not preclude linkage with existing clinical, pathological, and demographic information before subject identifiers are removed.

This material was or will be collected under protocol (*provide name and number of protocol*):

_____.

2. The Research Material was collected according to 45 CFR Part 46, "Protection of Human Subjects under Federal Wide Assurance Number **FWA00005897**. THIS RESEARCH MATERIAL MAY NOT BE USED IN HUMAN SUBJECTS.

3. Human Subject Protection

a. Human Subject Research: The Research to be conducted under this Agreement involves Human Subjects or human tissues within the meaning of 45 C.F.R. Part 46, and its performance will conform to applicable federal laws and regulations. Additional information is available from the HHS Office for Human Research Protections.

b. In order to respect the privacy of the human subjects, the RECIPIENT and the RECIPIENT SCIENTIST agree that it will not contact or make any effort to identify individuals, families, communities, tribes or populations which are or may be the sources of the Research Material.

4. This Research Material will only be used for research purposes by Recipient Scientist in his/her laboratory under suitable containment conditions for the Research Project described with specificity in the ***attached Appendix1***. Recipient agrees to comply with all Federal rules and regulations applicable to the Research Project and the handling of the Research Material.

5. Confidentiality

a. For the purpose of this agreement “Confidential Information” shall mean any information, raw data, or results disclosed or generated by any party to this agreement concerning the Research Material transferred under this Agreement whether or not stamped “Confidential”. Summary data, defined as tables of aggregate results, are not Confidential Information.

b. Recipient and any agent agree to maintain the confidentiality of the Confidential Information, such efforts to be no less than the degree of care employed to preserve and safeguard its own confidential information. The Confidential Information shall not be disclosed, revealed, or given to anyone by Recipient except to employees or agents of Recipient who have a need for the Confidential Information in connection with the Research Project, and such employees or agents shall be advised of the confidential nature of the Confidential Information and that the Confidential Information shall be treated accordingly.

c. The obligations of a Party under this Paragraph 5 shall not extend to any part of the Confidential Information:

(i) that can be demonstrated to have been in the public domain or publicly known at the time of disclosure; or
(ii) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to such Party from another source prior to the disclosure; or
(iii) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by such Party; or
(iv) that can be demonstrated as independently developed or acquired by such Party without reference to or reliance upon such Confidential Information.

d. Nothing herein shall prevent Provider or Recipient from complying with a legal obligation to disclose Confidential Information. Fulfillment of such a legal obligation does not release either party from the remaining confidentiality obligations of this Article 5.

6. This Research Material represents a significant investment on the part of Provider and is considered proprietary to Provider. Recipient's Scientist therefore agrees to retain control over this Research Material and further agrees not to transfer the Research Material to other people not under her or his direct supervision without advance written approval of Provider. Provider reserves the right to distribute the Research Material to others and to use it for its own purposes. When the Research Project is completed the unused Research Material, at the request of the Provider, will returned to the Provider or discarded in compliance with all applicable statutes and regulations. In addition:

a. The RECIPIENT and the RECIPIENT SCIENTIST agree to provide all results to the Provider Scientist within 30 days of completing each analysis. In all oral presentations or written publications concerning the Research Project, the RECIPIENT and the RECIPIENT SCIENTIST will acknowledge Provider's contribution of this Research Material unless requested otherwise.

b. Before the RECIPIENT or the RECIPIENT SCIENTIST submits a paper or abstract for publication or otherwise intends to publicly disclose information about the MATERIAL, RECIPIENT and the RECIPIENT SCIENTIST shall ensure that PROVIDER has at least thirty (30) days to review the proposed publication or disclosure. Provider reserves the right to delete or modify information that might reasonably be viewed as offensive to the human subjects involved.

7. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO RECIPIENT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties.

8. When Provider is the PHS: Recipient shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. Recipient agrees not to claim, infer, or imply endorsement by the Government of the United States of America (hereinafter referred to as "Government") of the Research Project, the institution or personnel conducting the Research Project or any resulting product(s). Unless prohibited by law from doing so, Recipient agrees to hold the Government harmless and to indemnify the Government for all liabilities, demands, damages, expenses and losses arising out of Recipient's use for any purpose of the Research Material.

9. When Recipient is the PHS: The PHS shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project. The PHS is not authorized to promise rights in advance for inventions developed under this Agreement. Provider acquires no intellectual property rights under this MTA, but may apply for license rights to any patentable invention that might result from this Research Project. It is the intention of PHS that Provider not be liable to PHS for any claims or damages arising from PHS's use of the Research Material; however, no indemnification is provided or intended.

10. The undersigned Provider and Recipient expressly certify and affirm that the contents of any statements made herein are truthful and accurate.

SIGNATURES BEGIN ON FOLLOWING PAGE

PROVIDER INFORMATION and AUTHORIZED SIGNATURE

Provider Scientist: _____
Provider Organization: National Institute of Diabetes and Digestive and Kidney Diseases
Name of Authorized Official: Rochelle S. Blaustein, J.D
Title of Authorized Official: Director, NIDDK Office of Technology Transfer and Development
Address: 9000 Rockville Pike, Building 12A Suite 3011
Bethesda, MD 20892-5632

_____ Date:_____
Signature of Authorized Official:

Certification of Provider Scientist: **The Research Material was collected and is provided in accordance with appropriate Federal and Local Laws, Assurances, and Institutional Review Board (IRB) approvals relating to Human Subjects Research. The approved IRB protocol in Article 1 above identifies the names of the Recipient Institution and Recipient Scientist as listed above to receive these human tissues for the stated Research Project.**

_____ Date__:_____
Signature of Provider Scientist:

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Scientist: _____
Recipient Organization: _____

_____ Date:__ _____
Authorized Signature for Recipient's Institution

Name of Authorized Signatory: _____
Title of Authorized Signatory: _____

Certification of Recipient Scientist: **I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.**

_____ Date: _____
Recipient Scientist Signature

Name of Recipient Scientist: _____
Title of Recipient Scientist: _____

Recipient's address for documents: _____
_____

E-mail for documents: _____

Recipient Scientist's address for materials: _____
_____

E-mail for Recipient 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).

APPENDIX 1

Research Project

S***specify project in detail:***