

Appendix 4. Sample Material Transfer Agreement

The following Material Transfer Agreement (MTA) is intended to serve as a sample agreement for use between biospecimen resources and approved end-users receiving biospecimens and/or data. This sample MTA may need to be modified depending on the material and data that are being transferred and the specific requirements of the research project. Please note, this MTA is intended for transfer of deidentified biospecimens and data. (Please see [Section C.5](#) of the *NCI Best Practices* for more information and additional recommendations related to MTAs).

Sample Material Transfer Agreement For Transfers from Biospecimen Resources to Approved Third-Party End Users

This Material Transfer Agreement (the “Agreement”) is by and between <insert name of biospecimen resource> (“Provider”) and <insert name of third-party institution> (“Recipient”) regarding the transfer of human specimens, with or without associated data, from the <insert name of biospecimen resource> to approved third-party end users for research purposes as further defined below. Throughout this Agreement, Provider and Recipient are collectively referred to as the “Parties.” This Agreement will become effective upon the date of the last signature affixed below.

The Provider and Recipient agree as follows:

1. DEFINITIONS. Within this Agreement, the following terms will have the same meaning and effect as those used in the Standards for Privacy of Individually Identifiable Health Information set forth in 45 CFR Parts 160 and 164 (“HIPAA Privacy Rule”). These terms are repeated here for convenience:

(a) “De-identified” information is information that formerly contained individually identifiable health information but which has had all unique identifying information, numbers, characteristics, and codes removed such that the information a record contains cannot be used alone or in combination with other information to identify the individual who is the subject of the information (45 CFR 164.514). Identifying information includes, but is not limited to, the 18 categories of identifiers described in 45 CFR 164.514(b)(2).

(b) “Protected Health Information” or “PHI” means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present, or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual, and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual (45 CFR 164.103).

2. DESCRIPTION OF MATERIAL AND DATA. The Provider will transfer to the Recipient the following biospecimens and/or derivatives (“MATERIAL”): <insert description of specific samples to be transferred> with the following data (“DATA”): <insert description of specific data to be transferred, if applicable>.

3. COLLECTION OF MATERIAL AND DATA. The MATERIAL and DATA were collected and/or processed from human biospecimens as part of <insert name of biospecimen resource> in accordance with appropriate Federal and local laws, Assurances, and Institutional Review Board approvals related to human subjects research, as appropriate.

4. TRANSFER OF MATERIAL AND DATA. The MATERIAL and DATA provided by Provider will be de-identified and all Protected Health Information (PHI), as defined by the Federal Health Insurance Portability and Accountability Act (HIPAA, 45 C.F.R. 164) will have been removed.

5. RESPONSIBILITIES AND AUTHORIZATIONS OF RECIPIENT

(a) Recipient agrees to use the MATERIAL and DATA for the approved research project only (see [Appendix 1](#) “Research Project”) and will not use the MATERIAL and DATA for any unapproved commercial purposes, including selling or transferring to a third party for commercial purposes.

(b) Recipient is responsible for obtaining any necessary Human Subjects research approvals or exemptions required to use the MATERIAL and DATA at the respective institution. The MATERIAL and DATA will be used by the Recipient in compliance with all applicable Federal, state, and local statutes and regulations.

(c) Recipient will allow the use of MATERIAL and DATA only by <insert name of third party P.I.> (“Recipient Investigator”) and Recipient Investigator’s research team that are under the direct supervision of Recipient Investigator, and only after they have been informed of and agreed to the provisions and restrictions stated herein. Any transfer of MATERIAL and DATA to other than Recipient Investigator’s research team requires the advanced written approval of the Provider.

(d) It is acknowledged that the Recipient may already have in its possession or will obtain from another source, PHI related to the MATERIAL and DATA, and to which the Recipient may be subject to additional restrictions or obligations under separate agreements. Recipient shall notify Provider in writing within five (5) working days of its discovery of any unauthorized use or disclosure of PHI related to the MATERIAL and DATA of which Recipient, its officers, employees, or agents become aware. Recipient shall take (i) prompt corrective action to cure any deficiencies or (ii) any action pertaining to such unauthorized disclosure required by applicable federal law.

(e) Recipient agrees to not identify or contact any donor, or living relative of a donor, who may have provided the MATERIAL or any DATA received by Recipient under this Agreement from Provider.

(f) Recipient agrees to report data, inventions, and publications resulting from the use of the MATERIAL and/or DATA to Provider.

6. THE MATERIAL AND DATA ARE NOT FOR USE IN HUMAN SUBJECTS OR FOR THE TREATMENT OR DIAGNOSIS OF HUMAN SUBJECTS.

7. DISCLAIMER. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE HUMAN MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. To the extent allowed by law, Recipient assumes liability for claims for damages against it by third parties which may arise from its use, storage, processing, distribution, or disposal of the MATERIAL except that, to the extent permitted by law, Provider shall be liable to Recipient when the damage is caused by the gross negligence or willful misconduct of Provider.

8. TERMINATION AND DISPOSAL. Either Party may terminate this Agreement with sixty (60) days written notice to the other Party. When the Research Project is completed or this Agreement is terminated, whichever comes first, any unused MATERIAL and DATA will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the Provider as requested by the Provider.

9. ACKNOWLEDGEMENT. In all oral presentations or written publications resulting from the use of the MATERIAL and DATA, the Recipient will acknowledge the *<insert name of biospecimen resource>* as the source of the MATERIAL and DATA, unless requested otherwise by Provider, as follows:

“Biospecimens (and/or Derivatives) and associated data were provided by the *<insert name of biospecimen resource>*, an initiative developed through funding from the *<insert funding source, if applicable>*.”

10. COST AND SHIPPING. The MATERIAL and DATA are provided at no cost to Recipient. Provider will notify Recipient when the MATERIAL and DATA are ready for shipment. Recipient will be responsible for the pick-up and shipment, including shipping costs, of the MATERIAL and DATA.

The Parties have executed this Agreement by their respective duly authorized officers on the day and year hereinafter written. Any communication or notice to be given shall be forwarded in writing to the respective addresses listed below.

SIGNATURES APPEAR ON THE FOLLOWING PAGE

Signatures for Provider

Provider Scientist:
Provider Organization:
Address:

Name of Authorized Official:
Title of Authorized Official:

Signature of Authorized Official Date

Certification of Provider Authorized Official: This Agreement __has / __has not been modified. If modified, the modifications are attached.

Signatures for Recipient

Recipient Scientist:
Recipient Organization:
Address:

Name of Authorized Official:
Title of Authorized Official:

Signature of Authorized Official Date

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 and DATA.

Scientist Receiving Material Date