



**The Cancer Human Biobank (caHUB)
Material Transfer and Data Use Agreement
For Transfers to the caHUB Comprehensive Biospecimen Resource (CBR) and the caHUB
Comprehensive Data Resource (CDR) from Biospecimen Source Sites (BSS)**

This Material Transfer and Data Use Agreement (the “Agreement”) is by and between *<insert name of BSS>* (“Provider”), *<insert name of subcontractor operating the CBR>* (“Biospecimen Subcontractor”) and *<insert name of subcontractor operating the CDR>* (“Data Subcontractor”) (hereinafter, the Biospecimen Subcontractor and the Data Subcontractor are collectively referred to as “Recipient”), regarding the transfer of human specimens and associated data to the Recipient as part of the Cancer Human Biobank (“caHUB”) initiative. 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.

WHEREAS, in order to improve the ability to diagnose, treat, and prevent cancer, the National Cancer Institute (“NCI”), a member of the National Institutes of Health, an agency of the federal government, has developed the caHUB as a continuous and reliable source of high-quality human biospecimens and associated data for the broader cancer community, including basic and clinical researchers and the biotechnology and pharmaceutical industries that rely on biospecimens for cancer diagnostics and drug development;

WHEREAS, the major organizational components of the caHUB include a Human Cancer Comprehensive Biospecimen Resource (“caHUB CBR”), and a Comprehensive Data Resource (“caHUB CDR”);

WHEREAS, the purpose of using a national Cancer Human Biobank is to provide a centralized, standardized source of high-quality, well-documented human biospecimens for cancer research;

WHEREAS, Provider is subject to the Health Insurance Portability and Accountability Act (“HIPAA”) of 1996, as amended, and accompanying regulations, and desires to transfer certain human biospecimens and associated data to Recipient for processing and/or further distribution to approved third party end users, as appropriate;

WHEREAS, the Biospecimen Subcontractor is funded to operate the caHUB CBR, and the Data Subcontractor is funded to operate the caHUB CDR, under subcontracts with NCI’s Operations and Technical Support (“OTS”) contractor to receive, process, exchange, and distribute human biospecimens, derivative materials, and associated data to approved third party end users; and

WHEREAS, Provider and Recipient desire to protect the privacy and provide for the security of certain information disclosed to Recipient in compliance with applicable laws and regulations;

NOW, THEREFORE, in consideration of the mutual promises in this Agreement and for other good and valuable consideration, the sufficiency of which is hereby acknowledged, the Parties hereby 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).

(c) A “limited data set” (herein “LDS”) is protected health information that excludes the 16 direct identifiers listed in that section. Any such information that identifies the individual who is the subject of the PHI, his or her relatives, employers, or household members must be removed for the PHI to constitute an LDS. Unlike de-identified PHI, an LDS may contain postal address information, in the form of a town, city, State, or zip code only; age; specific dates, for example, dates of birth, death, admission, treatment, or release; and any other information, not specifically listed in that section, that could be used alone or in combination with other information to identify a specific individual (45 CFR 164.514(e)(2)).

2. DESCRIPTION OF MATERIAL AND DATA.

(a) The material to be transferred (“ORIGINAL MATERIAL”) is a set of human biospecimens described specifically as: *<insert description of specific samples to be transferred>*

(b) The data to be transferred are clinical, biological, technical and/or other information describing the ORIGINAL MATERIAL (“DATA”). Some of the DATA may be Protected Health Information and will be transferred in the form of an LDS. The DATA to be transferred is described specifically as: *<insert description of specific data/limited data sets to be transferred>*

3. COLLECTION OF MATERIAL AND DATA. The Provider represents and warrants to Recipient that:

(a) all ORIGINAL MATERIAL and DATA provided by Provider to Recipient were collected pursuant to and in accordance with a protocol approved by an Institutional Review Board (“IRB”);

(b) the collection of the ORIGINAL MATERIAL and DATA was conducted in compliance with all applicable laws, regulations and policies for the protection of human subjects, including 45 CFR Part 46, “Protection of Human Subjects” (the “Common Rule”) and the HIPAA Privacy Rule, and any necessary approvals, authorizations, human subjects assurances, informed consent documents, and IRB approvals were obtained;

(c) the IRB’s oversight of the collection of any ORIGINAL MATERIAL and DATA included a review of all necessary informed consents and authorizations, which consents allow redistribution of the ORIGINAL MATERIAL or materials derived from the ORIGINAL MATERIAL, e.g., DNA and RNA products (“DERIVATIVE MATERIAL,” together with the ORIGINAL MATERIAL, the “MATERIAL”) or DATA in the manner described in Section 4 of this Agreement; and

(d) the transfer, processing and analysis of the ORIGINAL MATERIAL and DATA, as part of the operations of the caHUB, is authorized by the informed consent of the patient supplying such ORIGINAL MATERIAL and DATA, as determined by an IRB.

4. TRANSFER OF ORIGINAL MATERIAL AND DATA; PURPOSE.

(a) Provider agrees to provide to Recipient the ORIGINAL MATERIAL and DATA, in the form of an LDS pursuant to web portal instructions provided by the Recipient to the Provider, in accordance with all applicable laws, regulations and policies as stated in section 3(b) of this Agreement.

(b) Parties acknowledge and agree that the ORIGINAL MATERIAL will only be received and processed by the caHUB CBR.

(c) The sole and limited purpose of the Provider's transfer to Recipient of the DATA is to enable Recipient to receive, process, and distribute the MATERIAL and the DATA, in the appropriate form as indicated below, to approved third party end users in fulfillment of its contractual obligations to the NCI and the OTS contractor (the "Purpose"). The Parties expressly intend for this Agreement to constitute a data use agreement, authorizing use and disclosure only in furtherance of the Purpose, in accordance with 45 CFR 164.514(e)(4).

(d) Provider is responsible for removing all of the prohibited direct identifiers from the DATA, such that the DATA will be in the form of an LDS, before transfer to Recipient.

(e) Provider has the authority and hereby grants Recipient explicit permission to further distribute the MATERIAL and all De-identified DATA to third party end users with the appropriate human subjects approvals or exemptions and a research project approved by the caHUB Scientific Steering Committee.

(f) Provider has the authority and hereby also grants Recipient explicit permission to provide all or part of the LDS upon request to third parties, pursuant to separate data use agreements that are no less restrictive than this Agreement and that prohibit such third parties from further distributing the LDS.

(g) Provider acknowledges and agrees that all decisions regarding distribution of the MATERIAL and DATA, and approval of third party research projects, will be made exclusively by the caHUB. Provider will have no rights to review data or publications resulting from a third party's use of the MATERIAL and DATA.

(h) The Agreement does not restrict the Provider's right to distribute the MATERIAL and DATA to third parties.

5. RESPONSIBILITIES AND AUTHORIZATIONS OF RECIPIENT

(a) Recipient is authorized to receive the ORIGINAL MATERIAL and DATA under an IRB approved protocol or IRB granted waiver. Recipient agrees to handle and distribute the MATERIAL in accordance with all applicable laws, regulations and policies, including the Common Rule, the HIPAA Privacy Rule, and any necessary human subject's assurances, informed consents and IRB approvals.

(b) Recipient further agrees that it will only use and/or disclose the DATA for the Purpose described herein and shall not use or disclose the DATA in a manner inconsistent with the HIPAA Privacy Rule.

(c) Recipient is not authorized and shall not further disclose the DATA other than as permitted by this Agreement or as otherwise required by law.

(d) Recipient shall use appropriate administrative, technical, and physical safeguards to prevent use or disclosure of the DATA other than as provided for in this Agreement.

(e) Recipient shall notify Provider in writing within five (5) working days of its discovery of any use or disclosure of the DATA not permitted by this Agreement 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.

(f) Recipient shall ensure that any of its agents or subcontractors certify in writing that such agent or subcontractor will hold any DATA transmitted from the Recipient to such agent or subcontractor confidential and will use or disclose the information only for the purpose for which it was used or disclosed to the agent or subcontractor, or as required by law. Additionally, the agent or subcontractor shall notify Recipient of any instances, of which it is aware, in which the DATA has been used or disclosed inconsistent with this Agreement.

(g) 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. Furthermore, Recipient will not attempt to obtain or otherwise acquire any PHI associated with the MATERIAL beyond that which is provided in the DATA by the Provider.

(h) Recipient will retain and abide by this Agreement for as long as it retains the DATA or other PHI received from the Provider, plus 6 (six) years after the date it returns or destroys all such information.

6. BREACH OR VIOLATION. Provider is not responsible for Recipient's violations of this Agreement, unless Provider knows of a pattern of activity or practice that constitutes a material breach or violation of this Agreement, in which case it must take reasonable steps to cure the breach, end the violation or withhold the LDS or other PHI delivered to Recipient. If this is not possible, the breach will be reported to the Secretary of the Department of Health and Human Services. Recipient acknowledges that a breach of this Agreement is a violation of the HIPAA Privacy Rule and could subject Recipient to potential fines or imprisonment.

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

8. DISCLAIMER. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. SUBJECT TO THE REPRESENTATIONS IN SECTION 3 ABOVE WITH RESPECT TO THE MATERIAL OR DATA, 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 MATERIAL OR DATA 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.

9. DISPOSAL OF MATERIAL AND DATA. At the end of its subcontract with the NCI's OTS contractor, or upon the termination of this Agreement by either Party, Recipient will dispose of the MATERIAL and DATA in its possession in the manner decided at the sole discretion of the OTS contractor, in consultation with the caHUB Leadership. Such disposition may include, but is not limited to, continued storage for future research, transfer to the Provider, use in an expansion of the caHUB, transfer to another organization acting on behalf of the NCI or the OTS contractor, or destruction, as is consistent with law and the informed consent of the patient who provided such ORIGINAL MATERIAL. Provider acknowledges that any ORIGINAL MATERIAL transferred to Recipient may be destroyed as a consequence of processing conducted in accordance with the operations of the caHUB.

10. INTELLECTUAL PROPERTY. Recipient acknowledges that it serves only as the custodian of the MATERIAL and DATA, and therefore agrees that it does not by virtue of this Agreement acquire ownership of ORIGINAL MATERIAL and DATA, nor any intellectual property rights in the MATERIAL, nor any future intellectual property rights in any research conducted by third parties using the MATERIAL or DATA. Provider acknowledges and agrees that it does not by virtue of this Agreement acquire any intellectual property rights in the future inventions or discoveries made by third parties using the MATERIAL or DATA distributed by Recipient.

11. ASSIGNMENT; SUCCESSORS AND ASSIGNS; NO THIRD-PARTY RIGHTS. Recipient may not assign its rights or cause to be assumed its obligations hereunder without the prior written consent of the OTS contractor, which consent shall not be unreasonably withheld or delayed. Subject to the foregoing, this Agreement shall apply to, be binding in all respects upon and inure to the benefit of the Parties hereto and their respective successors and assigns. Nothing expressed or referred to in this Agreement shall be construed to give any person or entity other than the Parties hereto any legal or equitable right, remedy or claim under or with respect to this Agreement or any provision of this Agreement.

12. 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.

13. ENTIRE AGREEMENT. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes and replaces all prior agreements, understandings, commitments, communications and representations made between the Parties, whether written or oral, with respect to the subject matter hereof. This Agreement may not be amended, supplemented, or otherwise modified except by a written agreement executed by each of the Parties. Either Party has the right to terminate this Agreement at any time with written notice to the other Party. Articles 5(g), 5(h), 6, 8 and 10 shall survive termination.

14. EXECUTION OF AGREEMENT. This Agreement may be executed in two or more counterparts, each of which will be deemed to be an original copy and all of which, when taken together, will be deemed to constitute one and the same agreement. The exchange of copies of the Agreement and of signature pages by facsimile transmission will constitute effective execution

and delivery of this Agreement as to the Parties hereto and may be used in lieu of the original agreement for all purposes. Signatures of the Parties transmitted by facsimile will be deemed to be their original signatures for all purposes.

SIGNATURES APPEAR ON FOLLOWING PAGE

Signature for the Biospecimen Source Site (BSS)

Provider Scientist:
 Provider Organization:
 Address:

Name of Authorized Official:
 Title of Authorized Official:

Signature of Authorized Official Date

Signatures for the Cancer Human Biobank

| Comprehensive Biospecimen Resource | Comprehensive Data Resource |
|--|--|
| Recipient Scientist: Recipient Organization: Address: | Recipient Scientist: Recipient Organization: Address: |
| Name of Authorized Official: Title of Authorized Official: | Name of Authorized Official: Title of Authorized Official: |
| _____ | _____ |
| Signature of Authorized Official Date | 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. | 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. |
| _____ | _____ |
| Recipient Scientist Date | Recipient Scientist Date |