Material Transfer Agreement[1]
For the Transfer of De-identified Human Tissues and Specimens
Between
Non-profit Organizations Participating in the NIH Human Biomolecular Atlas Program

WHEREAS for the purposes of this Material Transfer Agreement, ("Agreement"), each institution signing this Agreement represents that it is a non-profit organization and that its signatory is authorized to bind the institution; each signatory institution may be referred to herein, individually as a "Party" and or "Provider" and or "Recipient"; and

WHEREAS each Party is a member of the NIH Human Biomolecular Atlas Program ("HuBMAP Program")[2] and one or more of its employees or faculty members are lab heads participating in the HuBMAP Program, referred to herein as Provider or Recipient Scientist; and

WHEREAS consistent with the terms of this Agreement, each Party may provide, receive, access and use the Original Material (as defined in this Agreement) for the purpose of performing the Research Purpose, as stated in Exhibit A hereto; and

WHEREAS each transfer of Materials subject to this Agreement will be documented with a completed Record of Transfer form, as attached in Exhibit B hereto, and made subject to the terms and conditions of this Agreement.

NOW THEREFORE, by signing this Agreement, each signatory institution hereby agrees to be bound by the terms of this Agreement to govern the transfer and use of the Original Material described herein.

Standard Terms

I. DEFINITIONS:

1. **Provider**: Organization(s) providing the Original Material. The name and address of each Providing Party is specified in the Record of Transfer, using Exhibit B to this Agreement.[3]

2. **Provider Scientist**: The name and address of this party is specified in the Record of Transfer, using Exhibit C to this Agreement.

3. **Recipient**: Organization receiving the Original Material. The name and address of this Party is specified in the Record of Transfer, using Exhibit B to this Agreement.

4. **Recipient Scientist:** The name and address of this party is specified the Record of Transfer, using Exhibit B to this Agreement.

5. **Original Material**: From HuBMAP Tissue Mapping Centers (TMCs) and/or Biorepository: 1) Frozen, Fixed or otherwise processed Human Tissue sections and/or blocks for cellular, molecular and/or imaging analysis, 2) one or more vials of dissociated primary tissue cells for culture or content analysis.

6. **Material**: Original Material and Unmodified Derivatives. The Material shall not include: (a) Modifications, or

[1] Modified from Uniform Biological Material Transfer Agreement ("UBMTA") published in the Federal Register on March 8, 1995

[2] Howard Hughes Medical Institute ("HHMI") is not a participant in the HuBMAP Consortium, but is a Party and signatory to MTAs for its employee, Dr. Jay Shendure, a member of the faculty of the University of Washington and participating scientist in the Consortium, to receive Materials governed by this MTA. The University of Washington is a member of the Consortium.

[3] When the Shendure lab is providing Original Material under the terms of this MTA, only the University of Washington will be identified as the Providing Institution and the University of Washington is responsible for compliance with the terms and conditions relating to providing materials, and not HHMI, consistent with the inter-instititutional agreement between them.

(b) other substances created by the Recipient through the use of the Material which are not Modifications, or Unmodified Derivatives.

7. **Unmodified Derivatives**: Substances created by the Recipient which constitute an unmodified functional subunit of the Original Material. Some examples include: Original Material or unmodified portions thereof fixed as tissue sections or in arrays, and unmodified proteins, RNA, or DNA extracted from Original Material.

8. **Modifications**: Substances created by the Recipient which contain/incorporate the Material but which are not Unmodified Derivatives. Some examples include genetic modification or manipulation of cells extracted from the Original Material.

9. **Commercial Purposes**: The sale, lease, license, or other transfer of the Material or Modifications to a for-profit organization. Commercial Purposes shall also include uses of the Material or Modifications by any organization, including Recipient, to perform contract research, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the Material or Modifications to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the Material or Modifications for Commercial Purposes *per se*, unless any of the above conditions of this definition are met.

10. **Nonprofit Organization(s)**: A university or other institution of higher education or a not-for-profit organization officially recognized or qualified under the laws of the country in which it is organized or located, or any nonprofit scientific or educational organization qualified under a federal, state or local jurisdiction's nonprofit organization statute. As used herein, the term also includes national, state or local government agencies.

II. TERMS AND CONDITIONS OF THIS AGREEMENT

1. The Provider retains ownership of the Material, including any Material contained or incorporated in Modifications.

2. The Recipient retains ownership of: (a) Modifications (except that, the Provider retains ownership rights to the Material included therein), and (b) those substances created through the use of the Material or Modifications, but which are not Unmodified Derivatives or Modifications (*i.e.*, do not contain the Original Material or Unmodified Derivatives). If either 2 (a) or 2 (b) results from the collaborative efforts of the Provider and the Recipient, joint ownership may be negotiated.

3. The Recipient agrees, and the Recipient Scientist acknowledges, that the Material:

   (a) is to be used only for the purpose as specified in Exhibit A. If Recipient desires to use Material for research other than that stated in Exhibit A, then Recipient must obtain written consent from Provider, before any such research is undertaken;

   (b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the Provider;

   (c) is to be used only at the Recipient organization and only in the Recipient Scientist's laboratory under the direction of the Recipient Scientist or others working under his/her direct supervision; and

   (d) will not be transferred to anyone else within the Recipient organization(s) without the prior written consent of the Provider.

4. The Recipient and the Recipient Scientist shall refer to the Provider any request for the Material from anyone other than those persons working under the Recipient Scientist's direct supervision. Following publication of the research, and to the extent supplies are available, the Provider or the Provider Scientist agrees to make the

Material available to other scientists (at least those at Nonprofit Organization(s)) who wish to replicate the Recipient Scientist's research under an agreement having terms consistent with the terms of this Agreement; provided that such other scientists reimburse the Provider(s) for any costs relating to the preparation and distribution of the Material.

5.

(a) The Recipient and/or the Recipient Scientist shall have the right, without restriction, to distribute substances created by the Recipient through the use of the Original Material only if those substances are not Unmodified Derivatives or Modifications.

(b) Under an agreement at least as protective of the Provider's rights as this Agreement, the Recipient may distribute Modifications to Nonprofit Organization(s) for research and teaching purposes only.

(c) Without written consent from the Provider, the Recipient and/or the Recipient Scientist(s) may NOT provide Modifications for Commercial Purposes. It is recognized by the Recipient that such Commercial Purposes may require a commercial license from the Provider, and the Provider has no obligation to grant a commercial license to its ownership interest in the Material incorporated in the Modifications. Nothing in this paragraph, however, shall prevent the Recipient from granting commercial licenses under the Recipient's intellectual property rights claiming such Modifications, or methods of their manufacture or their use.

6. The Recipient acknowledges that the Material is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of the Provider, including any altered forms of the Material made by the Provider. In particular, no express or implied licenses or other rights are provided to use the Material, Modifications, or any related patents of the Provider for Commercial Purposes.

7. If the Recipient desires to use or license the Material or Modifications for Commercial Purposes, the Recipient agrees, in advance of such use, to negotiate in good faith with the Provider to establish the terms of a commercial license. It is understood by the Recipient that the Provider shall have no obligation to grant such a license to the Recipient, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the Material to any third party(ies), subject to any pre-existing rights held by others.

8. The Recipient is free to file patent application(s) claiming inventions made by the Recipient through the use of the Material but agrees to notify the Provider upon filing a patent application claiming Modifications or method(s) of manufacture or use(s) of the Material.

9. 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 MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

10. Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage or disposal of the Material. The Provider will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, due to or arising from the use of the Material by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider.

11. This Agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the Material or the Modifications. The Recipient Scientist agrees to provide appropriate acknowledgement of the source of the Material in all publications.

12. The Recipient agrees to use the Material in compliance with all applicable statutes and governmental regulations for the protection of human subjects. The Recipient represents that it has obtained Institutional Review Board ("IRB") approval, as appropriate, to use the Material. The Research may be considered non-human subjects research as determined by a Party's IRB.

13. Provider Scientist will label, package, and transport the Original Material in accord with all applicable local, state and federal laws and regulations.

14. Provider ensure that the Original Material provided pursuant to this Agreement was collected or will be collected in accordance with the Provider's standard patient informed consent procedures in effect at the time of collection and subject to approval, exemption or non-human subjects research determination by the Provider's IRB or equivalent. Recipient may review the consent form used in collection of Original Material as well as any subsequent revisions thereof. The Original Material provided to Recipient will not be accompanied by personally identifiable patient information and for Original Material subject to U.S. laws, will not be accompanied by "Protected Health Information" ("PHI") as defined in 45 CFR 164.501 or personally identifiable information as described in 5 USC Section 522. However, if de-identified information ("Information") is provided that nevertheless could be used to identify an individual at a later time, a Recipient in the U.S. hereby agrees to treat such Information as PHI or personally identifiable information, as applicable. If Information is provided, it will be described in the Record of Transfer (Exhibit B to this Agreement). In any circumstances, the Recipient agrees to use the Information only for the Research Purpose (as set forth in Exhibit A) and to the extent necessary for that specific research and will not contact or make any effort to identify human subjects from whom the Original Material was obtained without specific written approval from the Provider.

15. The Parties acknowledge that applicable state and federal laws relating to data security and privacy are rapidly evolving and that amendment of this Agreement may be required to provide for procedures to ensure compliance with such developments. The Parties agree to take such action as is necessary to implement any amendments to the standards and requirements of such applicable laws or regulations relating to the security or confidentiality of patient information, including in the case of a U.S. Recipient, the Health Insurance Portability and Accountability Act ("HIPAA") Privacy and Security Rules or the Privacy Act of 1974, and other applicable laws and regulations relating to the security or confidentiality of PHI or personally identifiable information. The Parties further agree that if current or future applicable federal or state laws, rules, or regulations adversely impact a Party's performance under the Agreement, the Parties will negotiate in good faith to amend the Agreement, as necessary, to be consistent with the requirements of such applicable laws, rules or regulations. If the Parties are unable to modify the Agreement to fully comply with such applicable laws, rules and regulations, one or both parties may terminate this Agreement.

16. This Agreement will terminate on the earliest of the following dates: (a) on completion of the Recipient's current research with the Material, or (b) on thirty (30) days written notice by either the Provider or Recipient Party to the other, or (c) on the date specified by HuBMAP Program, provided that:

    (i) if termination should occur under 16(a) or (c) above, the Recipient will discontinue its use of the Material and will, upon direction of the Provider, return or destroy any remaining Material. The Recipient, at its discretion, will also either destroy the Modifications or remain bound by the terms of this Agreement as they apply to Modifications; and

    (ii) in the event the Provider terminates this Agreement under 16(b) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, upon written request from the Recipient, the Provider will defer the effective date of termination for a period of up to one (1) year to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, Recipient will discontinue its use of the Material and will, upon direction of the Provider, return or destroy any remaining Material. The Recipient, at its discretion, will also either destroy the Modifications or remain bound by the terms of this agreement as they apply to Modifications.

17. A transmittal fee shall be paid by Recipient to Provider for preparation and distribution costs, including the cost of shipping.

18. To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Provider's written information about the Original Material that is marked as "Confidential" when transmitted ("Confidential Information"). Any oral disclosures from Provider to Recipient shall be identified as being confidential by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Confidential Information does not include information that:

    a. has been published or is otherwise publicly available at the time of disclosure to the Recipient; or

    b. was in the possession of or was readily available to the Recipient without being subject to a confidentiality obligation from another source prior to the disclosure; or

    c. has become publicly known, by publication or otherwise, not due to any breach of this Agreement by the Recipient; or

    d. Recipient(s) can demonstrate it developed such information independently or acquired it without reference to or reliance upon Provider's Confidential Information; or

    e. is required to be disclosed by law, regulation, or court order.

19. Recipient agree that if genomic, transcriptomic, proteomic, metabolomics, phenomic and/or other Material-related data are generated from any Materials ("Material Data"), Recipient will promptly, in confidence, provide a report containing such Material Data to Provider. Use and/or sharing of any such Material Data will be consistent with the HuBMAP Data Use Agreement (final version date: May 6, 2019) and Data Sharing Policies, provided that any such use of the Material Data shall not preempt Recipient's first publication or presentation of Recipient's research results.

20. In the event a Party breaches the terms of this Agreement or terminates its participation in the performance of the Research Purpose, any Materials received and or Material Data generated by that Party in the performance of the Research Purpose using Materials received or Material Data generated in the performance of the Research Purpose shall remain available for use to the remaining Consortium participants consistent with the terms of this Agreement.

21. This Agreement may be amended only by written instrument signed by all Parties ("Amendment").

22. This Agreement may be executed in counterparts, each of which is deemed an original, but all of which together constitute one and the same agreement. Electronic signatures hereon are legal, valid, and enforceable as originals.

23. Paragraphs 6, 9, 10, 14, 18 and 20 of this Section II shall survive termination.

Exhibit A
Research Purpose

Research Purpose:

Collaborative projects between the HuBMAP Tissue Mapping Centers (TMCs), other HuBMAP Components and Investigators as approved by the HuBMAP Steering Committee, or their designee, to carry out studies on human organ and tissue development, injury and repair in order to improve human health.

Information to be provided with biospecimens:

Demographics including age, sex, race and ethnicity, and clinical history of donors of biospecimens, delivered in a manner that is de-identified (stripped of HIPAA identifiers, may include a limited dataset) and that cannot be used to readily ascertain subjects' identities, either directly or through linked identifiers.

Descriptions of biospecimens and their preparation.

There is potential for delivery of identifiable nucleic acid sequence, in which case the signatories, by MTA and DUA, have agreed the information will not be used to re-identify or to contact donors or relatives.

Exhibit B

Record of Transfer of De-identified Human Tissues and Specimens

Between

Non-profit Organizations Participating in the NIH Human Biomolecular Atlas Program

NOTE: This Material is provided / received subject to the terms and conditions of the MTA for NIH Human Biomolecular Atlas Program by and between the Provider and Recipient Institutions. You may not receive or send Material using this Record of Transfer unless your Institution has signed the referenced MTA.

Provider (the organization providing the Original Material)	**Recipient** (the organization receiving the Original Material)
Name: Address:	Name: Address:

Provider Scientist[+]	**Recipient Scientist**[+]
Name: Title:	Name: Title:

Material (description of the material being transferred)	**Shipping Address**
Date of Transfer:	Name: Address:

[+] **Provider and Recipient Scientist are each responsible for complying with his/her institution's requirements regarding receiving or sending research materials to another non-profit institution.**

Exhibit C

Signatory Page – Complete this Form and Sign

MTA SIGNATURE PAGE

The Institution identified below hereby agrees to the terms of the Material Transfer Agreement For the Transfer of De-identified Human Tissues and Specimens Between Non-profit Organizations Participating in the NIH Human Biomolecular Atlas Program ("MTA for NIH Human Biomolecular Atlas Program") Final Ver 8 20 2019, without modification, by the signature below of a representative or officer who is specifically authorized to execute documents of this type.

[Legal Name of Institution]

Address of Institution:

Signature: _____ Date: _____

Authorized Signatory: _____
(Printed Name)

Title: _____

Read and acknowledged by Provider / Recipient Scientist: _____
Printed Name

Scientist Signature: _____ Date: _____

Shipping Address for Materials: