

Human Health Exposure Analysis Resource (HHEAR) HHEAR Human Material Transfer Agreement (H-MTA)

NOTES

A Material Transfer Agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes. An MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.¹

The HHEAR Human Material Transfer Agreement (H-MTA) is used for transfer of human biological materials, such as blood, urine, saliva specimens, and so forth (Human Material), with or without accompanying fully de-identified data, between an academic or research institution (Provider) and the HHEAR Laboratory Hub (Recipient Hub) which directly receives human biological materials from the Provider.² The Recipient Hub is defined as HHEAR Laboratory Hub which receives Human Material directly from the Provider. The name and address of the Recipient Hub is specified in Section II of this document. For avoidance of doubt, the Recipient Hub shall include all cores and resources at the Recipient institution, collaborators and service providers working with or on behalf of the Recipient Hub for performance of the Laboratory Analysis Plan. A HHEAR H-MTA will be completed between Provider and the Recipient Hub prior to project initiation and transfer of any Human Material. A separate H-MTA will be completed between Provider and each Recipient Hub which directly receives Human Material from the Provider.

A HHEAR Human Material Collaboration Agreement (MCA) is in place for human materials which are sent from a Recipient Hub to another HHEAR Laboratory Hub, e.g., if the Recipient Hub aliquots samples and sends aliquots to another Hub for laboratory analysis, or if samples are sent from one Hub to another Hub as part of quality control or other analysis activities.

Ownership, transfer and use of “Research Data” resulting from the Recipient Hub’s or other HHEAR Hub’s laboratory analysis of transferred Human Material will be addressed in the HHEAR Data Repository Data Submission Agreement.

¹ https://en.wikipedia.org/wiki/Material_transfer_agreement

² For transfer of environmental samples, use the HHEAR Environmental Material Transfer Agreement (E-MTA).

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HHEAR Research Project ID: _____

HHEAR Research Project Title: _____

HHEAR H-MTA ID: _____

I. Definitions

1. Provider: Institution providing Human Material. The name and address of the Provider for purposes of this H-MTA is specified in Section II of this document.
2. Provider Principal Investigator: The Provider Investigator from the Provider Institution authorized to provide Human Material. The name and address of the Provider Investigator for purposes of this H-MTA is specified in Section II of this document.
3. Recipient Hub: The Recipient Hub is defined as HHEAR Laboratory Hub which receives Human Material directly from the Provider. The name and address of the Recipient Hub is specified in Section II of this document. For avoidance of doubt, the Recipient Hub shall include all cores and resources at the Recipient institution, collaborators and service providers working with or on behalf of the Recipient Hub for performance of the Laboratory Analysis Plan.
4. Recipient Hub Principal Investigator: The Investigator from the Recipient Hub authorized to receive the Human Material directly from the Provider. The name and address of the Recipient Hub Investigator for purposes of this H-MTA is specified in Section II of this document.
5. Human Material: Fully de-identified human biological materials, such as blood, urine, saliva specimens, and so forth, and accompanying related fully de-identified phenotypic or other data for use solely as outlined in the Laboratory Analysis Plan.
6. Laboratory Analysis Plan: Plan developed by the Recipient Hub and the Provider detailing the specifics of the laboratory analysis to be conducted for a specific HHEAR project, specific types and counts of samples involved, quality control procedures, shipping instructions and timeline.

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7. Research Data: Data obtained from Recipient Hub’s or other HHEAR Lab Hub’s analysis of Human Material.
8. Personally Identifiable Information (PII): Information that can be used to distinguish or trace an individual’s identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual.

II. Terms and Conditions of this Agreement:

This Human Material Transfer Agreement (H-MTA) is between the (Provider):

_____ located at _____
and the Human Health Exposure Analysis Resource (HHEAR) Laboratory Hub (Recipient Hub):

_____ having an address at _____
for the transfer of Human Material for research purposes as further defined below.

The Provider and Recipient Hub may each be referred to as Party or collectively as Parties. This H-MTA will become effective on the date of the last signature on the Signature Page (“Effective Date”).

Provider Principal Investigator (PI): _____

Recipient Hub Principal Investigator: _____

Recipient Hub and Provider agree as follows:

1. Provider will transfer to Recipient Hub the following biospecimens and data:

- List biospecimens to be transferred

- List data to be transferred

Further details on biospecimens, data and transfer conditions are provided in the Laboratory Analysis Plan for:

2. Provider represents that it has obtained Institutional Review Board approval, as appropriate, for obtaining and for proposed laboratory analysis of the Human Material (human biological material and any associated phenotypic data) provided to Recipient Hub pursuant to the Laboratory Analysis Plan, and its transfer under

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this H-MTA is authorized by donors under informed consent in accordance with applicable federal, state and local laws and regulations which address protection of human subjects in research, including 45 CFR part 46.

3. Provider will not provide Recipient Hub with personally identifiable information (PII) or the code to PII with the Human Material. A Recipient Hub may request phenotypic or other data from the Provider for interpretation of laboratory analysis results, but the data provided will not include PII. If PII is submitted to Recipient Hub, it will be returned to the Provider Investigator for de-identification and resubmission.
4. Provider will not provide Confidential Information to Recipient Hub.
5. Recipient Hub will perform the analysis and/or, as required, coordinate any transfer of Human Material to one or more of the designated HHEAR Laboratory Hubs for analyses per the Laboratory Analysis Plan. All HHEAR Laboratory Hubs have agreed to abide by the terms of this H-MTA via the HHEAR Human Material Collaboration Agreement located at www.HHEARprogram.org under Support Documents.
6. Recipient Hub agrees to use the Human Material solely as outlined in the Laboratory Analysis Plan and will not use the Human Material for any commercial purposes, including selling, offering for sale, commercial screening, or transferring Human Material to a third party for commercial or other purposes.
7. Recipient Hub agrees that Human Material shall not be used in humans or for any diagnostic, prognostic, or treatment procedures.
8. Recipient Hub will allow the use of Human Materials only by Recipient Hub Investigator and other employees of the Recipient Hub, collaborators, and service providers working with or on behalf of the Recipient Hub for the performance of the Laboratory Analysis Plan (or other HHEAR Laboratory Hub, if Human Materials are distributed to other Laboratory Hubs pursuant to Paragraph 5 of this Section II) only after they have been informed of and agreed to the terms and conditions at least as stringent as those stated herein. Any transfer of Human Material outside of the Recipient Hub or other HHEAR Laboratory Hub requires the advanced written approval of Provider.
9. Recipient Hub will not contact or make any effort to identify individuals who are or may be the sources of Human Material, without specific prior written approval from Provider.

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10. Recipient Hub represents that its intended use of Human Material for the Laboratory Analysis Plan has been approved or exempted by the relevant Institutional Review Board. Recipient Hub will comply with all laws, rules and regulations applicable to the handling and use of the Human Material, including but not limited to 45 CFR part 46 and the Health Insurance Portability and Accountability Act of 1996 as amended, and all similar applicable state laws and regulations (collectively, "HIPAA").
11. Provider and Recipient Hub agree that the data obtained from the Recipient Hub's analysis of Human Materials ("Research Data") will be submitted to the HHEAR Data Center. After review and quality control checks, all data will be provided to the Provider by the HHEAR Data Center. The use and transfer of Research Data will be governed by a HHEAR Data Repository Data Submission Agreement which all users of the Research Data will be required to sign.
12. When the Research Project is completed or this H-MTA is terminated, whichever comes first, any unused Human Material, or its derivatives, will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the Provider, as requested by the Provider.
13. In all oral presentations or written publications concerning the use of Human Material, Recipient Hub will acknowledge Provider's contribution of Human Material unless requested otherwise by Provider.
14. Any Human Material delivered pursuant to this H-MTA is understood to be experimental in nature and may have hazardous properties. Provider Investigator agrees and represents that universal precautions are sufficient for the handling of the Human Materials, or, alternatively, the following additional precautions are required:
15. Provider makes no representations other than as set forth in Paragraph 2 and Paragraph 14 of this Section II 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 human material will not infringe any patent, copyright, trademark, or other proprietary rights.
16. No indemnification for any loss, claim, damage, or liability is intended or provided by any Party under this H-MTA. To the extent permitted by applicable law, each shall be liable for its own loss, claim, damage, or liability that said Party incurs as a result of its activities under this H-MTA. If the provider is an agency of the U.S. it assumes liability only to the extent provided under the Federal Tort Claims Act, 28 USC § 2671 et seq.

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17. This Agreement shall remain in effect from the Effective Date until completion of the Laboratory Analysis Plan. Either Party may terminate this H-MTA with sixty (60) days prior written notice to the other Party.
18. This H-MTA may be executed in any of two counterparts, each of which, when executed, shall be deemed an original and both of which together shall constitute one and the same document. This Agreement may be executed by facsimile or PDF signatures, which shall have the same force and effect as original signatures.

SIGNATURES FOLLOW ON NEXT PAGE

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SIGNATURE PAGE

For Provider:

Provider's Investigator: *I have read and understood the terms and conditions of this H-MTA.*

Name of Provider Principal Investigator: _____

Signature of Provider Principal Investigator:

_____ Date: _____

Agreed:

Name and Title of Authorized Official for Provider: _____

Signature of Authorized Official for Provider:

_____ Date: _____

Email address for documents: _____

For Recipient Hub:

Recipient Hub's Investigator: *I have read and understood the terms and conditions of this H-MTA and I agree to abide by them.*

Name of Recipient Hub Investigator: _____

Signature of Recipient Hub's Investigator:

_____ Date: _____

Agreed:

Name and Title of Authorized Official for Recipient Hub:

Signature of Authorized Official for Recipient Hub:

_____ Date: _____

Email address for documents: _____