

Human Cell Atlas - Ethics Toolkit

Template: Material/Data Transfer Agreement (MDTA)

This template aims to provide **suggested language** for Human Cell Atlas (HCA) community, to assist participating institutions in drafting and finalizing their own Material/Data Transfer Agreement in line with the specificities of the HCA project. ***Use of this template is not compulsory and it is not intended to provide legal guidance or advice. It was developed as a tool by the Ethics Working Group of the HCA to serve as examples of language that institutions can use in their own agreements.***

Why a material and data transfer agreement template?

- Different data contribution scenarios may arise in the HCA. In particular, there may be cases where the research group/institution collecting tissue samples may need to transfer these tissues to another research group/institution in order to undertake molecular analysis (including sequencing).
- In such cases, to enable downstream contribution of data to the HCA, the collaborating institutions would need to ensure that their bilateral Material/Data Transfer Agreement do not contain any provisions that may limit contribution of data to the HCA project.
- This template provides examples of contractual clauses that can be adapted to such situations.

What are some examples of limitations that could impact ability to contribute data to the HCA and that should not be included in bilateral Material/Data Transfer Agreements?

- **Restrictions on use of Research Materials.** Providing Institutes should carefully assess and disclose any restrictions on the use of the Research Materials (e.g. in consent materials), as this may have an impact on whether derived Research Data can be deposited in a fully open (public) access database, or a managed access database (see Section 3). Alternatively, if the Providing Institute can demonstrate appropriate consents or permissions, clauses for fully open (public) sharing can be used (see Section 3.3).
- **Intellectual property.** Drafters of Material/Data Transfer Agreements should be particularly vigilant of any provisions related to ownership of Research Data, or of any licensing provisions that may restrict the ability of one of the Parties to contribute data to the HCA through restrictions on downstream use by HCA users. (See Section 9).

Sections and clauses specific to the HCA Project are the following:

Section	Description
Definitions	The following additional definitions are provided to facilitate contribution to the HCA: • “HCA Project” • “Research Data”

Section 1 (Purpose(s) of Use)	• Includes a suggested statement for future contribution of data derived from the Research Materials to the HCA
Section 6 (Contribution of Research Data to the HCA)	• Includes information on the process for submitting Research Data to the HCA as well as a requirement to comply with the HCA's Data Release Policy.
Section 8 (Confidentiality)	• Exempts Research Data contributed to the HCA from mutual confidentiality obligations.
Appendix A	• It is suggested that the Purpose of Use relating to contribution to the HCA be replicated in the Description of the Research Project in Appendix A. • Consider including a description or list of Research Data to be contributed to the HCA in this appendix.

Template: Material & Data Transfer Agreement

Use of this template is not compulsory and it is not intended to provide legal guidance or advice. It was developed as a tool by the Ethics Working Group of the HCA to serve as examples of language that institutions can use in their own agreements.

This agreement governs the transfer of Materials between the Providing Institute and the Receiving Institute for the purpose of generating Research Data from the Materials.

This Agreement is made and entered into on _____ (the “Effective Date”) by and between:

Providing Institute

The Providing Institute, [insert name of legal entity that is authorized to enter in this agreement], a [include type of legal entity, e.g. academic institution, foundation, charity, corporation, etc.], incorporated and duly constituted under the laws of [insert jurisdiction], with its principal office at [insert address].

Contact: [insert name and contact information of authorized representative]

Name of Providing Institute Principal Investigator or equivalent: [insert name of Principal Investigator or equivalent]

Receiving Institute

The Receiving Institute, [insert name of legal entity that is authorized to enter in this agreement], a [include type of legal entity, e.g. academic institution, foundation, charity, corporation, etc.], incorporated and duly constituted under the laws of [insert jurisdiction], with its principal office at [insert address].

Contact: [insert name and contact information of authorized representative]

Name of Receiving Institute Principal Investigator or equivalent: [insert name of Principal Investigator or equivalent]

(the Providing Institute and Receiving Institute individually a “Party” and collectively, the “Parties”).

WHEREAS, the Providing Institute is a [e.g. biobank, hospital, university, organ procurement service, commercial vendor, etc.] established with the aim to facilitate research through the collection of human biological samples;

WHEREAS, the Receiving Institute is a [e.g. biobank, hospital, university, organ procurement service, commercial vendor, etc.] willing to undertake the analysis of certain Materials from the Providing Institute and produce Research Data [Optional - add any specific project, if applicable, e.g.: for the purpose of contributing datasets to the Human Cell Atlas project and other repositories];

The Parties hereby agree to the provisions set forth in this Agreement.

1. Definitions

- 1.1. **"Research Materials"** consist of the Biospecimens, Research Data collected for the Research Project, and research documents used to manage the Project. The Research Materials and their means of transfer between the parties are further described in Appendix A.
- 1.2. **"Biospecimen"** means a quantity of tissue, blood, urine, or other human-derived material, as further described in Appendix A.
- 1.3. **"Research Data"** are the datasets collected by the Providing Institute or produced by the Receiving Institute from the analysis of the Research Materials, as part of the Research Project, further described in Appendix A. Research Data includes, but is not limited to,
[HCA data - include relevant data, for e.g.: transcriptome data such as single cell sequence data (scRNA seq; FASTQ or FASTA file format); sequence aligned scRNAseq data (scRNAseq, SAM or BAM file format); gene expression matrices; spatial transcriptomic data), etc.]
[Other data - add any other relevant data generated for e.g.: whole genome sequencing, exome sequencing, donor metadata etc.]
- 1.4. **"Providing Institute"** means the organization that has the authority to transfer the Research Materials to the Receiving Institute under this Agreement.
[Optional - if applicable: **"Providing Institute Principal Investigator"** means the individual having the scientific responsibility over the collection of the Research Materials]
- 1.5. **"Receiving Institute"** means the organization that has the authority to receive the Research Materials under this Agreement.
- 1.6. **"Receiving Institute Principal Investigator"** means the individual having the scientific oversight of the Research Project, pursuant to which the Research Materials are transferred.
- 1.7. **"Research Project"** means the research initiative [select appropriate scenario: lead by the Receiving Institute/ undertaken in collaboration by the Receiving Institute and Providing Institute] under which the Research Data is generated from the Research Materials, as further described in Appendix A.
- 1.8. **"HCA"** means the Human Cell Atlas research project.
- 1.9. **"Information"** is any information, unpublished or otherwise, owned, controlled, or generated by Providing Institute and communicated to the Receiving Institute by the Providing Institute during the term of this

Agreement, relating to the Research Materials, their collection, production, properties and/or experimental results observed using the Research Materials or their derivatives.

2. Purpose(s) of Use

The Research Materials are provided by the Providing Institute to the Receiving Institute for the following purposes, as more fully described in Appendix A (the “**Research Project**”):

[HCA example language: “*the analysis of the Material and generation of Research Data by the Receiving Institute, to enable contribution of Research Data to the Human Cell Atlas Project*”] [and/or]

[Other: *include any other relevant purposes*].

3. Restrictions on use

- 3.1. The Research Materials shall not be used for any purpose other than the Research Project.

[Where applicable, select one of the applicable options, depending on the nature of restrictions on Research Material. Please note that the options are mutually exclusive and only one option should be selected.]

- 3.2. [Option 1 - If there are restrictions on use of the Research Material: The Providing Institute agrees to provide the Receiving Institute a clear statement identifying all restrictions or limitations on the use or distribution of the Research Materials (e.g. disease-specific research only) specified in the consent documents signed by the research participant or donor.
- 3.3. [Option 2 – If there are no restrictions on the use of Research Materials: If no restrictions or limitations exist, the Providing Institute should write “NONE” in Appendix A. The Parties agree that notice will be provided to any third-party recipient [if sending data to the HCA: “*including the HCA*”].

[Where applicable, include a statement indicating that Research Data will be contributed to the HCA.]

- 3.4. [Optional - If there are no restrictions on the use of Research Material or that derived Research Data are available for fully open (public) sharing through the HCA: The Providing Institute hereby warrants that either:
- 3.4.1. there are no restrictions on the use of the Research Materials, or
- 3.4.2. appropriate consent has been obtained from the research participant or donor, or
- 3.4.3. an authorisation has been granted by a research ethics committee or other regulatory authority,
- in order to allow Research Data derived from the Research Material to be deposited to a fully open (public) access database, including the HCA.

4. Regulatory and ethics approvals

- 1.1. The Providing Institute hereby certifies that the Research Materials were collected, and are provided to the Receiving Institute for the Purpose(s) of use and the generation of Research Data, in accordance with all applicable laws and all assurances. Where applicable, the Providing Institute represents and warrants that it holds approval from a research ethics committee or other regulatory body to undertake research with human participants and to allow use of the materials for the Research Project.

5. Material Fees

[Select one or more of the applicable options, depending on the nature of the relationship or research collaboration between the parties]

- 5.1. **[Free of charge:** The Parties hereby agree that the Research Materials shall be provided by the Providing Institute to the Receiving Institute free of charge, and that the Research Data shall be generated by the Receiving Institute free of charge.]
- 5.2. **[Lump sum amount for transfer of Research Materials:** The cost of retrieval, transfer, packaging and shipment of the Research Materials will be charged by Providing Institute to the Receiving Institute at the following agreed rate *[insert rate]*]
- 5.3. **[Lump sum amount for generation of Research Data:** The cost of the analysis of the Research Materials to generate Research Data will be charged by the Receiving Institute to the Providing Institute at the following agreed rate *[insert rate]*]

6. [Optional clauses - Contribution of Research Data to the HCA]

- 6.1. [Attribution of contributors the HCA: The Parties agree that upon contribution of Research Data to the HCA, both the Providing Institute Research Team, as listed in Appendix A, and the Receiving Institute Research Team, as listed in Appendix A, shall be acknowledged as contributors, according to the HCA Data Release Policy, as may be amended from time to time by the HCA (available at: <https://www.humancellatlas.org/data-release-policy/>).]

[Select one of the following options, or adapt based on nature of collaboration between Receiving Institute and Providing Institute]

- 6.2. [Option 1 - Receiving Institute contributes to the HCA: For the purpose of contributing Research Data to the HCA, the Parties agree that the Receiving Institute will enter into a data contribution agreement with the HCA, and appropriately acknowledge all members of the Research Team, as described in Section 6.1]
- 6.3. [Option 2 - Providing Institute contributes to the HCA: For the purpose of contributing Research Data to the HCA, the Parties agree that, following the analysis of the Research Material, the Receiving Institute shall return Research Data to the Providing Institute, through processes detailed in Appendix A. The Providing Institute will enter into a Data Contribution Agreement with the HCA, and appropriately acknowledge all members of the Research Team, as described in Section 6.1].

7. Conditions of Use of the Research Materials

- 7.1. The Research Materials are supplied by the Providing Institute to the Receiving Institute solely for the Purpose(s) of Use, as set out in Section 2 and Appendix A.
- 7.2. The Research Materials shall not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the Providing Institute.
- 7.3. Other than for and within the Purpose(s) of Use, and as specifically described in Section 2 and Appendix A, the Research Materials shall not be transferred, offered for sale, or otherwise used without the prior written consent of the Providing Institute.
- 7.4. The Receiving Institute shall only allow Research Team Members, as listed in Appendix A, to have access and process the Research Materials.
- 7.5. The Receiving Institute shall require any Research Team Members, as listed in Appendix A, handling and/or using the Research Materials to comply with all relevant laws, rules, policies and regulations applicable to the use of such Research Materials.

8. Confidentiality

- 8.1. The Information may include confidential information of the Providing Institute. Accordingly, if and to the extent that any such Information is marked as “confidential”, the Receiving Institute shall during the Term of this Agreement and for a period of **[insert period]** following its termination, treat such Information as confidential and only disclose it under like obligations of confidentiality and Restrictions on Use as those contained herein. The Receiving Institute shall be deemed to have fulfilled its obligation if it **[insert local criteria applicable to confidentiality standards/requirements]**.
- 8.2. The above-mentioned obligations of confidentiality shall not apply to Information which:
 - 8.2.1. **[If contributing derived Research Data to the HCA:** Is identified as Research Data to be contributed to the HCA by the **Providing Institute/Receiving Institute**, as listed in Appendix A]; or
 - 8.2.2. Can be shown to have been known to the Receiving Institute at the time of its acquisition from Providing Institute; or
 - 8.2.3. Is acquired from a third party, not in breach of any confidentiality obligation to the Providing Institute; or
 - 8.2.4. Is independently devised or arrived at by, on behalf of, or for the Receiving Institute without access to the Information; or
 - 8.2.5. Enters the public domain otherwise than by breach of the undertakings set out in this Agreement.
- 8.3. In some cases, the Research Materials may also incorporate confidential Information pertaining to research participants or donors having provided the Research Materials. The Research Materials provided to the Receiving Institute have been **[enter information related to de-identification processes applied to the data, e.g. coded, double-coded, anonymized, anonymous (provide description of de-identification measures)]**. If the Receiving Institute inadvertently receives Information that identifies individual research participants or donors, the Receiving Institute will take all reasonable and

appropriate steps to protect the privacy and confidentiality of such Information. This may require immediate destruction of the Research Materials on request of the Providing Institute. The Receiving Institute agrees to make no intentional attempt to re-identify research participants or donors, through linkage of data or otherwise. The Receiving Institute will immediately report any identification of research participants or donors to the Providing Institute.

9. Intellectual Property

[Suggested clauses - to be adjusted based on agreement and nature of collaboration between the parties]

- 9.1. Except for the rights explicitly granted hereunder, nothing contained in this Agreement shall be construed as conveying any rights under any patents or other intellectual property which either Party may have or may hereafter obtain.
- 9.2. The *[Providing Institute/Receiving Institute]* shall retain ownership of the Research Materials and shall have the unrestricted right to use, assign, or distribute the Research Materials to any third parties for any other purposes, *[if contributing to the HCA add: except for the purpose of contribution of Research Data to the HCA in Section 6.]*
- 9.3. The *[Providing Institute/Receiving Institute]* hereby grants to the *[Providing Institute/Receiving Institute]* a royalty free, worldwide license, to use the Research Materials for the Research Project, and as specifically described in Section 2 and Appendix A. The *[Providing Institute/Receiving Institute]* agrees to implement licensing policies that will not obstruct further research using the Research Materials or Research Data. The *[Providing Institute/Receiving Institute]* agrees not to exercise any copyrights, sui generis database rights, patents, and other associated rights in the Research Materials
- 9.4. The *[Providing Institute/Receiving Institute]* must not make intellectual property claims on the Research Materials. However, the importance of downstream inventions made following the use of Research Materials is recognized, and patents on such inventions are permitted. In doing so, the Receiving Institute agrees to implement licensing policies that will not obstruct further research using the Research Materials or Research Data.
[Select one of the options below, or adapt to collaboration scenario]
[Option 1: If Receiving Institute owns Research Data and Receiving Institute Contributes to the HCA [combine with Section 6.1]: The Receiving Institute will own all Research Data, results, inventions, copyright in datasets, sui generis database rights, and all associated rights, which arise which arise under the Research Project described in Appendix A.]
[Option 2: If Providing Institute owns Research Data and Providing Institute contributes to the HCA [combine with Section 6.2]: The Providing Institute will own all Research Data, results, inventions, copyright in datasets, sui generis database rights, and all associated rights which arise which arise under the Research Project described in Appendix A.]
- 9.5. *[Select one of the options below, if applicable]*
[Option 1: Licence from Receiving Institute to Providing Institute: The

Receiving Institute does, however, grant to the Providing Institute a perpetual, non-cancellable, royalty free, worldwide license with right to sublicense, to use Research Data for all purposes.]

[Option 2: Licence from Providing Institute to Receiving Institute: The Providing Institute does, however, grant to the Receiving Institute a perpetual, non-cancellable, royalty free, worldwide license with right to sublicense, to use Research Data for all purposes.]

10. Research Data & Publications

- 10.1.** Upon completion of the Research Project, the Receiving Institute will send to the Providing Institute **[e.g. copy of the Research Data, report, publications, etc.]**.

[Select one of the options below, or adapt based on the nature of the collaboration between the parties]

- 10.2.** **[Option 1: Acknowledgement]** The Receiving Institute must endeavour to publish results in an open access academic journal or database. The Receiving Institute agrees to acknowledge the Providing Institute in any publication, presentation or presentation on work derived in whole or in part from the Research Materials and to supply Providing Institute with a copy of any publication.

[Option 2: Joint authorship] The Receiving Institute must endeavour to publish results in an open access academic journal or database. The Receiving Institute agrees to offer the Providing Institute joint-authorship opportunities, where such authorship meets the international Committee of Medical Journal Editors (ICMJE, <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>) on authorship in any publication, presentation or presentation on work derived in whole or in part from the Research Materials. If authorship criteria are not deemed to be met, the Receiving Institute agrees to acknowledge the Providing Institute in any publication, presentation or presentation on work derived in whole or in part from the Research Materials and to supply Providing Institute with a copy of any publication.

- 10.3.** **[Return of individual-level result - Optional - Select one of the examples below, or develop a customized clause, depending on the scenario applicable and local institutional/ethical requirements and if participants/donors have agreed to the return of results. If using clauses pertaining to the return of individual-level results, please ensure that language is consistent across agreements and study documents (e.g. consent forms, study protocols, return of research findings policies, etc.)]**

[Example 1: No Return of Individual-level Results: Individual research results and incidental findings related to the analysis of the Research Materials will not be returned to the Providing Institute.]

[Example 2: Return of Individual-level Results: Research participants or donors recruited by the Providing Institute have consented to the return of individual research results and incidental findings that are clinically significant, analytically valid and actionable (i.e. treatable or preventable conditions). If in

the course of their research the Receiving Institute comes across such findings, they must be returned to the Providing Institute.]

11. Warranties and Liabilities

- 11.1. Providing Institute makes no warranty, either express or implied, of the fitness for purpose of the Research Material. However, to the best of Providing Institute's knowledge, the use of the Research Materials within the Purpose of Use shall not infringe on the proprietary rights of any third party.
- 11.2. Providing Institute will not be liable for damages related to the provision of Research Materials to the Receiving Institute. This includes but is not limited to damages in relation to inaccuracies, lack of comprehensiveness, or use of the Research Materials, or any delays or break in supply by the Providing Institute. The Receiving Institute acknowledges that the Providing Institute makes no guarantee that the Research Materials are free of contamination from viruses, latent viral genomes, or other infectious agents. The Receiving Institute agrees to treat the Research Materials as if they were not free from contamination, to ensure that appropriate biosafety training is provided to research personnel, and to implement appropriate biohazard containment measures.
- 11.3. The Receiving Institute agrees that, except as may explicitly be provided for in this Agreement, the Providing Institute has no control over the use that is made of the Research Materials or the Information by the Receiving Institute in accordance with the terms of this Agreement. Consequently, the Receiving Institute agrees that Providing Institute shall not be liable for such use.
- 11.4. The Receiving Institute will not be liable for damages incurred by the Providing Institute in providing the Research Materials to the Receiving Institute. This includes but is not limited to damages incurred through the Providing Institute's breach of contract or statute, its breach of institutional policy, research ethics requirements, as well as any tortious or extracontractual liability incurred.

12. Term of Agreement

- 12.1. This Agreement shall remain in full force as from the Effective Date and for a duration of *[insert duration of term]*.

13. Amendment, Extension, Termination and Survival

- 13.1. Any amendment to the terms of this Agreement, including extension of the Term of this Agreement, shall be in writing and executed by the duly authorized officers of both parties.
- 13.2. Notwithstanding the conditions set forth in this Agreement, in particular the Purposes of Use, Restrictions on Use, and Confidentiality obligations, either party may terminate this Agreement with sixty (60) days prior written notice to the other party.
- 13.3. When the Research Project is completed or the Agreement is terminated, whichever comes first, any unused Biospecimen will either be destroyed in compliance with all applicable laws and regulations, or will be returned to the Providing Institute upon Providing Institute's request.

- 13.4. Upon termination of the Agreement, the Parties will remain bound by all obligations, and shall retain all rights, which by their nature should survive the termination of this Agreement. These include, but are not limited to, Sections *[include relevant sections, depending on options selected]*.

14. Notices

- 14.1. Method of notice.** All notices and other communications provided for or permitted hereunder shall be made in writing either by first-class mail (registered or certified, return receipt requested) to the institutional address specified in this Agreement, or to the institutional e-mail address specified.
- 14.2. Notice period.** Notices must be communicated to Parties within twenty (20) business days of the occurrence giving rise to the obligation to provide notice. If a Section of this Agreement specifies a different notification period, that Section shall supersede this one as regards that notice. Notice periods begin to run on the first business day following the date of the occurrence giving rise to the obligation to provide notice.
- 14.3. Receipt of Notice.** A notice given under this agreement will be effective on the other party's receipt of it or, if mailed, on the fifth (5th) business day after the transmission thereof.

If to Providing Institute:

Name of recipient: _____

E-mail address: _____

Corporate / institutional address:

If to Receiving Institute:

Name of recipient: _____

E-mail address: _____

Corporate / institutional address:

15. Choice of Laws & Jurisdiction

- 15.1. This Agreement is governed by the laws of **JURISDICTION** and is deemed to have been formed in that jurisdiction.

16. Dispute Resolution

- 16.1. All disputes arising out of or in connection with this Agreement shall be settled under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules.
- 16.2. The Parties agree, pursuant to Article 30(2)(b) of the Rules of Arbitration of the International Chamber of Commerce, that the Expedited Procedure Rules shall apply, provided the amount in dispute does not exceed US\$ [specify amount] at the time of the communication referred to in Article 1(3) of the Expedited Procedure Rules.
- 16.3. The Parties agree that arbitration shall be conducted in [CITY] at [PLACE].
- 16.4. Legal proceedings brought by a Party while this Agreement is in force, and legal proceedings brought by a Party arising out of or in connection with this Agreement may only be brought in the courts of [JURISDICTION] at [JUDICIAL DISTRICT]. This clause shall only have effect if, for any reason, a dispute cannot be brought to arbitration pursuant to the preceding clauses.

17. Miscellaneous

- 17.1. Nothing in this Agreement shall be interpreted as establishing a partnership between the Parties or establishing one Party as the agent of the other or conferring a right on one party to bring the other, except as may be specifically set out herein.
- 17.2. [Adjust as necessary based on pre-existing agreements]: This Agreement sets forth the entire understanding between the Parties and supersedes any prior agreements, written or verbal.

[Remainder of page left intentionally blank]

[Signatures]

[Providing Institute]

Authorized official:

Name: _____

Title: _____

Date: _____

[Receiving Institute]

Authorized official:

Name: _____

Title: _____

Date: _____

Principal Investigator:

Name: _____

Title: _____

Principal Investigator:

Name: _____

Title: _____

Appendix A: Description of Research Materials, Research Project and Research Teams

1. Providing Institute:

Research Team members:

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Description of context for the collection of the Material [*if applicable, for example, in the case of joint research undertaking: and of Research Project*]:

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Description of all restrictions and limitations on the use of the Research Materials (enter "None" if there are no restrictions):

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2. Receiving Institute:

Research Team members:

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Description of molecular analyses undertaken on the Material and Research Project:

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3. Means of transfer of Biospecimen and Research Data

Transfer and shipment of Biospecimen:

[Include information on how Biospecimen will be shipped, and any particular technical requirements associated with the shipment]

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Transfer of Research Data:

[Include information on how Research Data will be transferred, in particular, if any cloud-based thin client/service provider will be used to analyse/share data between the Providing Institute and Receiving Institute]

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4. *[Optional - If contributing derived Research Data to the HCA]* Contribution of Research Data to the HCA

[Include information on the type of derived Research Data that will be contributed to the HCA, in accordance with the optional clauses selected as part of the agreement]

The Parties agree that the following Research Data generated as part of the Research Project will be contributed to the HCA:

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