Implementing Letter Template (Two-Parties)

Note for researchers: This template should be completed for each individual project for which data and/or materials transfer will occur between two or more signatory institutions to the Umbrella Data and Material Transfer Agreement (DMTA). See our Website for more information and guidance.

Purpose of the Implementing Letter:
Completion of this Implementing Letter template is intended to establish agreement on additional terms related to specific projects for which Data and/or Material will be transferred between signatory institutions under the Umbrella Data and Material Transfer Agreement (DMTA).

Implementing Letter completion process:

For each project under the Umbrella DMTA:

1. Complete this Implementing Letter template with the information requested. The primary responsible Party for completing each section is listed under the section heading. Researchers should refer questions about completing the Implementing Letter to their respective contacts
2. Attach any appropriate documentation (e.g. protocols, specific terms).
3. Obtain appropriate Provider and Recipient institutions' approval and signatures.

Note on ethics approval:

All patient-derived/human-subjects data and materials must be collected and transferred under a **protocol** and **consent/waiver** approved by the appropriate ethics review board(s). For the U.S. and Canada, these are the institutions' Institutional Review Board (IRB) and Research Ethics Board (REB), respectively.

Questions about requirements for ethics review should be referred to the Provider's and/or Recipient's home contact listed here.

REQUIRED INFORMATION

Complete the following **mandatory** fields on this sheet. Depending on the type of Data being transferred (if any) additional terms may apply.

1. **IDENTIFICATION OF PARTIES**
   To be completed by both Parties

   a. **Provider Name and Address**:
   b. **Provider DMTA Contact:**
   c. **Provider Scientist**:
   d. **Recipient Name and Address**:
   e. **Recipient DMTA Contact:**
   f. **Recipient Scientist**:

2. **MATERIAL AND DATA TO BE TRANSFERRED**
   To be completed by both Parties

   a. **Description of "Primary Material" (if any):** [Please describe the materials to be transferred]

   b. **Description of "Data" (if any):** [Please describe the data to be transferred]

c. **Description of the "Purpose":** [Describe the project in 3-4 sentences, including the scope of work and the intended use of the Data and/or Materials. An attachment with details may be provided if desired.]

d. **Description of Parties' respective roles:** [Describe roles of the collaborators at the respective signing institutions (if applicable) and any deliverables or milestones (if applicable).]

3. ETHICS – PROVIDER

To be completed by the Provider

Notes:

- **The Provider should contact their respective home institutions' primary contact for consultation on completing this section.**
- **All patient-derived/human-subjects data and materials must be collected and transferred under a protocol and consent/waiver approved by the appropriate ethics review board(s). These are the institutions' Institutional Review Board (IRB) in the United States and Research Ethics Board (REB) in Canada. Please attach protocol(s) approved by the relevant ethics board(s), if applicable**
- **Keep any protocol, approval, and consent documents shared between the Provider and Recipient confidential.**

a. Will the **Provider** be transferring any Data or Materials derived from humans?

☐ Yes ☐ No
If yes, please complete this section
If no, provide explanation of exemption here and skip to section 4:

b. Is the **Provider** based in the U.S.?
☐ Yes ☐ No
If yes, complete Section 3c
If no, check "Not applicable" in Section 3c

c. Will the U.S.-based **Provider** be sharing any of the below direct or limited identifiers with the Recipient*? (If unsure how to classify data into the below categories, Provider should contact their home institution's primary contact and the reference information for examples of where some types of data may fit into the below categories.)*

☐ Yes, Direct Identifiers

☐ Yes, Limited Dataset Information but **NO** Direct Identifiers

☐ No, the Materials and Data will be fully de-identified

☐ Not applicable

Direct Identifiers
(i) Names;
(ii) Postal address information, other than town or city, State, and zip code;
(iii) Telephone numbers;
(iv) Fax numbers;
(v) Electronic mail addresses;
(vi) Social security numbers;
(vii) Medical record numbers;
(viii) Health plan beneficiary numbers;
(ix) Account numbers;
(x) Certificate/license numbers;
(xi) Vehicle identifiers and serial numbers, including license plate numbers;
(xii) Device identifiers and serial numbers;
(xiii) Web Universal Resource Locators (URLs);
(xiv) Internet Protocol (IP) address numbers;
(xv) Biometric identifiers, including finger and voice prints; and
(xvi) Full face photographic images and any comparable images.

Limited Dataset Information
(i) Dates such as admission, discharge, DOB, DOD;
(ii) City, state, five digit or more zip code; and
(iii) Ages in years, months or days or hours.

d. Is the **Provider** based outside the U.S.?
☐ Yes ☐ No
If yes, add terms and conditions for the data set based on the sensitivity of the data according to provincial and/or federal regulatory or policy requirements law *(e.g. British Columbia applicable terms under Freedom of Information and Protection of Privacy Act (FIPPA). Consult appropriate institutional primary contact for more information)*
If no, skip to Section 3e

e. Is an institutional ethics approval or waiver required for the **Provider**?
☐ Yes ☐ No
If unsure, the Provider should consult appropriate institutional contact.
If yes, Provider organization approval information (Institutional Review Board (IRB) for U.S. or Research Ethics Board (REB) for Canada):

Study Title:
IRB or REB ID#:
(Note: In rare cases, this Implementing Letter would be executed before ethics (IRB/REB) approval or waiver: if that is the case, additional details should be

*included to outline how ethics approval will be ensured and documented. If required, approval MUST be obtained and documented **PRIOR to** Data or Materials transfer)*
Additional terms (if applicable):

f. Are there additional written conditions imposed by the **Provider's** IRB/REB?
☐ Yes ☐ No
If yes, please describe and/or attach additional terms and conditions (e.g. standardized FDP terms and conditions):

4. ETHICS – RECIPIENT
To be completed by the Recipient

a. Is institutional ethics approval or waiver required for the **Recipient**? *(If unsure, Recipient should contact their home institution's primary contact).*
☐ Yes ☐ No
If yes, Provider organization approval information (Institutional Review Board (IRB) for U.S. or Research Ethics Board (REB) for Canada):
Study Title:
IRB or REB ID#:
*(Note: In rare cases, this Implementing Letter would be executed before ethics (IRB/REB) approval or waiver: if that is the case, additional details should be included to outline how ethics approval will be ensured and documented. If required, approval MUST be obtained and documented **PRIOR to** Data or Materials transfer)*
Additional terms (if applicable):

5. SECURITY
To be completed by the Provider

Notes:

- **The Provider should contact their respective home institutions' information primary contact for consultation on completing this section.**
- **Data use or transfer may require security controls adequate to protect Personally Identifiable Information and be compliant with widely-recognized information security best practices and standards to ensure that only Authorized Persons have access to the Data, to maintain appropriate control over the Data at all times, and to prevent unauthorized transmission or export.**

a. Would the Data be considered controlled-access Data under the standard set by the NIH Genomic Data Sharing Policy? (I.e. Data that do not contain direct identifiers, but are nevertheless sensitive and could potentially be re-identified or linked back to individuals or groups)
☐ Yes ☐ No

If yes, describe how the Data will be secured in alignment with standards in the NIH Security Best Practices for Controlled-Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy:

b. Does the Provider have additional specific Data security requirements for the storage or use of Data other than those agreed to in Section 4: PROHIBITED USES and Section 6: CONFIDENTIALITY in the Umbrella Agreement?
☐ Yes ☐ No
If yes, describe:

6. <u>OTHER INFORMATION AND TERMS OF TRANSFER</u>
To be completed primarily by Recipient (in consultation with the Provider)

a. Will the Recipient share some or all the results (as specified below) it creates with the Provider/Provider Scientist (to be treated as confidential by Provider/Provider Scientist until publication of the Results by Recipient)?
☐ Yes ☐ No
If yes, please describe any results to be shared with Provider:

b. Will the Recipient share the Data and/or Materials with one or more third parties as part of the Purpose? (e.g. when the Purpose includes creation of a resource that is intended to be used by third parties or other situation)
☐ Yes ☐ No
If yes, please describe what will be shared and how the Data and/or Materials will be used:

If yes, please identify the additional parties, if known. If additional parties are unknown, please specify the reasons parties are yet unknown:

If yes, please describe terms of use:

If yes, please indicate whether an additional written agreement is required:

If yes, please attach written agreement and/or written confirmation from the Provider that third-party transfer is accepted.
(Do NOT transfer Data and/or Material to third party without prior written confirmation by the Provider that this is acceptable and under what terms)

c. Does the Recipient anticipate merging the Data with one or more data sets?

☐ Yes ☐ No
If yes, please describe and indicate any restrictions, if applicable:

d. Will there be costs incurred by either Party related to Materials and/or Data transfer other than shipping costs? Note: Recipient generally expected to provide FedEx/shipping information.

☐ Yes ☐ No
If yes, describe anticipated costs:
If no, skip to 6f.

e. If there are costs incurred, will there be payment between the Parties for costs incurred?
☐ Yes ☐ No
If yes, describe costs, cost structure, or how final costs will be determined:

f. Will any "Commercial Use" exceptions be allowed under this Implementing Letter? (Note: the most common use of this exception will likely be to specifically allow for Industry Sponsored Academic Research.)

Definition of "Commercial Use" from the Umbrella agreement: "Commercial Use" shall mean the sale, lease, license, or other transfer of the Material, Modifications, Confidential Information, or Data to a for-profit organization. Commercial Use shall also include uses of the Material, Modifications, Confidential Information, or Data in any research that is subject to consulting or licensing obligations to any for-profit organizations.

☐ Yes ☐ No
If yes, provide a description of the exception and any additional information or terms:

g. Should the Provider or Provider's resource be cited in publications, presentations, grant applications, or other communication materials that relate to the use of the Data and/or Materials?
☐ Yes ☐ No
If yes, describe citation requirements:

h. Are there other terms or restrictions (e.g. obligations to a 3rd party involved in funding or material/data creation, in-kind contributions, biosafety considerations, animal care, intellectual property, instructions for return/destruction of Materials or Data)?
☐ Yes ☐ No
If yes, describe additional terms or restrictions and attach any relevant documentation:

This Implementing Letter ("Implementing Letter"), effective as of the date of the last signature ("Effective Date"), is by and between the below listed signatory institutions to the Umbrella Materials and Data Transfer Agreement ("DMTA"), signed October 16, 2020. The Recipient and Provider institutions designated in the Implementing Letter cover page and signed below, hereby agree to be bound to the terms of the DMTA and of the Implementing Letter for the Materials and/or Data transferred between them under this Implementing Letter.

FOR PROVIDER:

_____

(Signature of Authorized Official) Date

_____

(Printed Name and Title)

FOR RECIPIENT:

_____

(Signature of Authorized Official) Date

_____

(Printed Name and Title)

RECIPIENT INVESTIGATOR:

I have read and understood the terms and conditions of this Implementing Letter and I agree to abide by them in the receipt and use of the Data and/or Material.

_____

(Signature) Date

(Printed Name and Title)