Implementing Letter Template (more than two Parties)

Note for researchers: This template should be completed by all research groups involved in transfers of materials and/or data within the described research project. Given there may be multiple directions of sharing within a single project, each research group should describe their roles as both a provider and recipient of materials/data as applicable. See the Website for more information, contacts, 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 direction of sharing within this project, each research group involved should:

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 primary agreement contact (see section one below or the Website).
2. Attach any appropriate documentation (e.g. protocols, specific terms)
3. Work with the other research groups and the respective primary agreement contacts.
4. Obtain appropriate institutional 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.

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, MATERIALS, AND DATA**
   To be completed/confirmed by all Parties. The same organization may be listed as both a Recipient and Provider. Primary agreement contacts for each institution are listed next to the name of the institution.

Parties Providing Materials and/or Data (Providers)		Parties Receiving Materials and/or Data (Recipients)	
Provider 1	**Organization:** **Scientist:** **Material and/or Data:**	**Recipient 1**	**Organization:** **Scientist:** **Material and/or Data:**

Provider 2	**Organization:** **Scientist:** **Material and/or Data:**	**Recipient 2**	**Organization:** **Scientist:** **Material and/or Data:**
Provider 3	**Organization:** **Scientist:** **Material and/or Data:**	**Recipient 3**	**Organization:** **Scientist:** **Material and/or Data:**
Provider 4	**Organization:** **Scientist:** **Material and/or Data:**	**Recipient 4**	**Organization:** **Scientist:** **Material and/or Data:**
Provider 5	**Organization:** **Scientist:** **Material and/or Data:**	**Recipient 5**	**Organization:** **Scientist:** **Material and/or Data:**

2. <u>DESCRIPTION OF PROJECT</u>
To be completed/confirmed by all Parties.

a. 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.]

b. 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 – PROVIDERS

To be completed/confirmed by each Provider

Notes:

- **The Providers should contact their respective home institutions' primary agreement contact (see section 1) 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 any **Provider** be transferring Data or Materials derived from humans?
☐ Yes ☐ No
If yes, please complete this section
If no, provide explanation (e.g. materials/data derived from animal models) here and skip to section 4:

b. Are any institutional ethics approvals or waivers required for the **Providers**?
☐ 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):

Provider #1
Study Title:
IRB or REB ID#:

Provider #2
Study Title:
IRB or REB ID#:

Provider #3
Study Title:
IRB or REB ID#:

Provider #4
Study Title:
IRB or REB ID#:

Provider #5
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):

c. Are any **Providers** based in the U.S.?
☐ Yes ☐ No
If yes, complete Section 3c for U.S.-based Providers
If no, check "Not applicable" in Section 3c

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

☐ Yes, Direct Identifiers
List which Providers (e.g. Provider 1):
☐ Yes, Limited Dataset Information but **NO** Direct Identifiers
List which Providers:
☐ No, the Materials and Data will be fully de-identified
List which Providers:
☐ 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.

e. Are any **Providers** based outside the U.S.?
☐ Yes ☐ No
If yes, add terms and conditions for each 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 contacts and see the Website for more information)*
If no, skip to Section 3e

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

4. ETHICS – RECIPIENTS
To be completed by the Recipients

a. Are institutional ethics approvals or waivers required for the **Recipients**? *(If unsure, Recipient should contact their home institution's primary contact.)*
☐ Yes ☐ No
If yes, provide organization approval information (Institutional Review Board (IRB) for U.S. or Research Ethics Board (REB) for Canada):
Recipient #1
Study Title:
IRB or REB ID#:

Recipient #2
Study Title:

IRB or REB ID#:

Recipient #3
Study Title:
IRB or REB ID#:

Recipient #4
Study Title:
IRB or REB ID#:

Recipient #5
Study Title:
IRB or REB ID#:

Additional terms (if applicable):

5. SECURITY

To be completed by the Providers

Notes:

- **The Providers 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 [see Website] 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 any Data being transferred 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, identify which Providers will share these Data and 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 [see Website and policy documentation]:

b. Do any of the Providers 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 Recipients (in consultation with the Providers)

a. Will the Recipients share some or all the results (as specified below) they create with the Providers/Provider Scientists (to be treated as confidential by Providers/Provider Scientists until publication of the Results by Recipients)?
☐ Yes ☐ No
If yes, please briefly describe any results to be shared with Providers or other parties:

b. Will the Recipients 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. Do the Recipients anticipate merging Data with one or more other data sets?
☐ Yes ☐ No
If yes, please describe which Data will be merged and indicate any restrictions, if applicable:

d. Will there be costs incurred by any Party related to Materials and/or Data transfer other than shipping costs? Note: Recipients are generally expected to cover material shipping

costs and should provide FedEx and/or other applicable shipping information to Provider.

☐ Yes ☐ No

If no, skip to 6f.

If yes, describe anticipated costs:

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 Providers or Providers' resources 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, instructions for return or destruction of Materials/Data, in-kind contributions, biosafety considerations, animal care, intellectual property)?

☐ Yes ☐ No

If yes, describe additional terms or restrictions and attach any relevant documentation:

Notes to Researchers and Institutions

Do Not Transfer Data and/or Material Until:

(a) the Umbrella Data and Material Transfer Agreement (DMTA) is signed and Implementing Letter is completed and signed by both parties. In addition to all terms and conditions specified under the DMTA, patient-derived/human-subjects data will be subject to further restrictions, depending on data type.

(b) the relevant REB/IRB has approved or a waiver/exemption has been confirmed (approval and/or Protocol must clearly indicate the intent to distribute the materials to non-Provider parties and a description of the research activities to be performed by any non-Provider Recipient Scientist with the materials);

(i) ***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. Approval MUST be obtained and documented PRIOR to Data or Materials transfer)***

(c) the Implementing Letter has been reviewed and approved by the appropriate Provider and Recipient institutional administrative representatives (review should consider the jurisdiction(s) of the parties to this Implementing Letter, as this transfer and any subsequent use may be subject to specific provincial, state, and/or federal laws and policy guidance); and

(d) **the Implementing Letter has been signed by the Provider and Recipient institutional representatives**.

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 PARTY 1:

_____

(Signature of Authorized Official) Date

_____

(Printed Name and Title)

FOR PARTY 2:

_____

(Signature of Authorized Official) Date

_____

(Printed Name and Title)

FOR PARTY 3:

_____

(Signature of Authorized Official) Date

_____

(Printed Name and Title)

FOR PARTY 4:

_____

(Signature of Authorized Official) Date

_____

(Printed Name and Title)

FOR PARTY 5:

_____

(Signature of Authorized Official) Date

_____

(Printed Name and Title)

FOR PARTY 6:

_____

(Signature of Authorized Official) Date

_____

(Printed Name and Title)

FOR PARTY 7:

_____

(Signature of Authorized Official) Date

_____

(Printed Name and Title)