Multi-Party Data and Material Transfer Agreement (DMTA)

Contents

Information for researchers at participating institutions 1

Umbrella Data and Material Transfer Agreement 2

List of Signatory Institutions 14

Implementing Letter Template 15

Reference Information 23

Information for researchers at participating institutions

This agreement consists of two sections:

1. The Umbrella Data and Material Transfer Agreement (DMTA)
    a. Purpose: This agreement is a multi-party agreement with standard terms for data and materials transfer aimed at reducing the time needed for academic researchers to share data with one another
    b. When to use: The Umbrella DMTA will be signed once every 5 years by participating institutions. **The Umbrella DMTA DOES NOT need to be negotiated or signed again for individual projects** where data and materials will be shared between signatory organizations.
2. Implementing Letter Template
    a. Purpose: Completion of the Implementing Letter template (Schedule 2) 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 DMTA.
    b. When to use: **Researchers representing Parties to this Umbrella DMTA and who intend to share Data and/or Materials under specific projects should complete ONLY the Implementing Letter template for each new project.**

Umbrella Data and Material Transfer Agreement

("DMTA" or "Agreement")

This DMTA, effective as of the _____ day of _____, 2020 ("Effective Date"), is entered into between the Parties listed in Schedule 1 to govern the transfer of Data and/or Material for the Purposes as defined below.

WHEREAS, the Parties wish to provide and share certain Data and/or Materials amongst each other;

WHEREAS, an Implementing Letter, in the form attached in Schedule 2, will specify the Data and Materials and Purpose(s) for which such are shared between Providers and Recipients

WHEREAS, The Parties to this Agreement may engage any other Parties as either Providers or Recipients under Implementing Letters as defined herein; and

WHEREAS, upon execution of an Implementing Letter the Parties agree to be bound by the terms of this Agreement

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

Definitions

1. **"Commercial Use"**, shall mean the sale, lease, license of the Material, Modifications, Confidential Information or Data, and includes any 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.
2. "**Confidential Information**" has the meaning set out in section 6 of this Agreement;
3. "**Consent**" means any applicable consent provided by a Subject authorizing the collection, use or disclosure of the Subject's Data or Materials in connection with the activities described in an Implementing Letter;
4. **"Data"** means all data and information transferred to a Recipient, as specified under an Implementing Letter.
5. "**Data Linking**" means the linking or combining of Individually Identifiable data in one database with Individually Identifiable data in another database if the purpose of linking or combining the data is different from the purpose for which the information in each database was originally obtained or compiled;
6. "**Individual Identifiers**" means information that identifies or could be used to identify a Subject, including name, contact information, personal health number, date of birth, etc.;
7. "**Individually Identifiable**" means Data or Materials about or pertaining to an identifiable person if it or they can be linked to that individual or from which the identity of the individual about whom it or they pertain could reasonably be inferred or discovered;
8. "**Implementing Letter"** means an executed letter in the format as provided in the Schedule 2 attached hereto, which shall provide a record of a Data and/or Material transfer between two or more Parties to this Agreement;
9. **"Primary Material(s)"** has the meaning as set out in the Implementing Letter.

10. **"Material(s)"** means the Primary Material, Progeny, and Unmodified Derivatives. The Material shall not include: (a) Modifications, or (b) other substances created by the Recipient through the use of the Material which are not Modifications, Progeny, or Unmodified Derivatives.
11. **"Modification(s)"** shall mean substances created by the Recipient which contain or otherwise incorporate Material (in whole or in part), or otherwise are modified derivatives of the Material;
12. **"Progeny"** shall mean unmodified descendant(s) from the Primary Material, such as (for example) a cell from a cell, cells from tissue, cells from a xenotransplant, or an organism from an organism;
13. "**Provider**" means the Party specified in the Implementing Letter who is supplying the Data and/or Materials to the Recipient;
14. **"Purpose"** means any specific research plan as outlined in the Implementing Letter. This would include the protocol as approved by the Provider's ethics review board (e.g. REB/IRB) if applicable ("**Protocol**") as attached to Implementing Letter as Schedule "X".
15. **"Recipient"** means the Party specified in the Implementing Letter as receiving the Data and/or Materials supplied by the Provider;
16. "**Results**" means all data and information arising from the performance of the Purpose by the Recipient, but excludes any Data or Materials in Individually Identifiable form.
17. "**Subject**" means any individual whose Data or Materials is transferred under this Agreement in Individually Identifiable form;
18. **"Unmodified Derivatives"** shall mean any substance constituting an unmodified functional or structural subunit or product expressed by, or isolated from, the Primary Material or Progeny.

Parties' Obligations

1. **NON-TRANSFERABILITY**
   This DMTA is not transferable.

2. **COMPLIANCE**

   a) In transferring and using the Materials, Modifications, Confidential Information, Data, and Results, the Parties shall comply with all jurisdictionally applicable laws, regulations, guidelines and policies, including, as applicable, the British Columbia *Freedom of Information and Protection of Privacy Act* ("Applicable Law").
   b) For Individually Identifiable Data or Materials, the Provider will prepare and furnish the Data and/or Material in accordance with Applicable Law including without limitation by ensuring that all required and appropriate authorizations, consents or waivers for the use of such Data and/or Materials have been obtained from Subjects or other organizations whose consent or authorization is required under Applicable Laws for the use or transfer of the Data and/or Materials;
   c) Where the use of Data and/or Materials will constitute research involving human subjects, as defined under the Applicable Laws, the Data and/or Material will not be collected and/or transferred until both the Provider and the Recipient have obtained any required ethics review and/or privacy board approvals (Research Ethics Board "REB" or Institutional Review Board "IRB").
   d) Data and Materials shall not be provided in Individually Identifiable form unless the Provider is satisfied that (a) the provision of the Individually Identifiable Data or Materials is authorized by the Subject in a Consent, and the Data and Materials has been voluntarily provided by Subjects; or (b) consent has been waived by the applicable research ethics board and is authorized under Applicable Laws. The Implementation

Letter shall set out measures to ensure that all Individual Identifiers are destroyed by the Recipient at the earliest possible time.

e) The Data and Materials may not be used by the Recipient for the purposes of Data Linking, unless (a) the Recipient is satisfied that the Data-Linking is not harmful to Subjects; (b) the benefits arising from the Data Linking are in the public interest, and (c) the Data Linking is expressly approved in writing by the Provider in the Implementation Letter.

f) The Provider retains the right but not the obligation to conduct, at its own expense, audits of Recipient's compliance with this Agreement upon reasonable advance written notice to the Recipient and at mutually acceptable times.

g) If there is a breach of the Agreement by the Recipient, the Provider may require that all Materials and/or Data be returned promptly to Provider or destroyed in a secure manner at the Providers' option. In the event of any disclosure of Individually Identifiable Data or Materials or Results, contrary to this Agreement or Applicable Laws, the Recipient will notify the Provider promptly, no later than 24 (twenty-four) hours from becoming aware of the breach and will cooperate, at the Recipient's own expense, with the Provider on any remediation plans.

h) All Protocols are considered Confidential Information (as defined in section 6) of the Disclosing Party.

For the avoidance of doubt, this Section 2 applies to all Data and/or Material transferred under this DMTA, including, without limitation, all data and information in Individually Identifiable form generated or derived therefrom, and any Data and/or Material stored in a Provider repository or prospectively collected by the Provider.

3. **PERMITTED USES**

a) Recipient will only use Data and/or Material (i) for the Purpose, (ii) in compliance with Applicable Laws, (iii) in compliance with the terms and conditions contained in this DMTA and the corresponding Implementing Letter; and (iv) in compliance with the terms of any applicable Consents.

b) THE MATERIAL MAY NOT BE USED IN HUMANS, INCLUDING FOR PURPOSES OF DIAGNOSTIC TESTING.

c) In order to share and/or provide Data and/or Material with and between each other for any specific project, the Parties will be required to complete a specific Implementing Letter (attached as **Schedule 2**).

d) The Recipient and Provider (as applicable) of Data and/or Material under an Implementing Letter hereby agrees:

   i. the Recipient shall use the Data and/or Material only as specified under an Implementing Letter and only for academic research, educational, and patient care purposes but not for Commercial Use, unless otherwise outlined in the Implementing Letter and expressly approved in writing by the Provider; and

   ii. the Recipient shall securely store the Data and/or Material received as appropriate for said Material and/or Data, including by making all commercially reasonable efforts to protect the Data and Material against such risks as unauthorized access, collection, use, disclosure, loss and theft;

   iii. the Provider shall provide access to or transfer of the Data and/or Material as outlined in the Implementing Letter, but reserves the right to terminate or suspend such access and transfer in the event of any actual or suspected breach of this Agreement; and

iv. the Recipient will be permitted to distribute the Data and/or Material to third parties only as described in the Implementing Letter, if allowed, and then only with express written permission of the Provider, and/or as required by Applicable Law.

4. **PROHIBITED USES**

For the purposes of certainty and clarity, and unless expressly authorized in this Agreement or by the Provider in the Implementing Letter, the Recipient shall not engage in:

a. Any Commercial Use of the Material, Data, Confidential Information, or Modifications as applicable and as defined in the Implementing Letter;
b. Any research utilizing the Material, Data, and/or Modifications that is subject to consulting or licensing obligations to any third party;
c. The creation or generation of Modification(s) except as outlined in the Purpose;
d. Use of the Confidential Information, Material, Data, or Results for any purpose relating to re-identifying an individual or contacting a person, including contacting a person to participate in research;
e. Use of Confidential Information, Material, Data or Results for the purposes of Data-Linking; or
f. Any use of the Confidential Information, Data or Materials for other research or other purposes not contemplated in this MDTA or the Implementing Letter without the express written permission of Provider, which the Provider may, in its sole discretion and for any reason, refuse to provide.

For greater certainty, any use or disclosure of the Confidential Information, Material, Data, or Results in Individually Identifiable form is prohibited except as expressly authorized in an Implementing Letter and this MDTA or as otherwise expressly approved in writing by the Provider.

5. **MATERIAL HANDLING**

The Materials may contain one or more infectious agents and may have additional unknown and hazardous properties. The Recipient represents and warrants that it has the expertise necessary to handle the Materials with care and without danger to any person or entity, including without limitation the Recipient, any affiliate, any employees of the Recipient or of any affiliate, Provider or the public. The Recipient shall not accept delivery of the Confidential Information or the Materials until it has first requested and received from the Provider all necessary information and has sought and obtained any necessary advice or expertise to ensure that it is capable of handling the Confidential Information and the Materials in a safe and prudent manner and in compliance with all Applicable Laws, regulations, and ordinances whether Federal, State, Provincial, County, Municipal or otherwise.

6. **CONFIDENTIALITY**

a) All confidential or proprietary data or information ("Confidential Information") that is transferred from a "Disclosing Party" to a "Receiving Party" under this DMTA is subject to the following:
    i. Subject to paragraph ii of this section 6(a), all information to be deemed confidential under this DMTA shall be clearly marked "CONFIDENTIAL" by the Disclosing Party and maintained in confidence by the Receiving Party for a period of five (5) years from the Receiving Party's receipt of the Confidential Information.

ii. Any and all data constituting Individually Identifiable information of a Subject, whether or not marked as confidential, will constitute Confidential Information
iii. Subject to paragraph ii of this section 6(a), if disclosed orally, graphically or in some other non-tangible form, the Confidential Information must be identified by the Disclosing Party as confidential at the time of first disclosure.
iv. Notwithstanding the foregoing, information will be treated as Confidential Information, whether or not marked or designated as confidential, if such information would be understood by a reasonable person to be confidential in light of the nature of the information and/or the circumstances of disclosure hereunder.
v. All Confidential Information must be maintained in confidence by the Receiving Party, notwithstanding the termination or expiration of this DMTA or the corresponding Implementing Letter and must be used and disclosed only as authorized by the Disclosing Party in this DMTA, the Implementing Letter or otherwise in writing.
vi. The Disclosing Party shall have the right to request that the Receiving Party securely destroy all Confidential Information.
vii. Confidential Information, except Confidential Information in Individually Identifiable form, does not include information that:
    1. has been published or is otherwise publicly available at the time of disclosure to the Receiving Party;
    2. was in possession of or was readily available to the Receiving Party without being subject to a confidentiality obligation from another source prior to the disclosure;
    3. has become publicly known, by publication or otherwise, not due to any unauthorized act of the Receiving Party;
    4. the Receiving Party can demonstrate it developed independently, or acquired without reference to, or reliance upon such Confidential Information; and
    5. is required to be disclosed by law, regulation or court order.

b) the Recipient will not attempt to contact or make any effort to identify Subjects who are or may be the sources of the Primary Material and/or Data, without specific written approval from Provider.
c) Recipient shall use appropriate safeguards to prevent any unauthorized use or disclosure of the Data and/or Material and shall report any unauthorized use or disclosure of Recipient becomes aware to the Provider.
d) Recipient shall securely destroy or return the Materials, Confidential Information, and/or Data in its possession upon termination of the associated Implementing Letter, as otherwise set out in the applicable Implementing Letter, or as requested by the Provider or in accordance with any applicable Consents.
e) Results will be kept under the stewardship of the Party that created them. Results, or some portion thereof, may be shared between Parties as described in the Implementation Letter.
f) Any disclosure of Confidential Information required under applicable Canadian Law, including the BC Freedom of Information and Protection of Privacy Act, shall not give rise to a breach of this Agreement, provided that the party making the disclosure first provides the Disclosing Party with written notice of the disclosure.

7. **LAW**
   In the event of any dispute arising between two or more of the Parties concerning this Agreement, its enforceability, or its interpretation, the involved Parties shall first attempt in good faith to resolve any dispute by negotiation and consultation between their respective executives having authority to resolve the dispute. If the executive leadership of each involved Party are unable to resolve the dispute within thirty (30) days, the Parties shall attempt in good faith to settle the dispute through mediation by a neutral third party, before submitting the case to a court of competent jurisdiction.

8. **INTELLECTUAL PROPERTY**
   For each respective Implementing Letter, the Recipient agrees to promptly disclose to the Provider, on a confidential basis, any new invention, development, or discovery resulting from the performance of the Purpose (collectively referred to as "Invention"). Ownership shall follow inventorship. Should an Invention occur that is jointly owned by the Provider and Recipient, the Provider and Recipient agree to negotiate in good faith an inter-institutional agreement which shall provide for fair and equitable sharing of patent costs, income, and invention management responsibilities based on the respective institutions' roles and contributions to the Invention. Subject to any pre-existing rights, obligations, options to license, or licenses granted by the Provider and/or Recipient to a third party, the Recipient and Provider retain or are granted a non-exclusive royalty-free license to use an Invention developed under the Purpose for their own research, educational, patient care purposes but not for Commercial Use unless otherwise outlined in the Implementing Letter.

9. **INDEMNIFICATION**
   Unless otherwise agreed between the Recipient and the Provider in an Implementing Letter or as required by Applicable Law, no indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this DMTA. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party's activities under this DMTA.

10. **TERM AND TERMINATION**

    a) This DMTA will commence on the Effective Date and shall continue in force for five (5) years (the "Term"), unless extended by mutual agreement in writing between all Parties or terminated earlier.
    b) Any Party may terminate their obligations and participation under this DMTA and all associated Implementing Letters with sixty (60) days written notice to the other Parties.
    c) Any Party may terminate their obligations and participation under any Implementing Letter with thirty (30) days written notice to the other Party(ies) associated with said Implementing Letter.
    d) For each Implementing Letter, when the Purpose is completed or upon Provider request, any unused Data and/or Material will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the Provider as requested by the Provider, unless otherwise outlined in the Implementing Letter.

11. **PUBLICATION**
    For the research conducted under each respective Implementing Letter, both the Provider and Recipient agree to use good faith efforts to collaborate on a joint publication as appropriate under current academic standards. In any case, the publishing Party (likely the Recipient) shall provide any proposed publications or disclosures to the other Party thirty (30) days prior to

submission to a journal or any public disclosure. The non-publishing Party shall have such thirty (30) day period to identify any Confidential Information or potentially patentable information and provide comments to the publishing Party. Requests to remove potential Confidential Information of the non-publishing Party will be considered in good faith by publishing Party. Any Confidential Information comprising information about Subjects in Individually Identifiable form shall be removed prior to publication. Upon the written request of the non-publishing Party, the publishing Party agrees to delay for an additional thirty (30) days to allow for the filing of any relevant patent applications. In accordance with scientific custom, the publishing Party agrees to note the contributions of the non-publishing Party through acknowledgment or co-authorship, as appropriate. Both Parties shall hold all such communications in confidence until published.

12. **REPRESENTATIONS AND WARRANTIES**

Any Material, Results, Confidential Information, and/or Data delivered pursuant to this DMTA is understood to be experimental in nature and may have hazardous properties. EXCEPT AS PROVIDED HEREIN, NEITHER PARTY PROVIDES ANY REPRESENTATIONS NOR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING CONCERNING THE ACCURACY, COMPLETENESS, QUALITY OR CORRECTNESS OF THE DATA, THERE ARE NO EXPRESSED OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL, RESULTS, CONFIDENTIAL INFORMATION, AND/OR DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

GENERAL

a) No Party will use the name or logo of any other Party in any advertising or other form of publicity without the prior written consent by an authorized individual of the other Party.
b) Upon expiration or termination of this DMTA, all terms and conditions that, by their nature should remain in effect will remain in effect.
c) No Party shall be entitled to assign or transfer this DMTA or the rights and obligations hereunder to any third party.
d) With the exception of Schedule 1 with regards to the addition of more parties, this DMTA shall not be amended, modified, varied or supplemented except in writing signed by each of the Parties.
e) Additional parties may sign onto this DMTA, provided they do not modify it in any way.
f) Upon expiration of this DMTA, renegotiation may occur between Parties that have signed onto the original who desire to enter a revised agreement.
g) The Implementing Letter template (as attached in Schedule 2) will be assessed for completeness and ease-of-use after one year by each signing Party organization's selected designees. At that time, the Implementing Letter template may be updated, provided that:
    i. There is express written agreement by the Parties to the Implementing Letter to any proposed changes to the Implementing Letter
    ii. All Parties to the DMTA are notified in writing of the update to the Implementing Letter template and the reasons for the change(s) to the template.
    iii. The updated Implementing Letter template is readily available to all Parties to the DMTA
    iv. Prior versions of the Implementing Letter are readily available to all Parties in an archive for reference

v. Previously signed implementing letters remain in force and do not need to be updated to align with the updated template.
vi. Parties to previously-executed implementing letters may update those previously signed implementing letters if mutually agreed by those Parties.

13. This DMTA and the Implementing Letters set forth the entire understanding between the Parties and supersedes all other understandings, whether written or oral, between the Parties with respect to the same subject matter. Subject to any pre-existing obligations to a third party associated with Data and/or Material transferred under an Implementing Letter, in the event of a conflict between the terms of this DMTA and any Implementing Letters, or any appendices to this DMTA, the terms of this DMTA shall govern. If any one or more provisions of this Agreement is held invalid, illegal or unenforceable in any respect by a court having competent jurisdiction, the validity, legality and enforceability of this Agreement and the remaining provisions contained herein shall not in any way be affected or impaired thereby.

14. This DMTA may be signed in counterparts, and each counterpart may be delivered by signed PDF by email. Each counterpart shall constitute an original, and when taken together, shall constitute one and the same instrument.

SIGNATURE PAGES TO FOLLOW

Schedule 2 of DMTA:

Implementing Letter Template

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).

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 [see List of Signatory Institutions] under the Umbrella Data and Material Transfer Agreement (DMTA) [see Umbrella Data and Material Transfer Agreement].

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 [see Reference Information]
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 [see Reference Information]

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. **Recipient Address**: [Legal Address of Receiving Organization]
   b. **Recipient Scientist**: [Name of Scientist receiving the Data and/or Materials]
   c. **Provider Scientist**: [Name of Principal Investigator transferring the Data and/or Material]
   d. **Recipient Authorized Official**: [Name of Official authorized to sign for Receiving Institution]
   e. **Provider DMTA Contact:** [Contact Information for Contract/Legal Officer of Providing Institution]

f. **Recipient DMTA Contact:** [Contact Information for Contract/Legal Officer of Receiving Institution]

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

a. **Description of "Primary Material" (if any):** [Describe the material to be transferred]
b. **Description of "Data" (if any):** [Describe any clinical or other 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.]
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 [see** Reference Information**] 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 patients/human-subjects?
☐ 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 [see* Reference Information*].)*
☐ Yes, Direct Identifiers

(If Provider is U.S.-based, see Reference Information*: Additional Terms and Conditions for Personally Identifiable Information for sample standardized agreement language)*

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

(If Provider is U.S.-based, see Reference Information*: Additional Terms and Conditions for Limited Data Sets for sample standardized agreement language)*

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

(If Provider is U.S.-based, see Reference Information*: Additional Terms and Conditions for De-identified Data about Human Subjects for sample standardized agreement language)*

☐ 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 and see* Reference Information *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. (See here Reference Information for a list of institutional primary contacts for consultation)

If yes, Provider organization approval information (Institutional Review Board (IRB) for U.S. or Research Ethics Board (REB) for Canada):

Study Title: [Title of the Study]

IRB or REB ID#: [XX-XXXX]
*(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 [see Reference Information]):

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 [see Reference Information].)*
☐ Yes ☐ No
If yes, Provider organization approval information (Institutional Review Board (IRB) for U.S. or Research Ethics Board (REB) for Canada):
Study Title: [Title of the Study]
IRB or REB ID#: [XX-XXXX]
*(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 [see Reference Information] 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 Reference Information] 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 [see Reference Information and policy documentation]:

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. OTHER INFORMATION AND TERMS OF TRANSFER
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?
☐ Yes ☐ No
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 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)?
☐ 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**.

Fred Hutch Ref# COL210703

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 _____. 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

Fred Hutch Ref# COL210703

DMTA

Reference Information

Updated 4/21/2020

General Resources

Information about the Multi-Party Data and Material Transfer Agreement (DMTA)

Background: The DMTA was developed through efforts of the Cascadia Data Alliance and the Specimen Acquisition Network to streamline and standardize the process of data and/or materials transfer between academic research partners. While the effort started in the Pacific Northwest region of North America, it is not intended to be limited to the original geographic area. Organizations that agree to the standardized terms of the DMTA may join as signatories.

How it works: The DMTA consists of two sections: (1) the Umbrella Data and Material Transfer Agreement and (2) the Implementing Letter Template. The Umbrella DMTA is a multi-party agreement with standard terms for data and materials transfer aimed at reducing the time needed for academic researchers to share data with one another. The Umbrella DMTA will be signed once every 5 years by participating institutions. The Umbrella DMTA DOES NOT need to be negotiated or signed again for individual projects where data and materials will be shared between signatory organizations. The Implementing Letter template is intended to identify and establish agreement on additional terms related to specific projects for which Data and/or Material will be transferred between signatory institutions under the Umbrella DMTA. Researchers at the signatory organizations who intend to share Data and/or Materials under specific projects need to complete only the Implementing Letter template for each new project.

Signatory organizations

BC Cancer: http://www.bccancer.bc.ca/
Benaroya Research Institute: https://www.benaroyaresearch.org/
Fred Hutchinson Cancer Research Center: https://www.fredhutch.org/
Oregon Health & Science University: https://www.ohsu.edu/

Last updated April 22, 2020

Primary agreement contacts at each signatory organization

Researchers planning to share data and/or material between signatory organizations should begin by contacting their home institution's primary contact listed below for assistance in completing the Implementing Letter template:

BC Cancer:
Technology Development Office – email: tdoadmin@phsa.ca
Benaroya Research Institute:
Business Development – email: bizdev@benaroyaresearch.org
Fred Hutchinson Cancer Research Center:
Business Development and Strategy – email: mta@fredhutch.org
Oregon Health & Science University:
Research Grants and Contracts – email: goldenep@ohsu.edu

Deciding when you need a data use or materials transfer agreement

Federal Demonstration Partnership guidance chart to help decide when a data use agreement is needed (U.S. focused)
http://thefdp.org/default/assets/File/Documents/dtua_guidance_chart.pdf

Federal Demonstration Partnership Data Stewardship site
http://thefdp.org/default/committees/research-compliance/data-stewardship/

Ethics and Privacy

Ethics and privacy law and policy references

Common Rule – Federal Policy for the Protection of Human Subjects (U.S.)

The U.S. Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and codified in separate regulations by 15 Federal departments and agencies. The HHS regulations, 45 CFR part 46, include four subparts: subpart A, also known as the Federal Policy or the "Common Rule"; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

HIPAA – Health Insurance Portability and Accountability Act, Privacy Rule (U.S.)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of the U.S. Department of Health and Human Services (HHS) to develop regulations protecting the privacy and security of certain health information. To fulfill this requirement, HHS published what are commonly known as the HIPAA Privacy Rule and the HIPAA Security Rule.

Privacy Rule: The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically. The Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made

of such information without patient authorization. The Rule also gives patients rights over their health information, including rights to examine and obtain a copy of their health records, and to request corrections: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

FIPPA – Freedom of Information and Protection of Privacy Act (B.C. Public Institutions, Canada)

The purposes of FIPPA are to make public bodies more accountable to the public and to protect personal privacy by (a) giving the public a right of access to records, (b) giving individuals a right of access to, and a right to request correction of, personal information about themselves, (c) specifying limited exceptions to the rights of access, (d) preventing the unauthorized collection, use or disclosure of personal information by public bodies, and (e) providing for an independent review of decisions made under this Act. FIPPA does not replace other procedures for access to information or limit in any way access to information that is not personal information and is available to the public. http://www.bclaws.ca/Recon/document/ID/freeside/96165_00

Researchers working at BC Cancer must abide by the Freedom of Information and Protection of Privacy Act (British Columbia) ("FIPPA" or "FOIPPA"),which applies to public bodies in BC. According to the FIPPA, the definition of personal information is quite broad. Schedule 1 of this Act defines it as follows: "recorded information about an identifiable individual other than contact information." The Act defines contact information as "information to enable an individual at a place of business to be contacted and includes the name, position name or title, business telephone number, business address, business email or business fax number of the individual".

Additional definitions relating to data used by pubic bodies in BC were produced by the BC Ministry of Health in a 2018 Access to Health Data for Research Policy Instrument as shown below.

- "de-identification" means a process that removes, or transforms, direct and indirect identifiers in a record using methods that can include generalization, suppression, aggregation and randomization, and for unstructured data can include redacting or severing, with deidentification processes resulting in partial de-identification or anonymization;
- "direct identifiers" means information that identifies an individual without additional information, with examples including an individual's name or a unique identifier such as a personal health number;
- "indirect identifiers" means information that is not a direct identifier but which may identify an individual when it is connected with other pieces of information to single out an individual, with indirect identifiers being considered personal information if they can be combined together to identify an individual, due to what is commonly referred to as the mosaic effect;
- "partial de-identification" means a de-identification process that removes direct identifiers and manages the indirect identifiers that could potentially be combined to identify an individual. Partially de-identified records contain personal information. Therefore, the disclosure of partially de-identified records would require

appropriate authorization under Part 3 of Freedom of Information and Protection of Privacy Act;

Additional information: BC Ministry of Health in a 2018 Access to Health Data for Research Policy Instrument https://www2.gov.bc.ca/assets/gov/health/conducting-health-research/data-access/access-to-health-data-for-research.pdf

TCPS – Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Canada)

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS or the Policy) is a joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or "the Agencies."

This Policy expresses the Agencies' continuing commitment to the people of Canada to promote the ethical conduct of research involving humans. It has been informed, in part, by leading international ethics norms, all of which may help, in some measure, to guide Canadian researchers, in Canada and abroad, in the conduct of research involving humans. TCPS 2 (2018): https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

Ethics and privacy agreement resources

U.S. Federal Demonstration Partnership resources that may be helpful when establishing terms and conditions for certain classes of data:

Tool for classifying Human Subjects Data (U.S. focus)
http://thefdp.org/default/assets/File/Documents/human_subject_data_classification_tool.pdf

Guidance chart for Provider to select the most appropriate Standard Terms and Conditions document
http://thefdp.org/default/assets/File/Documents/dtua_provider_guidance_chart_1-16-2019.pdf

Standard terms and conditions for de-identified data about human subjects
http://thefdp.org/default/assets/File/Documents/dtua_attachment_2_deidentified_data.pdf

Standard terms and conditions for limited data sets
http://thefdp.org/default/assets/File/Documents/dtua_attachment_2_limited_data.pdf

Standard terms and conditions for Personally Identifiable Information – Common Rule only
http://thefdp.org/default/assets/File/Documents/Att2_Identifiable_Common_Rule_Feb_2019.pdf

Standard terms and conditions for Personally Identifiable Information – HIPAA
http://thefdp.org/default/assets/File/Documents/Att2_Identifiable_HIPAA_Feb_2019.pdf

Standard terms and conditions for Personally Identifiable Information – FERPA
http://thefdp.org/default/assets/File/Documents/Att2_Identifiable_FERPA_Feb_2019.pdf

Potential categories for common examples of data types and uses

The following is intended to outline where common data types may be categorized. Because there may be differences in local policy and law, as well as differences in each data set, prospective data providers should consult their home institution prior to sharing.

Categories:

- Non-human subjects data sets
    - Animal data, human cell line data
- De-identified data about human subjects
- Limited dataset but no direct identifiers
- Direct identifiers
    - Personally Identifiable Information – Common Rule
    - Personally Identifiable Information – HIPAA
    - Personally Identifiable Information - FERPA

Security

Security law and policy references

HIPAA – Health Insurance Portability and Accountability Act, Security Rule (U.S.)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of the U.S. Department of Health and Human Services (HHS) to develop regulations protecting the privacy and security of certain health information. To fulfill this requirement, HHS published what are commonly known as the HIPAA Privacy Rule and the HIPAA Security Rule.

Security Rule: The Security Standards for the Protection of Electronic Protected Health Information establish a national set of security standards for protecting certain health information that is held or transferred in electronic form. The Security Rule operationalizes the protections contained in the Privacy Rule by addressing the technical and non-technical safeguards that organizations called "covered entities" must put in place to secure individuals' "electronic protected health information" (e-PHI). Within HHS, the Office for Civil Rights (OCR) has responsibility for enforcing the Privacy and Security Rules with voluntary compliance activities and civil money penalties: https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html

Security standards and best practices resources

NIST 800-53 (U.S.)

NIST 800-53 is published by the U.S. National Institute of Standards and Technology. NIST 800-53 is a publication that recommends security controls for federal information systems and organizations and documents security controls for all federal information systems, except those designed for national security. NIST creates and promotes the standards used by U.S. federal agencies to implement the Federal Information Security Management Act (FISMA) and manage other programs designed to protect information and promote information security. https://nvd.nist.gov/800-53

NIH Security Best Practices for Controlled-Access Data

Example of guidance for controlled-access data that while not containing direct identifiers, are sensitive and must be protected. The resource provides an outline of the NIH's expectations for the management and protection of NIH controlled access data transferred to and maintained by institutions whether in their own institutional data storage systems or in cloud computing systems. The information contained in this document is targeted at two distinct audiences: scientific professionals including institutional signing officials and investigators that will use the data, and information technology professionals, including Chief Information Officers (CIOs), Information Systems Security Officer (ISSOs) and operations staff working for both central IT organizations and embedded within research groups. https://osp.od.nih.gov/wp-content/uploads/NIH_Best_Practices_for_Controlled-Access_Data_Subject_to_the_NIH_GDS_Policy.pdf