SIMPLE DATA/MATERIAL TRANSFER AND USE AGREEMENT ("Agreement")

THIS AGREEMENT effective as of the date of last signature below (the "Effective Date") is between the PROVIDER INSTITUTION and RECIPIENT INSTITUTION who have executed this Agreement as of the Effective Date (collectively, the "Parties", and each individually, a "Party") and who have joined the Memorandum of Understanding effective December 10, 2021 (the "MOU").

Upon execution of Schedule A, the PROVIDER INSTITUTION and RECIPIENT INSTITUTION agree to be bound by the terms and conditions set out in Schedule B.

BACKGROUND

The parties of the MOU include, inter alios, The Governing Council of the University of Toronto, University Health Network, The Hospital for Sick Children, Centre for Addiction and Mental Health, Toronto East Health Network, North York General Hospital, Baycrest Centre for Geriatric Care, Sinai Health Systems, Sunnybrook Research Institute, Unity Health Toronto, Trillium Health Partners, Women's College Hospital, Holland Bloorview Kids Rehabilitation Hospital, and such other institutions from time to time who have indicated their commitment to facilitating the efficient transfer of materials and/or data among researchers across the participating institutions by joining the MOU.

Other institutions are encouraged to join the MOU in order to implement the use of this Agreement within their respective institutions.

This Agreement is intended to facilitate the routine transfer of DATA/MATERIAL to the RECIPIENT for academic research pursuits.

This Agreement will apply to the transfer of materials such as chemicals, compounds, molecules, peptides, reagents, plasmids, cell lines, viral vectors, bacterial strains, antibodies, human-derived material, and animals, as well as data, including human-derived data. This Agreement will also apply to confidential information that is provided in connection with the transfer of materials or data.

This Agreement is **NOT** to be used to transfer DATA /MATERIAL in circumstances where:

- Funding or money is also being transferred between the Parties in connection with the Permitted Purpose, in which case a service agreement, sub-grant or sub-site agreement may be more appropriate;

- the DATA/MATERIAL relates to a collaboration or joint research initiative between the PROVIDER and RECIPIENT (e.g., the PROVIDER is involved in the Permitted Purpose for which the RECIPIENT will use the DATA/MATERIAL), in which case a collaboration agreement or sub-site agreement may be more appropriate.

- the DATA/MATERIAL is to be used by the RECIPIENT for COMMERCIAL PURPOSES, in which case a license agreement may be more appropriate;

- Large or bulk quantities of DATA/MATERIAL (e.g., data/materials from more than 100 patients) are to be transferred in which case a more comprehensive agreement would more appropriate).

The PROVIDER SCIENTIST and RECIPIENT SCIENTIST must complete the RESEARCHER DECLARATION attached hereto as Schedule A in order to initiate the expedited review of this Agreement within their respective institutions. The PROVIDER SCIENTIST and RECIPIENT SCIENTIST must also acknowledge and agree to abide by the terms and conditions set forth in Schedule B.

SCHEDULE A – RESEARCHER DECLARATION

We, the PROVIDER SCIENTIST and RECIPIENT SCIENTIST, intend to exchange DATA/MATERIAL, and/or confidential information for academic and research purposes only.

1. **Description of DATA/MATERIAL being provided**

DESCRIPTION OF DATA/MATERIAL:

_____

2. **Permitted Purpose(s)**

RECIPIENT WILL USE THE DATA/MATERIAL FOR THE PURPOSES OF:

_____

3. **Research Ethics Board Approvals:**

- To be completed by the **PROVIDER SCIENTIST**. The PROVIDER SCIENTIST declares:
    - If the collection of the DATA/MATERIAL required REB approval from the PROVIDER's REB, the following is the relevant PROVIDER REB#**:**

      PROVIDER REB#: _____

      and the transfer of the DATA/MATERIAL for use for the Permitted Purpose(s) is consistent with the PROVIDER's REB approval.

- To be completed by the **RECIPIENT SCIENTIST**. THE RECIPIENT SCIENTIST declares:
    - The research study in which the DATA/MATERIAL will be used has REB approval from the RECIPIENT's REB. The following is the relevant REB # of the RECIPIENT:
    - RECIPIENT REB#: _____

- The RECIPIENT REB protocol is either ☐ approved and valid as of the date of the RECIPIENT SCIENTIST signature or ☐ will be approved and valid as of the date of use by RECIPIENT of the DATA/MATERIAL

- The Permitted Purpose is consistent with the RECIPIENT's REB approved protocol.

4. <u>RESEARCHER DECLARATION:</u>

By checking the following boxes, each of the **PROVIDER SCIENTIST** and **RECIPIENT SCIENTIST** agree:

	PROVIDER SCIENTIST	**RECIPIENT SCIENTIST**
• I am the Principal Investigator at my institution of the research from which the DATA/MATERIAL was collected.	☐	
• I am the Principal Investigator at my institution of the research study for which the DATA/MATERIAL will be used.		☐
• Funding or money is not being transferred between the PROVIDER INSTITUTION and RECIPIENT INSTITUTION in connection with the Permitted Purpose.	☐	☐
• The PROVIDER SCIENTIST is not collaborating or involved in a joint research initiative relating to the transfer of the DATA/MATERIAL with the RECIPIENT SCIENTIST.	☐	☐
• The DATA/MATERIAL will not be used by the RECIPIENT for a COMMERCIAL PURPOSE.		☐

• Large or bulk quantities of DATA/MATERIAL (e.g., data/materials from more than 100 patients) are not being transferred.	☐	☐
• The PROVIDER INSTITUTION retains ownership of the DATA/MATERIAL	☐	☐
• The RECIPIENT INSTITUTION will own all de-identified, analyzed data, and results derived from its the use of the DATA/MATERIAL for the Permitted Purpose.	☐	☐
• Ownership of Inventions shall follow inventorship as determined in accordance with Canadian patent law.	☐	☐
• The RECIPIENT will acknowledge the PROVIDER as the source of the DATA/MATERIAL in all resulting publications reporting use of DATA/MATERIAL.		☐

Researchers are encouraged to contact their contract services group/in-house legal counsel if any of these items are not able to be acknowledged, as a different agreement may be needed, i.e., collaboration, service, license, sub-out, etc.

5. ACKNOWLEDGEMENTS:

READ AND ACKNOWLEDGED BY PROVIDER SCIENTIST:

_____
(signature)

Name: _____

Title: _____

Date: _____

READ AND ACKNOWLEDGED BY RECIPIENT SCIENTIST:

_____
(signature)

Name: _____

Title: _____

Date: _____

6. SIGNATURES BY THE PARTIES:

PROVIDER INSTITUTION:

_____
(signature)

Name: _____

Title: _____

Date: _____

RECIPIENT INSTITUTION:

_____
(signature)

Name: _____

Title: _____

Date: _____

SCHEDULE B – TERMS & CONDITIONS

The PROVIDER INSTITUTION and RECIPIENT INSTITUTION hereby agree as follows:

A. DEFINITIONS

"**COMMERCIAL PURPOSE**" means: (i) the sale, lease, licence, or other transfer of any DATA, MATERIAL or MODIFICATIONS to a for-profit organization; (ii) use of DATA/MATERIAL by any organization or person, including RECIPIENT, to perform contract research, to screen compound libraries, or to produce or manufacture products for general sale; (iii) to conduct research activities that result in any sale, lease, licence, or transfer of DATA/MATERIAL OR MODIFICATIONS to a for-profit organization; or (iv) any activity which commercially exploits the DATA/MATERIAL or MODIFICATIONS. For clarity, industry sponsored academic research will not be considered a COMMERCIAL PURPOSE, unless it also constitutes (i), (ii), (iii) or (iv) above, in which case it will constitute a COMMERCIAL PURPOSE.

"**CONFIDENTIAL INFORMATION**" means: information (other than DATA/MATERIAL which are governed by other terms herein), including without limitation, any Inventions, that one Party ("Disclosing Party") provides to the other Party ("Receiving Party") in connection with a transfer of DATA/MATERIAL and that is marked in writing as "confidential" at the time of disclosure; or, if not so marked, or if provided verbally, which a reasonable person would consider to be of a confidential nature given the subject matter of the information and the circumstances of its disclosure; provided that CONFIDENTIAL INFORMATION does not include any information that Receiving Party can substantiate based on cogent and reliable evidence:

(a) was already known to the Receiving Party prior to receipt from the Disclosing Party;

(b) was or is disclosed to the Receiving Party by a third party who, to the best of the Receiving Party's knowledge, had a right to make such disclosure without any obligation of confidentiality to the Disclosing Party;

(c) is at the time of disclosure, or becomes, part of the public domain other than as a consequence of a breach by Receiving Party of its obligations herein; or

(d) was or is independently developed by Receiving Party without use of CONFIDENTIAL INFORMATION.

"**DATA**" means: the data described in a specific RESEARCHER DECLARATION that is being transferred to the RECIPIENT.

"**DATA/MATERIAL**" means: collectively, any and all DATA or MATERIAL transferred to the RECIPIENT hereunder.

"**GENETIC SEQUENCING DATA"** means: data that is whole genome sequencing data or methylation sequencing data that is either transferred from the PROVIDER to the RECIPIENT or generated by the RECIPIENT in using MATERIAL.

"**HUMAN-DERIVED DATA**" means: data or information which has been collected from an individual, or about an individual. If **PROVIDER** has internally received the appropriate institutional approvals, such as from the REB, to determine that a dataset has had all direct identifiers removed, and has furthermore been sufficiently de-identified so that it is no longer considered to contain personal health information, then such dataset does not constitute HUMAN-DERIVED DATA. Notwithstanding the foregoing, for the purposes of this Agreement, all GENETIC SEQUENCING DATA is deemed to be HUMAN-DERIVED DATA.

"**HUMAN-DERIVED MATERIAL**" means: human-derived biological material.

"**INVENTION**" means: any invention or improvement arising out of the use of the MATERIAL.

"**MATERIAL**" means: collectively, the ORIGINAL MATERIAL, PROGENY and UNMODIFIED DERIVATIVES; MATERIAL does not include (i) MODIFICATIONS, or (ii) other substances created by the RECIPIENT through the use of the MATERIAL that are not MODIFICATIONS, PROGENY OR UNMODIFIED DERIVATIVES.

"**MODIFICATIONS**" means: substances created by the RECIPIENT that contain/incorporate the MATERIAL.

"**ORIGINAL MATERIAL**" means: the material described in a specific RESEARCHER DECLARATION that is being transferred to the RECIPIENT.

"**PERMITTED PURPOSE(S)"** means: those purpose(s) as outlined in the RESEARCHER DECLARATION.

"**PROGENY**" means: unmodified descendant(s) from the MATERIAL. For example, virus from virus, cell from cell, cells from tissue, cells from a xenotransplant, organism from organism, etc.

"**PROVIDER**" means: collectively, the PROVIDER INSTITUTION and PROVIDER SCIENTIST.

"**PROVIDER INSTITUTION**" means: the Party named in a specific RESEARCHER DECLARATION that transfers DATA/MATERIAL under this Agreement and who is a party to the MOU.

"**PROVIDER SCIENTIST**" means: the researcher at PROVIDER INSTITUTION named in a specific RESEARCHER DECLARATION who transfers DATA/MATERIAL under this Agreement.

"**RECIPIENT**" means: collectively, the RECIPIENT INSTITUTION and RECIPIENT SCIENTIST.

"**RECIPIENT INSTITUTION**" means: the Party named in a specific RESEARCHER DECLARATION that receives DATA/MATERIAL under this Agreement and who is a party to the MOU.

"**RECIPIENT SCIENTIST**" means: the researcher at the RECIPIENT INSTITUTION named in a specific RESEARCHER DECLARATION who receives DATA/MATERIAL under this Agreement.

"**RESEARCHER DECLARATION**" means: an implementing agreement entered into between a RECIPIENT and PROVIDER in the form provided in Schedule A.

"**UNMODIFIED DERIVATIVES**" means: substances created by the RECIPIENT that constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. For example, subclones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA, monoclonal antibodies secreted by a hybridoma cell line, etc.

B. GENERAL TERMS

1. Prior to transferring DATA/MATERIAL under this Agreement:

    a) the PROVIDER SCIENTIST and the RECIPIENT SCIENTIST must complete and sign the RESEARCHER DECLARATION in Schedule A; and
    b) an authorized signing authority of the PROVIDER INSTITUTION and the RECIPIENT INSTITUTION must execute Schedule A.

2. The DATA/MATERIAL shall remain the property of the PROVIDER INSTITUTION, including any MATERIAL contained or incorporated in MODIFICATIONS.

3. The RECIPIENT agrees to acknowledge the source of the DATA/MATERIAL in any publications reporting use of DATA/MATERIAL. The RECIPIENT will not publish any data or results in a form that could reasonably enable a person to ascertain the identity of the individual who is the subject of the DATA/MATERIAL.

4. The RECIPIENT agrees that DATA/MATERIAL will only be used for the PERMITTED PURPOSE(S) at the RECIPIENT INSTITUTION by RECIPIENT employees or personnel under the direction of the RECIPIENT SCIENTIST and it will not be shared with any other persons within the RECIPIENT INSTITUTION or with any third party without the express written consent of the PROVIDER INSTITUTION.

5. The RECIPIENT shall not use the DATA/MATERIAL for any COMMERCIAL PURPOSE.

6. The RECIPIENT shall promptly disclose in writing to the PROVIDER any Inventions required to be disclosed by RECIPIENT SCIENTIST to the RECIPIENT INSTITUTION pursuant to the RECIPIENT INSTITUTION'S institutional intellectual property policy; and hereby grants to the PROVIDER a non-exclusive, non-transferrable, royalty-free license to use Inventions for internal non-commercial academic research purposes, subject to any third party rights or obligations owed to third parties that would prevent, restrict or limit such license back to PROVIDER.

7. Ownership of Inventions shall follow inventorship as determined in accordance with Canadian patent law. The RECIPIENT shall promptly notify the PROVIDER upon filing any patent for any Inventions arising out of the use of the DATA/MATERIAL.

8. The MATERIAL may be experimental in nature and may have hazardous properties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PROVIDER MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT OF PROPRIETARY RIGHTS. THE MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS UNDER ANY CIRCUMSTANCES, INCLUDING CLINICAL TRIALS AND DIAGNOSTIC TESTING PURPOSES.

9. The PROVIDER will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the transfer, handling, storage, use or disposal of the DATA/MATERIAL by the RECIPIENT. The RECIPIENT assumes all liability for damages which may arise from the RECIPIENT's use, handling, storage and/or disposal of the DATA/MATERIAL and in respect of all matters associated with any data or results derived from the RECIPIENT's use of the DATA/MATERIAL, except to the extent caused by gross negligence or willful misconduct of, or breach of this Agreement by, the PROVIDER. The PROVIDER INSTITUTION will be liable for all breaches of this Agreement by its PROVIDER SCIENTIST. The RECIPIENT INSTITUTION will be liable for all breaches of this Agreement by its RECIPIENT SCIENTIST.

10. Upon the written request of the PROVIDER, the RECIPIENT shall cease to use the DATA/MATERIAL and upon direction of the PROVIDER shall return or destroy any remaining DATA/MATERIAL.

C. CONFIDENTIAL INFORMATION

If the DATA/MATERIAL is accompanied by CONFIDENTIAL INFORMATION, then the following supplemental terms apply:

1. The Parties may disclose CONFIDENTIAL INFORMATION to one another from time to time to facilitate the use of the DATA/MATERIAL. The Receiving Party shall only use the CONFIDENTIAL INFORMATION as reasonably required to fulfill the purpose of the overarching transfer set out in the RESEARCHER DECLARATION. The Receiving Party shall safeguard the CONFIDENTIAL INFORMATION using the same efforts it uses to protect its own confidential information, and in any case, no less than reasonable care and not disclose it to any third party. The obligations of confidentiality and non-disclosure set out in this Agreement with respect to CONFIDENTIAL INFORMATION will continue for five (5) years beyond the Effective Date. The Receiving Party shall immediately notify Disclosing Party upon discovering any unauthorized use or disclosure of CONFIDENTIAL INFORMATION.

2. Notwithstanding any other provision herein, the Receiving Party will be permitted to disclose CONFIDENTIAL INFORMATION as required to comply with a legal requirement to

disclose, including a judicial or governmental order, provided that the Receiving Party must (i) minimize the scope of disclosure to that which is required by such legal requirement to disclose; (ii) provide the Disclosing Party prompt notice of becoming aware of the legal requirement to disclose, except where the legal requirement itself does not permit such notice.

3. At Disclosing Party's request, the Receiving Party shall deliver all files, documents and other materials (and all versions, copies and reproductions of any of the foregoing whether on paper, hard drive, disk, tape and/or other media) in the Receiving Party's possession or control which contain or pertain to CONFIDENTIAL INFORMATION, provided that Receiving Party may retain one (1) archival copy of such files, documents and other materials in a secure location.

D. HUMAN-DERIVED DATA/MATERIAL

If the DATA/MATERIAL being transferred pursuant to a RESEARCHER DECLARATION constitutes HUMAN-DERIVED MATERIAL or HUMAN-DERIVED DATA, then the following supplemental terms apply:

1. In effecting the transfer, the PROVIDER and RECIPIENT shall each comply with section 44 of Ontario's *Personal Health Information Protection Act* (PHIPA), and regulations made pursuant thereto, as applicable.

2. The PROVIDER specifically warrants that the transfer of DATA/MATERIAL for use in the Permitted Purpose(s) are permitted under (i) the REB approved subject informed consent form provided by each of the individuals from whom the DATA/MATERIAL was collected ("ICF") or (ii) an REB-approved waiver of consent (i.e., a research ethics board has reviewed the proposed transfer and approved an alteration to the requirements for consent under the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) ("REB Waiver"). (Such ICF or REB Waiver, as applicable, is incorporated by reference into the applicable RESEARCHER DECLARATION).

3. The RECIPIENT specifically warrants that: (a) the RECIPIENT will not use the DATA/MATERIAL until the RECIPIENT obtains written confirmation from the PROVIDER (in the form of the ICF, REB Waiver or other written confirmation) defining the scope of consented uses of the DATA/MATERIAL ("Approved Scope"); and (b) The RECIPIENT shall only use DATA/MATERIAL in accordance with the Approved Scope and the RECIPIENT's REB approved protocol detailing the Permitted Purpose(s) as set out in the RESEARCHER DECLARATION.

4. The RECIPIENT shall have the right to use the analyzed, de-identified data and results (which for clarity does not include GENETIC SEQUENCING DATA which is dealt with below) derived from its use of the DATA/MATERIAL as part of a publication or presentation arising from the Permitted Purpose, and shall own such de-identified, analyzed data and results. The RECIPIENT shall not include any personally identifying information in any publication or

presentation. The PROVIDER's contribution of DATA/MATERIAL shall be acknowledged appropriately in any such publication or presentation in accordance with academic standards.

5. The PROVIDER shall retain ownership/control rights over the GENETIC SEQUENCING DATA to ensure protection of such GENETIC SEQUENCING DATA for privacy purposes, and the RECIPIENT shall only use such GENETIC SEQUENCING DATA for the Permitted Purpose(s) at the RECIPIENT INSTITUTION by the RECIPIENT employees or personnel under the direction of the RECIPIENT SCIENTIST and it will not be shared with any other persons within the RECIPIENT INSTITUTION or with any third party without the express written consent of the PROVIDER INSTITUTION. The RECIPIENT shall not use the GENETIC SEQUENCING DATA for any COMMERCIAL PURPOSE.

6. In the event that the RECIPIENT is requested to make GENETIC SEQUENCING DATA or other genomic data available through use of a restricted- or controlled-access database for publication purposes, the RECIPIENT agrees to refer to the PROVIDER any such request and the PROVIDER (including the PROVIDER REB) and RECIPIENT agree to work in good faith to make such GENETIC SEQUENCING DATA and other genomic data available to other academic researchers for research uses consistent with the ICF through use of a restricted- or controlled-access database acceptable to the publisher, to the extent required for purposes of supporting any publication.

7. The RECIPIENT shall use appropriate safeguards to prevent any unauthorized use or disclosure of the DATA/MATERIAL and GENETIC SEQUENCING DATA and shall promptly (and in any event within 48 hours) report to the PROVIDER any unauthorized use or disclosure of DATA/MATERIAL and GENETIC SEQUENCING DATA of which the RECIPIENT becomes aware. The RECIPIENT shall not use the DATA/MATERIAL or GENETIC SEQUENCING DATA to identify or directly or indirectly attempt to make contact with the individuals from whom such DATA/MATERIAL was collected or GENETIC SEQUENCING DATA was generated. The PROVIDER may conduct reasonable audits of the RECIPIENT concerning the maintenance of appropriate security safeguards to ensure compliance with this Agreement.

8. The PROVIDER shall be entitled to have RECIPIENT return or destroy DATA/MATERIAL or GENETIC SEQUENCING DATA in the RECIPIENT'S possession upon completion of the Permitted Purpose or if earlier terminated as outlined herein.

E. ANIMAL MATERIAL

If the MATERIAL consists of animals or animal material, then the following supplemental terms apply:

All animal biological materials have the potential for carrying viruses, latent viral genomes and other infectious agents in an unapparent state. The MATERIAL must always be handled carefully by trained persons who follow all safety guidelines recommended when working with animals under laboratory conditions, which afford adequate biohazard containment.

F. GENERAL

i. **Amendments**. This Agreement may only be amended by mutual written agreement of the Parties.

ii. **Governing Law and Attornment**. This Agreement shall be governed by and construed under the laws of the Province of Ontario and the laws of Canada applicable therein. The Parties attorn to the exclusive jurisdiction of the courts of the Province of Ontario.

iii. **Waivers**. No waiver of any breach of any provision of this Agreement will be effective or binding unless made in writing and signed by the party purporting to give the same and, unless otherwise provided, will be limited to the specific breach waived.

iv. **Assignment**. Neither Party may assign this Agreement or any of its rights or obligations hereunder without the prior written consent of the other Party.

v. **Entire Agreement**. This Agreement, including its schedules, constitutes the entire agreement between the Parties with respect to the subject matter hereof and thereof and cancels and supersedes any prior understandings and agreements, written or oral, among the Parties with respect thereto.

vi. **Independent Contractors**. The Parties are independent contractors. Nothing contained in this Agreement will be deemed to create any partnership, joint venture, agency or employment relationship between the Parties or to provide either Party with the right, power or authority, whether express or implied, to create any duty or obligation on behalf of the other Party.

vii. **Enurement**. This Agreement enures to the benefit of and is binding upon the respective successors and permitted assigns of the Parties.

viii. **Counterparts and Electronic Execution**. This Agreement may be executed in counterparts, each of which will be deemed to be an original and which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page to this Agreement by either Party by electronic transmission will be as effective as delivery of a manually executed copy of this Agreement by such Party.