Material Transfer Agreement ("MTA")
Instructions for
HUMAN TISSUE TRANSFER PURSUANT TO A RESEARCH STUDY

Examples of Human Tissue Material:
Human bodily fluids (i.e. blood, saliva, urine, etc.), biopsy samples (i.e. tumour samples), etc.

DO NOT TRANSFER MATERIALS UNTIL:
(a) The REB has approved the Protocol (which must clearly indicate the intent to distribute the materials to non-Regional Health Authority A parties and include a description of the research work activities to be performed with the materials by any non-Regional Health Authority A Recipient Scientist); **and**
(b) The MTA has been signed by Regional Health Authority A and the Recipient Institution/Recipient Scientist.

Document completion process:

NOTE: REB approval must be obtained prior to any MTA being signed and issued by Regional Health Authority A.

1) Please complete the fields indicated by **bold instructions** in the agreement that follows:
   - Date;
   - "Recipient Institution" name, jurisdiction and address;
   - Recipient Scientist name;
   - Particulars of "Permitted Use" for the material;
   - Description of "Primary Material" to be transferred;
   - Particulars of "REB Approval Information";
   - Regional Health Authority A "Transferring Scientist(s)" or "Transferring Physician(s)" name(s);
   - Authorized official name and title;
   - Recipient Scientist details.

2) Once reviewed and (2) originals are signed by the Recipient Institution and the Recipient Scientist, both originals should be sent to the Research Centre for final Regional Health Authority A signatures:

   Research Centre
   Vitalité Health Network
   330 Université Avenue
   Moncton, New Brunswick E1C 2Z3 Canada
   T: 506-862-3762 F: 506-862-4373
   E: recherche.research@vitalitenb.ca

3) One original of the fully signed MTA will be returned to the Recipient Institution while the second original will be retained by the Research Centre for its records. A copy of the fully executed MTA will be e-mailed to the Regional Health Authority A Transferring Scientist or Transferring Physician, at which time he or she can release the Material.

MATERIAL TRANSFER AGREEMENT
(For human tissue; pursuant to a Research Study)

This Material Transfer Agreement ("**Agreement**") for human tissue pursuant to a Research Study is made as of the day of **Insert Month Insert Year** ("**Effective Date**") by and between the following Parties:

Regional Health Authority A
A New Brunswick corporation incorporated under the *Regional Health Authorities Act, SNB 1997*, *c R-5.05,* operating under the name "Vitalité Health Network" and having a principal office at 275 Main Street, Bathurst, New Brunswick E2A 1A9 Canada
("**Region A**")

AND
Insert Institution Name
Insert Institution Jurisdiction
Insert Institution Principal Address
("**Recipient Institution**")

AND
Insert Scientist Name
("**Recipient Scientist**")

(As used in this Agreement, "**Recipient**" shall mean both Recipient Scientist and Recipient Institution collectively.)

WHEREAS the Recipient desires to obtain Material from Region A for the Permitted Use pursuant to a Research Ethics Board ("**REB**") approved Research Study and Region A is willing to allow the transfer of such Material to the Recipient in accordance with the terms and conditions of this Agreement;

IN CONSIDERATION of the mutual covenants made in this Agreement and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. **DEFINITIONS.** For the purposes of this Agreement, the following terms shall have the respective meanings set out below and grammatical variations of such terms shall have corresponding meanings:
   a) "**Generated Data**" means all data, information and any other matter or deliverable arising from the performance of the Permitted Use by the Recipient;
   b) "**Material**" means Primary Material, Progeny, Unmodified Derivatives and Modification(s), *and further includes* any accompanying or related know-how, data or information, including personal health information, that is transferred by Region A to the Recipient;
   c) "**Modification(s)**" means substances created by the Recipient that contain or otherwise incorporate Primary Material, Progeny or Unmodified Derivative(s);
   d) "**Permitted Use**" means **"Insert a description of the REB approved Permitted Uses for the Material"**;
   e) "**Primary Material**" means **"Insert description of human tissue or bodily fluid to be transferred"**;
   f) "**Progeny**" means 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;
   g) "**REB Approval Information**" means **"Insert protocol/study title, number, approval date and expiration date under which materials have been obtained and authorizing "Permitted Uses" and transfer to the Recipient"**;
   h) "**Transferring Scientist(s)**" or "**Transferring Physician(s)**"means **Insert Name(s)**; and

i) "**Unmodified Derivative(s)**" means any substance constituting an unmodified functional or structural subunit or product expressed by, or derived from, the Primary Material or Progeny.

2. **PERMITTED USE.** The Recipient agrees to use the Material solely for the Permitted Use pursuant to the clinical trial identified in the REB Approval Information definition above and in accordance with all terms and conditions contained in this Agreement. All other uses of the Material are strictly prohibited. **UNLESS FOR AN OTHERWISE EXPLICIT "PERMITTED USE," THE MATERIAL MAY NOT BE USED IN HUMANS, INCLUDING FOR PURPOSES OF DIAGNOSIS OR ANY OTHER TESTING.**

3. **LEGAL TITLE TO MATERIAL, GENERATED DATA, MODIFICATIONS AND INTELLECTUAL PROPERTY.** Legal title to the Material and in any Generated Data and Modifications shall be unaffected by this Agreement or the transfer of any Material hereunder. As between Region A and the Recipient, Region A shall be the entrusted custodian of all rights and title to the Material (sole ownership of which always belongs to the donors of the human tissues). Generated Data and in any intellectual property (i) specifically and directly arising from the Permitted Use, or (ii) arising from any other non-permitted use of the Material will be negotiated in good faith by the parties hereto depending upon their relative contribution to the creation of said Generated Data and Modifications, and any applicable laws relating to inventorship. The Recipient shall promptly inform Region A of the creation of any intellectual property arising from the Permitted Use or otherwise from any other use of the Material, and shall acknowledge and/or share its rights in and to any such intellectual property with Region A.

4. **NON-EXCLUSIVE LICENCE.** The transfer of the Material constitutes a non-exclusive licence to use the Material (and, as appropriate, the Generated Data) solely for the Permitted Use. The transfer of the Material does not grant to the Recipient any additional rights to the Material or the Generated Data other than as specifically set forth in this Agreement.

5. **RETURN OF MATERIAL AND GENERATED DATA.** Upon the expiration or the earlier termination of this Agreement, the Recipient shall destroy or return to Region A (at Region A's direction) all unused Material and shall forward to Region A all Generated Data.

6. **REPRESENTATIONS AND WARRANTIES.** The Recipient covenants that it will use the Material and the Generated Data in compliance with all applicable laws, governmental regulations and guidelines, including, without limitation, any laws, regulations or guidelines applicable to research with human materials or recombinant DNA and any applicable Canadian Institute of Health Research or National Institute of Health guidelines. In respect of the protection of personal information or personal health information, the Recipient covenants that it will comply with any and all applicable laws and regulations in force as of the date of this Agreement or that come into force during the term of this Agreement concerning the protection of Personal Information and Personal Health Information and/or conferring privacy rights on individuals ("**Privacy Laws**"). As such, the Recipient shall not collect, use or disclose any confidential personal information or personal health information for any purpose other than as required for the Permitted Use and in compliance with the provisions of this Agreement.

7. **DISCLAIMER. ANY MATERIAL DELIVERED PURSUANT TO THIS AGREEMENT IS UNDERSTOOD TO BE EXPERIMENTAL IN NATURE AND IS PROVIDED "AS IS." THE RECIPIENT UNDERSTANDS AND ACKNOWLEDGES THAT THE MATERIAL MAY CONTAIN ONE OR MORE INFECTIOUS AGENTS AND MAY HAVE ADDITIONAL UNKNOWN AND HAZARDOUS PROPERTIES. THE RECIPIENT SHALL USE THE MATERIAL WITH PRUDENCE AND APPROPRIATE CAUTION AND SAFEGUARDS SINCE NOT ALL OF ITS CHARACTERISTICS ARE KNOWN. REGION A MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OR CONDITIONS OF ANY KIND, EITHER EXPRESSED OR IMPLIED, WHATSOEVER IN RESPECT OF THE MATERIAL. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OR CONDITIONS OF MERCHANTABILITY, SAFETY, EFFICIENCY, POTENCY, IDENTITY, COMPOSITION, PURITY AND ACTIVITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE MATERIAL, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.**

8. REPORTS, DISCLOSURE AND CONFIDENTIAL INFORMATION.

8.1 Reports. The Recipient agrees to furnish Region A with a report encompassing the Generated Data arising from the use of the Material at the conclusion of the performance of the Permitted Use, or as otherwise agreed to by the parties. A copy of any publication containing the Generated Data shall be provided to Region A for review and comment prior to submission for publication or other proposed public disclosure. The Recipient shall acknowledge Region A as the source of the Material in any publication or disclosure of Generated Data. Notwithstanding the above, there shall be no publication or disclosure of the Generated Data without the prior written consent of Region A.

8.2 Disclosure. Neither the Recipient, nor any other person authorized to use the Material and Generated Data under this Agreement, shall make available or disclose any portion of the Material and Generated Data to any person or entity other than laboratory personnel or contractors under the immediate and direct control of the Recipient Scientist. No person authorized to use the Material and Generated Data shall be allowed to take, send, provide and/or otherwise disclose the Material and/or Generated Data to any location other than the Recipient Scientist's laboratory without Region A's prior written consent.

9. PERSONAL HEALTH INFORMATION.

9.1 Privacy. For the purposes of this Agreement, Personal Health Information (PHI) is defined as identifying information about an individual in oral or recorded form if the information (a) relates to the individual's physical or mental health, family history, or health care history, including genetic information about the individual, (b) is the individual's registration information, including the Medicare number of the individual, (c) relates to the provision of health care to the individual, (d) relates to information about payments or eligibility for health care in respect of the individual, or eligibility for coverage for health care in respect of the individual, (e) relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any body part or bodily substance, (f) identifies the individual's substitute decision-maker, or (g) identifies the individual's health care provider. The Recipient shall limit access to PHI to only its internal personnel or agents who need access for the purposes authorized herein and who are bound by the same confidentiality obligations contained herein.

9.2 Non-Disclosure. The Recipient agrees that it shall:

(a) Maintain PHI in confidence and not disclose PHI except as permitted by this Agreement;

(b) Use PHI solely for the purposes of the Permitted Use and in compliance with:

(i) The study protocol as approved by Region A's REB and as amended from time-to-time provided that the amendments are approved by Region A's REB;

(ii) Any written conditions imposed by Region A's REB or the Recipient's REB;

(iii) The study subject's consent consistent with the informed consent form approved by Region A's REB or, if the requirement to obtain consent has been waived by Region A's REB, the waiver of consent given by Region A's REB; and

(iv) Any other conditions or restrictions imposed by Region A relating to the use, security, return or disposal of PHI as set out in this Agreement.

(c) Not disclose any PHI except as required by law, judicial process, court or regulatory order, provided that the Recipient gives prior written notice of such intended disclosure to Region A and takes all reasonable and lawful actions to obtain confidential treatment for such disclosure and, if possible, to minimize the extent of such disclosure; and

(d) Not contact or attempt to make contact with the individual directly or indirectly, unless Region A first obtains the individual's consent to being contacted (except to the extent that the Recipient is otherwise the individual's health information custodian).

9.3 Safeguards and Destruction. The Recipient shall use appropriate safeguards (including, without limitation, with respect to encrypting identifying numbers, linking files, storing and retrieving files from secured locations)

to prevent unauthorized use or disclosure of PHI. The Recipient shall notify Region A in writing immediately if it becomes aware of any unauthorized use or disclosure or other breach of this Agreement with respect to PHI. The Recipient shall securely destroy the PHI as required by the study protocol and provide a written confirmation of the manner of destruction in a form acceptable to Region A, unless otherwise specified by Region A.

9.4 Publication. The Recipient shall have the right to use (a) the analyzed, de-identified data derived from the use of the PHI; and (b) information and results arising out of analysis of the PHI, as part of a publication or presentation of the results of the study. The Recipient shall not include any PHI or personally identifying information in any publication or presentation, nor publish or present information in a form that could reasonably enable a person to ascertain the identity of an individual.

10. WAIVER AND INDEMNIFICATION. TO THE FULL EXTENT PERMITTED BY THE LAWS OF THE PROVINCE OR STATE AND COUNTRY BY WHICH THE RECIPIENT IS GOVERNED, THE RECIPIENT ASSUMES ALL LIABILITY FOR DAMAGES THAT MAY ARISE FROM THE RECIPIENT'S ACCEPTANCE, USE, HANDLING, STORAGE AND/OR DISPOSAL OF THE MATERIAL. REGION A WILL NOT BE LIABLE TO THE RECIPIENT FOR ANY LOSS, CLAIM OR DEMAND MADE BY THE RECIPIENT OR ANY OTHER PARTY, OR MADE AGAINST THE RECIPIENT BY ANY OTHER PARTY, DUE TO OR ARISING FROM ANY ACCEPTANCE, USE, HANDLING, STORAGE AND/OR DISPOSAL OF THE MATERIAL BY THE RECIPIENT, EXCEPT TO THE EXTENT PERMITTED BY LAW WHEN CAUSED BY THE GROSS NEGLIGENCE OR WILFUL MISCONDUCT OF REGION A. THE RECIPIENT INSTITUTION AGREES TO INDEMNIFY, DEFEND AND HOLD HARMLESS REGION A AND CORPORATE AFFILIATES OF REGION A AND THEIR RESPECTIVE BOARDS OF GOVERNORS, TRUSTEES, DIRECTORS, OFFICERS, EMPLOYEES, STAFF, REPRESENTATIVES AND AGENTS AGAINST ALL LIABILITY, DAMAGES, EXPENSES (INCLUDING WITHOUT LIMITATION LEGAL EXPENSES), CLAIMS, DEMANDS, JUDGMENTS, AWARDS OR OTHER LOSSES BASED UPON OR ARISING FROM THE RECIPIENT'S ACCEPTANCE, USE, HANDLING, STORAGE AND/OR DISPOSAL OF THE MATERIAL.

11. TERM AND TERMINATION. This Agreement shall expire at the conclusion of the performance of the activities conducted pursuant to the Permitted Use. This Agreement may be terminated earlier by either party upon fourteen (14) days' notice to the other party. Upon the expiration or earlier termination of this Agreement, the Recipient's rights to use the Material shall end.

12. GENERAL.

11.1 This Agreement shall be construed in accordance with the laws of the Province of New Brunswick and the federal laws of Canada applicable therein, and each party consents to the non-exclusive jurisdiction of the courts of the Province of New Brunswick and all courts competent to hear appeals therefrom.

11.2 This Agreement is not alterable or assignable without the prior written consent of Region A.

11.3 Sections 1 through 11 in their entirety shall survive termination of the Agreement until such time as the parties agree to the release of the obligations contained therein.

11.4 This Agreement represents the entire agreement between the parties with regard to the Material and supersedes any previous understandings, commitments or agreements, whether written or oral. If any provision of this Agreement is wholly or partially unenforceable for any reason, all other provisions will continue in full force and effect.

11.5 All notices given under this Agreement must be in writing and delivered by courier or registered mail, return receipt requested, or facsimile, to the following:

For Region A:

Research Centre
Vitalité Health Network
330 Université Avenue
Moncton, New Brunswick E1C 2Z3 Canada

T: 506-862-3762 F: 506-862-4373

For Recipient:

Insert Recipient Notification Information

IN WITNESS WHEREOF, the parties or the duly authorized officers of the parties have executed this Agreement

REGIONAL HEALTH AUTHORITY A	**RECIPIENT INSTITUTION**
Authorized Official: **Gilles Beaulieu**	Authorized Official: **Insert Authorized Official Name**
Title: **Vice-President, Academic Affairs, Research, Communication and Engagement**	Title: **Insert Authorized Official Title**
Signature:_____	Signature: _____
Date:_____	Date:_____

ACKNOWLEDGMENT
I have read and understood this Agreement and agree to be bound by the terms and conditions herein.

RECIPIENT SCIENTIST

Name: **Insert Recipient Scientist Name**

Title: **Insert Recipient Scientist Title**

Signature: _____

Date: _____

Telephone:

Fax:

E-mail:

Shipping Address:

Courier Company & Account #: