**[Delete this introductory page before execution] :**

**This is a template Participating Site Agreement (the “Template”) developed by 50+ research sites across Canada that includes standard terms and conditions applicable to research partnerships between two or more academic health institutions. The intention of the institutions involved in developing this template was to have standard language that is still flexible enough to meet each sites’ needs. You can see these changes through the Template in blue along with instructions of what to consider and recommended ways to communicate with negotiators at the other sites.**

**It is possible to make additional revisions to the Template as the Parties deem necessary. Further changes to the draft should be noted either via track changes or via side comments, and the reviewer suggesting revisions is encouraged to provide an explanation via an embedded comment. As discussed during the consultation process preceding approval of the Template, these additional changes should, ideally, be limited to study or site-specific items (e.g. requirements from the funder, identification of third parties receiving data/personal health information, data ownership information about study drugs, responsibility re-assigned due to the involvement of a third party).**

**Notwithstanding the foregoing, the negotiating parties are free to adapt this agreement as required to meet their needs with the shared goal of having an appropriate agreement negotiated in a timely manner.**

**PARTICIPATING SITE AGREEMENT**



This Participating Site Agreement is made and entered into as of the Effective Date (as defined below) by and between:

**[Institution A Name]** (“**Lead Institution**”);

**[NTD: If Principal Investigator is a Party, add below]**

**[PI name** (“**Principal Investigator**”);**]**

and

**[Institution B Name]** (“**Participating Institution”**);

**[NTD: If Site Investigator is a Party, add below]**

**[PI name (“Site Investigator”)**]

Lead Institution, [**Principal Investigator]**, Participating Institution, and **[Site Investigator]** shall hereinafter be individually referred to as a “**Party**” and collectively as the “**Parties**”.



**WHEREAS,** Lead Site has received funding (“**Study Funds**”) from the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“**Funder**”) for the purposes of a study titled “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_” (hereinafter the “**Study**”), as detailed in the protocol attached hereto as Schedule “A”;

**WHEREAS,** the Study is a **[observational/interventional] [Health Canada regulated/unregulated]** study.

**[NTD: If Principal Investigator is not a Party, add: [WHEREAS, the principal investigator at Lead Institution is [insert Principal Investigator] ("Principal Investigator )”;]**

**[NTD: If Site Investigator is not a Party, add: WHEREAS, the principal investigator at Participating Institution is [insert Site Investigator] (“Site Investigator);]**

**[NTD: include additional recitals as needed]**

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

1. **DEFINITIONS**
   1. **“Agreement”** means this Participating Site Agreement including all schedules, attachments and appendices as may be amended from time to time.
   2. **“Applicable Laws”** means all applicable federal and provincial statutes, local laws and regulations, rules and guidelines as well as all generally accepted and established ethical, medical and scientific standards applicable to the conduct of the Study, including without limitations, Health Canada’s *Food and Drugs Act*(R.S.C., 1985, c. F-27) and its associated regulations, the *International Conference on Harmonization (ICH E6: Guidelines for Good Clinical Practice* (the “ICH-GCP“ Guidelines), the Tri-council Policy Statement: Ethical Conduct for Research Involving Humans, the Declaration of Helsinki, and the Privacy Laws as defined in article 1.13.
   3. **“Confidential Information”** means (i) Study-related materials, records and information concerning a Study Product (to the extent applicable); or (ii) any other Study related information that has been gathered or developed pursuant to this Agreement duly identified as confidential, in electronic, written, graphic or other tangible form, and in oral form promptly reduced to writing including any non-health related data that falls outside the definition of Data herein. Notwithstanding the foregoing, a failure to duly identify information as being confidential or a failure to confirm in writing an oral disclosure shall not mean that information would not be covered under the definition of Confidential Information when a reasonable person in the field of clinical research would understand it to be confidential in nature.
   4. **"Data”** means all data collected through the conduct of the Study in accordance with the REB Approval, and specifically excluding original medical records and source documents.
   5. **“Data/Samples”** means Data and/or Samples, as applicable. **[NTD: delete this line if there are no Samples]**
   6. “**Disclosing Party**” means the Party providing Data**[/Samples]** and/or Confidential Information to Receiving Party as outlined herein.
   7. “**Effective Date**” means the date of the last signature on the signature page of this Agreement.
   8. **“Health Canada Regulated Study”** means a Study subject to the *Food and Drugs Act*(R.S.C., 1985, c. F-27) and its associated regulations.
   9. **“ICF”** means the informed consent in a form and content approved by the REB;
   10. **“Intellectual Property”** means all materials, know-how, formulae, inventions, improvements, industrial designs, processes, patterns, machines, manufactures, compositions of matter, compilations of information, patents and patent applications, copyrights, technology, technical information, software, prototypes and specifications, including any rights to apply for protections under statutory proceedings available for those purposes, provided they are capable of protection under Applicable Laws.
   11. **“Lead Site”** means Lead Institution **[NTD add if there are additional parties to the agreement: [together with [Principal Investigator/add additional parties as relevant]**, **however their rights, obligations, and liabilities under this Agreement shall be several and not joint].**
   12. **“Personal Information”** means any identifying information of an individual, which may include personal health information, as defined by the Privacy Laws.
   13. **“Privacy Laws”** means all applicable laws and regulations regarding protection of personal information, including, but not limited to, Canada’s *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5 (“PIPEDA”), and the applicable health privacy laws in each province or territory including but not limited to, *Freedom of Information and Protection of Privacy Act,* R.S.O. 1990, c. F.31 (Ontario), *Personal Health Information Protection Act, 2004*, S.O. 2004, c. 3 (“PHIPA”) (Ontario), the Act respecting Access to documents held by public bodies and the Protection of personal information, RLRQ., c. A-2.1, the *Act Respecting Health Services and Social Services*, CQLR c S-4.2, the *Act respecting the protection of personal information in the private sector* (Quebec), the *Health Information Act*, RSA 2000, c H-5 (“HIA”) (Alberta); Personal Health Information Act (“PHIA”) (Nova Scotia), *The Personal Health Information Act*, C.C.S.M.c. P33.5 (“Manitoba PHIA”) (Manitoba), The Freedom of Information and Protection of Privacy Act (“Manitoba FIPPA”), the *Health Information Protection Act* (Saskatchewan) (“HIPA”); *Freedom of Information and Protection of Privacy Act* (“FIPPA”) (British Columbia); *Personal Health Information Privacy and Access Act*, SNB 2009, c P-7.05 (New Brunswick), *Personal Health Information Act*, SNL 2008, c P-7.01 (Newfoundland and Labrador), and *Health Information Act*, RSPEI 1988, c H-1.41 (Prince Edward Island), and any regulations issued pursuant thereto.
   14. “**Protocol”** means the REB-approved protocol attached at Schedule “A” herein, by reference, which may be amended from time to time.
   15. **“REB”** means Research Ethics Board.
   16. **“REB Approval”** means all aspects of the Study that have been approved by the REB, including but not limited to the ICF and the Protocol.
   17. “**Receiving Party”** means the Party receiving Data**[/Samples]** and/or Confidential Information from Disclosing Party;
   18. **“Representatives”** means any of a Party’s employees, **[NTD to add or adapt if an investigator is not a party: investigators,]** students, volunteers, agents, appointees, trustees, directors, officers, contractors and any other individual involved in the conduct of the Study.
   19. **“Samples”** means biological samples derived from human subjects that are provided by Disclosing Party to Receiving Party for the purpose of carrying out the Study.
   20. **“Site”** means Participating Institution **[NTD add if there are additional parties to the agreement: [together with Site Investigator][add additional parties as relevant], however the Parties acknowledge and agree that their rights, liabilities and obligations under this Agreement shall be several and not joint].**
   21. **“Sponsor”** means the regulatory sponsor of the Study as further definedin the *Food and Drugs Act* (R.S.C., 1985, c. F-27) and its associated regulations.
   22. **“Study”** means the Study identified in the recitals.
   23. **“Study Activities”** means the governing, administrative, coordinating and related activities conducted by the Parties for the day-to-day support and running of the Study as well as any other activity related to the Study, such as the conduct of the Study, in accordance with the REB Approval.
   24. **“Study Funds”** means funds provided to Lead Institution by Funder for the Study and conduct of Study Activities.
   25. “**Study Participant**” means an individual who has consented or, where applicable, whose legal representative has consented on behalf of the individual, in accordance with the REB Approval, to participate in the Study.
   26. **“Study Product**” means the drug or any investigational device used for purposes of the Study as outlined and as defined in the Protocol and article 2.11.
2. **PERFORMANCE OF STUDY** 
   1. The Study is: **[NTD: select the appropriate option for you, and delete the rest of the items (no tracked changes). These are factual items and not generally negotiable].**

not a Health Canada Regulated Study.

**Or**

a Health Canada Regulated Study, phase **[NTD insert phase]** study,and the Sponsor is **[NTD insert sponsor**] . Sponsor shall be responsible for all sponsorship and regulatory obligations under Applicable Laws.

* 1. **[NTD: If Principal Investigator is not a Party, add: [All references to the responsibilities of Principal Investigator shall be deemed to be responsibilities of the Lead Institution by virtue of their employment or appointment at Lead Institution.]] [NTD: If Site Investigator is not a Party, add: [All references to the responsibilities of Site Investigator shall be deemed to be responsibilities of the Participating Institution by virtue of their employment or appointment at Participating Institution.]]** The Principal Investigator has conceived of and shall be responsible for all scientific and technical aspects of the Study including, but not limited to the drafting of the Protocol and overall design of the Study. To the extent applicable, the **[Principal Investigator/Lead Institution/Lead Site]** shall obtain and maintain all applicable government and/or regulatory approvals for the Study in Canada, including but not limited to Health Canada No Objection Letter (“NOL”) as may be required, prior to and during the Study. Site Investigator shall obtain and maintain any additional approvals pertaining to Study Activities to be conducted only at Participating Institution. The Parties agree to conduct the Study in compliance with this Agreement, Applicable Laws, the Protocol, REB Approvals and generally accepted ethical, medical and scientific practice standards, the attached schedules, **[the Funder guidelines (as incorporated herein),]** their own institutional policies and procedures, the signed Study Participant’s ICF(as applicable). Participating Institution and the Site Investigator may deviatefrom the Protocol to the extent required to address a medical emergency. Site Investigator shall promptly record any such deviationsfrom the Protocol in the source documents, promptly report the variation to the other Parties and, as necessary, to the REB. Any such variation shall not constitute a failure to follow the Protocol or, more generally, a breach of this Agreement.

The Principal Investigator and Site Investigator shall each be responsible for obtaining and maintaining, prior to involving human subjects in the conduct of the Study at their respective institution and transferring Data**[/Samples]** to another Party, in accordance with article 6, as applicable, (a) approvals from a duly constituted REB and from any applicable authorities (regulatory or otherwise) and (b) if applicable, an executed ICF from each Study Participant. The Site Investigator shall provide Principal Investigator with a copy of each annual renewal of REB approvals, if applicable [**NTD: add if there is funding provided:] and as requested, for inclusion in yearly reports to the Funder by the Lead Institution**.

* 1. The Study will be carried out at the Participating Institution under the oversight, direction and supervision of the Site Investigator, who will have responsibility for the scientific and technical conduct of the Study at the Participating Institution. The Site Investigator will be responsible for ensuring that all Representatives are properly informed as to the procedures specified in the Protocol and to the confidentiality and other requirements set out in this Agreement.
  2. The Participating Institution will provide all reasonably necessary resources, personnel, materials, equipment and any support necessary to commence and complete the Study at the Participating Institution, except where otherwise specified herein or in accordance with the Protocol. The Participating Institution and Site Investigator will perform their functions and devote the time and attention required to carry out the Study. Site Investigator shall disclose conflicts of interest that materially impacts their conduct of the Study to the Lead Site.
  3. The Participating Institution and Site Investigator each confirms that it/he/she possesses the requisite skill, experience, knowledge, staff, facilities and access to potential Study Participants to conduct and complete the Study.
  4. The Intellectual Property, Data, **[NTD: Samples,]** and Results are provided on an “as-is” basis and the Participating Institution and Site Investigator make no representations or warranties whatsoever, express or implied, including as to the usefulness, efficacy, suitability of the Intellectual Property, Data **[NTD: Samples,]** Results for any purpose, or that the use of the Intellectual Property, Data, **[NTD: Samples,]** or Results will not infringe any patents, copyrights, trademarks, trade secrets or other proprietary rights with respect thereto. The Participating Institution and the Site Investigator also make no representations or warranties whatsoever, express or implied, that: (1) the Study will achieve any particular result; or (2) regarding any Intellectual Property, Data, **or** Results that may be created; or (3) as to how many Study Participants will be successfully recruited to the Study at Participating Institution. The Lead Institution and the Principal Investigator accept that there are no representations, warranties, conditions or liabilities expressed or implied herewith in relation to the Intellectual Property, Data, **[NTD: Samples,]** and Results provided by the Participating Institution and Site Investigator or its Representatives or affiliates under this Agreement.
  5. The Site Investigator shall report to the Principal Investigator all adverse events affecting any Study Participant at the Participating Institution, in accordance with the Protocol. The Site Investigator will promptly (within twenty-four (24) hours of becoming aware) in accordance with the Protocol, report all serious Study-related adverse events to the Principal Investigator or his/her Representatives who will report same to the relevant regulatory authorities and any Funders and/or industry suppliers, as required by legal obligations or Applicable Laws. The Principal Investigator shall promptly notify the Participating Institution, the Site Investigator of any information that could: (i) adversely affect the health, welfare, or safety of the current or former Study Participants or their ICF (if applicable); (ii) impact the conduct of the Study; (iii) or alter the REB’s approval of the Study. The Principal Investigator shall additionally expedite such reporting to the regulatory authority and the data safety monitoring board (if any) of all adverse events and/or reactions that are both serious and unexpected in accordance with the regulatory authority’s requirements. For the avoidance of doubt, any Party may report Study-related serious adverse events to the appropriate regulatory authorities, to the REB of the participating sites, and directly to Study Participants and/or their lawful representatives as required to obtain or maintain informed consent.
  6. Site Investigator will provide to Principal Investigator written progress reports on the Study in accordance with the Protocol or as reasonably requested by Principal Investigator during the term of the Study. Within thirty (30) days following the completion or premature termination of the Study at the Participating Institution, Site Investigator shall furnish Principal Investigator and/or Lead Institution with the final Data**[/Samples]** of the Study prepared by the Site Investigator, as well as all reports and other information generated in direct relation to the Study in accordance with the Protocol, unless Lead Institution directs otherwise in writing.
  7. **Samples. [NTD: select the appropriate option for you, and delete the rest of the items (no tracked changes). These are factual items and not generally negotiable].**

No Samples transferred under this Agreement.

**Or**

Samples transferred under this Agreement between the Parties. The Parties acknowledge that the Samples may contain one or more infectious agents and may have additional unknown and hazardous properties. Receiving Party shall use the Samples under appropriate containment conditions.

* 1. **Study Product. [NTD: select the appropriate option for you, and delete the rest of the items (no tracked changes). These are factual items and not generally negotiable].**

The Study does not involve the use of a Study Product.

**Or**

The Study involves the use of the Study Product \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[**NTD: insert product details, including relevant placebos]** (which shall be procured by\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[**NTD:** **insert procurement method of the Study Product]** and is

**investigational/approved** under Health Canada regulations.

The Lead Institution shall ensure that the Site is provided with sufficient quantities of the Study Product required to conduct the Study, as outlined in the Protocol, together with guidelines and descriptions for the safe and proper handling, use, storage, and disposal of the Study Product.

Site shall receive such Study Product free of charge. The Site shall ensure that the Study Product is stored, dispensed and administered under proper conditions and in accordance with the Protocol, investigator’s brochure (if any), the Applicable Laws, the approved product specifications and, where relevant, Lead Institution’s or supplier’s written instructions, shall ensure that the Study Product is only used for the purposes outlined in the Protocol, and shall maintain complete and accurate records relating to the Study Product.

* 1. **Study Product Warranty. [NTD: select the appropriate option for you, and delete the rest of the items (no tracked changes). These are factual items and not generally negotiable. If no warranty is given, it may be helpful to provide a comment explaining why.]**

There is no Study Product, so no Study Product warranty is needed.

**Or**

The Lead Institution has obtained a warranty, disclaimers, or other assurances related to the Study Product as follows, **[NTD to add where possible: including in relation to shipping and importation:]**

**[NTD: insert warranty terms]**

At the reasonable request of Site, Lead Site agrees to take reasonable steps to enforce any such liability/warranty obtained or reasonably assist Participating Institution and Site Investigator in enforcing this liability/warranty.

**Or**

The Lead Institution has notobtained a warranty, disclaimers, or other assurances related to the Study Product, including in relation to shipping and importation.

1. **MANAGEMENT OF FUNDS AND PAYMENT**
   1. **Funding. [NTD: select the appropriate option for you, and delete the rest of the items (no tracked changes). These are factual items and not generally negotiable].**

No Study Funds are transferred under this Agreement. **[NTD: if you select this, then please delete the rest of article 3 following this].**

**Or**

No Study Funds are transferred under this Agreement, but the Funder requires any site working on this Study to be bound by the Funder’s requirements and articles 3.2-3.6 are applicable.

**Or**

Payments will be made to the Participating Institution in accordance with the budget, which is attached as Schedule B, and articles 3.2-3.6 are applicable. To the extent that Study Funds originate from the Funder, payment shall be conditional upon continued support from the Funder. In the event that support from the Funder ceases to be available to Lead Institution, Lead Institution shall give prompt written notice of that fact to Site, and this Agreement may be amended or terminated in accordance with this Agreement. The Parties acknowledge that the compensation set forth in the budget is acceptable to all Parties and has not been determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between Lead Site and Site.

* 1. **Financial Reporting.** **[NTD: select the appropriate option for you, and delete the rest of the items (no tracked changes). These are factual items and not generally negotiable].**

No financial reporting required.

**Or**

In compliance with Funder guidelines, policies and procedures, the Party receiving the funds agrees to complete and submit a detailed annual financial report of revenues and expenditures as follows:

**[NTD:** **insert funding reporting requirements**]

* 1. To the extent applicable, Lead Institution will not be responsible for any amounts Participating Institution spends outside the approved Study budget.
  2. **Return of Funds**. **[NTD: select the appropriate option for you, and delete the rest of the items (no tracked changes). These are factual items and not generally negotiable].**

Any unused and uncommitted Study Funds must be returned to Lead Institution after the termination of this Agreement.

**Or**

The Parties agree to remain silent on the return of unused and uncommitted Study Funds.

**Or**

The Parties agree to the following language regarding the return of Study Funds: **[NTD: insert language]**

* 1. Ongoing payment of Study Funds is conditional on continued compliance with the terms and conditions of this Agreement. If, at any time, Lead Site reasonably determines that (1) the Study Activities were not conducted in accordance with this Agreement, (2) that the Study Funds provided by Lead Institution were not used in compliance with this Agreement, (3) that the Study Participants were not properly enrolled under the terms of the Protocol, (4) the Study Activities were not conducted under the conditions set out in the Protocol, or (5) the Data has not yet been received and verified by the Lead Site, then Lead Institution reserves the right to withhold payment of amounts in dispute from Participating Institution, in accordance with article 14 of this Agreement.
  2. Site shall maintain appropriate accounting records according to generally accepted accounting practices for costs claimed as incurred in the performance of this Agreement and shall keep these records for a minimum of seven (7) years. Participating Institution shall also make such records available, upon request, to authorized entities for audit purposes in accordance with article 5.

1. **TERM AND PERIOD OF PERFORMANCE OF THE AGREEMENT**
   1. This Agreement shall be effective as of the Effective Date and shall continue in full force and effect until \_\_\_\_\_\_\_\_\_\_\_\_\_\_**[NTD: insert termination trigger or date]** unless otherwise extended, renewed, or amended by mutual written consent of the Parties or unless terminated earlier in accordance with the terms hereof.
   2. In the case that the Site Investigator can no longer participate in the Study as the lead investigator at the Participating Institution, the Participating Institution may propose an alternative Site Investigator. If the Principal Investigator and Lead Institution approve this choice of an alternative Site Investigator, approval not to be unreasonably withheld, then the Parties shall amend this Agreement to reflect that change. In the case that the Participating Institution omits to propose an alternative or no suitable alternative is available, any Party may terminate this Agreement in accordance with the termination provisions herein.
2. **AUDIT AND MONITORING**
   1. Lead Institution, **[Funder,]** Sponsor, may, at their own expenses, audit all financial accounts and financial records relating to the Study and may undertake reviews of the Study’s administrative, financial and Study processes. The Parties agree, on reasonable written notice and at mutually agreeable times during regular business hours, and in compliance with Participating Institution’s internal policies and Applicable Laws, to give Lead Institution, **[Funder]** and/or its Representatives remote or in-person access to all financial records related to the Study, as they may require, to carry out the financial audits. The Lead Institution, Principal Investigator, **[Funder]** and/or their Representatives shall abide by the Participating Institution’s privacy, security, confidentiality and health and safety requirements during such financial audits.
   2. Upon reasonable advance written notice and at mutually agreeable times during Participating Institution’s regular business hours and to the extent permitted under the ICF and in accordance with Applicable Laws, the Participating Institution and the Site Investigator shall permit the Lead Institution, the Principal Investigator and/or its/his/her Representatives, including but not limited to the REB, supervised access to the relevant facilities at Participating Institution and relevant Study Participant medical records, to monitor the conduct of the Study, to audit records, study case report forms (“CRFs”), source documents, and any other data relating to the Study, in order to comply with regulatory requirements, for data verification, and to verify the Participating Institution’s and the Site Investigator’s compliance with their obligations herein. Nothing herein shall be construed as permitting the Lead Institution, Principal Investigator and/or its/his/her Representatives to remove or copy from the Participating Institution any medical records, source documents or other records and information containing Personal Information, and all source documents and medical records shall remain the property of the Participating Institution. The Lead Institution, Principal Investigator and its/his/her Representative(s) shall: (i) comply with the Participating Institution’s policies and procedures governing access to Participating Institution’s facilities, electronic systems and records, and attendances on site; (ii) comply with Participating Institution’s privacy, security, confidentiality and health and safety requirements during such audits and monitoring visits; (iii) comply with the confidentiality and privacy terms of this Agreement; (iv) comply with the Study Participant's ICF; (v) hold in confidence any information learned as a result of monitoring the Study; and (vi) immediately notify the Site in the event the privacy or security of any information collected or learned as a result of monitoring the Study may be compromised. The Lead Institution and the Principal Investigator shall be responsible for all actions of its respective authorized Representative(s) who conduct audit activities and/or monitoring on Site’s premises. If, as a result of Study monitoring, the Lead Institution, Principal Investigator or its Representative(s) requests reasonable corrective and/or preventive action, the Parties shall collaborate in good faith to create and implement a corrective and/or preventive action plan to address the deficiency acceptable to all Parties in a timely manner.
   3. Upon request by any regulatory authority having oversight over the Study, the Participating Institution and/or the Site Investigator shall permit such regulatory officer(s) to inspect the conduct of the Study at the Site in accordance with Applicable Laws.
3. **TRANSFER OF DATA[/SAMPLES] AND PROTECTION OF PERSONAL INFORMATION.** 
   1. **Compliance.** Disclosing Party wishes to share the Data**[/Samples]** with Receiving Party for the above-referenced Study. In transferring the Data**[/Samples]**, the Parties shall comply with all Applicable Laws. Disclosing Party will collect and furnish the Data**[/Samples]** in accordance with Applicable Laws including without limitation obtaining all appropriate consents (if required). The Parties hereto shall use a secure method to transfer the Data**[/Samples]** from Disclosing Party to Receiving Party. The Data**[/Samples]** will not be collected and/or transferred until Disclosing Party’s REB and, if applicable Receiving Party’s REB, have: a) approved the Protocol; and b) approved the Study ICF or waived the requirement to obtain consent, to the extent applicable. Disclosing Party retains the right to conduct audits of Receiving Party’s compliance with the privacy obligations in this article 6, upon reasonable advance written notice to Receiving Party and at mutually acceptable times. In conducting such audits, Disclosing Party shall: (i) comply with the Receiving Party’s institutional policies and procedures governing access to its facilities, electronic systems and records, and attendance on site; and (ii) comply with Receiving Party’s institutional privacy, security, confidentiality and health and safety requirements. If there is a breach of this Agreement by Receiving Party, Disclosing Party may require that all applicable Data**[/Samples]** be returned promptly to Disclosing Party or destroyed in a secure manner, at Disclosing Party’s option, to the extent feasible. Disclosing Party retains the right, acting on reasonable grounds, to refuse the transfer of the Data**[/Samples]** requested hereunder.
   2. **Non-Disclosure of Data[/Samples].** Except as otherwise permitted by the REB Approval, Receiving Party shall limit access to the Data**[/Samples]** only to its Representatives with a need to know for the purpose of conducting the Study, and who are made aware and will be required to comply with either the terms of this Agreement or terms no less stringent than those contained herein. Receiving Party agrees that it/he/she shall, and shall require its/his/her Representatives to:
      1. maintain the Data**[/Samples]** in confidence, and not disclose the Data**[/Samples]** except as permitted by this Agreement for the conduct of the Study;
      2. use the Data**[/Samples]** solely for the purposes of the Study or other expressly consented purposes, in compliance with:
         1. the REB Approval as approved by Disclosing Party’s REB and as amended from time to time, provided that such amendments are approved by Disclosing Party’s REB;
         2. any written conditions imposed by Disclosing Party’s or Receiving Party’s REB;
         3. the ICF approved by Disclosing Party’s REB or, if the requirement to obtain consent has been waived, or otherwise determined to be unnecessary, by Disclosing Party’s REB, the waiver of consent given by Disclosing Party’s REB;
         4. any other conditions or restrictions imposed by Disclosing Party relating to the use, security, disclosure, return or disposal of the Data[/Samples] as set out in this Agreement; and
         5. Applicable Laws.
      3. not use the Data**[/Samples]** to identify or attempt to re-identify any individuals from whom such Data**[/Samples]** were collected, unless expressly permitted by the applicable REBs and/or the ICFs, if applicable;
      4. if applicable, use any Personal Information transferred hereunder exclusively for the purposes of the Study and in accordance with this Agreement and Applicable Laws;
      5. not disclose, transfer, update, distribute, market, sell, or make any other use of the Data**[/Samples]** to any third parties without the prior written consent of Disclosing Party. Notwithstanding the foregoing, Receiving Party may transfer the Data**[/Samples]**:
         1. to regulatory authorities, provided that Receiving Party gives prior written notice of such intended disclosure to Disclosing Party;
         2. as otherwise permitted by the ICF or waiver of consent; or
         3. in order to comply with Applicable Laws or judicial process, or with a court or regulatory order, provided that, if reasonable in the circumstances, Receiving Party gives prior written notice of such intended disclosure to Disclosing Party and takes all lawful actions that are reasonable in the circumstances to minimize the extent of such disclosure and obtain confidential treatment for such disclosure.
      6. securely destroy the Data**[/Samples]** as required by the REB Approval or as instructed by Disclosing Party and provide a written confirmation of the manner of destruction in a form acceptable to Disclosing Party; and/or,
      7. in the event that Receiving Party retains a third party to house or maintain the Data**[/Samples]** in a database, biobank, or otherwise transfers the Data**[/Samples]** to a third party in accordance with article 6.2.5. of this Agreement, that Receiving Party will ensure that any such third party is contractually bound by obligations of patient confidentiality, privacy, security and non-use with respect to the Data**[/Samples]** no less stringent than those contained herein. The Receiving Party shall remain responsible and liable for the third party’s actions as it pertains to the Data**[/Samples]**. Notwithstanding the foregoing, all such transfers to third parties shall be in accordance with the REB Approval.
   3. **Safeguards and Notification**. Receiving Party shall use appropriate privacy, security, administrative and technical safeguards, specifically safeguards that are no less stringent than those that Receiving Party employs to protect its own confidential and proprietary information (including, without limitation, with respect to encrypting identifying numbers, linking files, storing and retrieving files from secured locations) to prevent any unauthorized access, use or disclosure of the Data**[/Samples]**, and shall promptly report to Disclosing Party any unauthorized access, use or disclosure of which Receiving Party becomes aware. The above shall apply to any copies of the Data**[/Samples]** made by Receiving Party and kept at their premises. Receiving Party shall take appropriate care in the disposal or destruction of the Data**[/Samples]** to prevent unauthorized parties from gaining access to them. The Parties shall make their Representatives aware of the importance of maintaining the confidentiality of any collected or transferred Personal Information.
   4. If approved by the applicable REBs, the Parties may exchange Data**[/Samples]** as required for the Study in accordance with this Agreement and Applicable Laws. In the event of an unauthorized transfer of Data**[/Samples]** to Receiving Party or its Representatives, Receiving Party and its Representatives shall not use or disclose such Data**[/Samples]** and shall: (1) immediately notify Disclosing Party in writing of receipt of such Data**[/Samples]** upon becoming aware of same; (2) promptly destroy or return such Data**[/Samples]** in a secure fashion (at Disclosing Party’s option); and (3) promptly certify such destruction, if applicable, in writing to Disclosing Party.
   5. **Contact with Subjects/Individuals.** Unless expressly permitted by the applicable REB Approval, Receiving Party shall not make contact or attempt to make contact with an individual from whom the Data**[/Samples]** were collected unless Disclosing Party first obtains the individual’s consent to be contacted, except to the extent that Receiving Party is otherwise the individual’s or Study Participant’s health information custodian or trustee.
   6. The provisions of this article 6 regarding the protection of Data**[/Samples]** shall survive the completion or earlier termination of this Agreement. Each Party shall be liable for the actions of its/his/her Representatives respecting the access, collection, use or disclosure of Data**[/Samples]** under this Agreement and for ensuring compliance with Applicable Laws.
4. **CONFIDENTIALITY**
   1. In furtherance of the conduct of the Study, it may be necessary or desirable for the Parties to disclose Confidential Information to one another. All such Confidential Information shall remain the property of the Party disclosing it. Each Party hereto agrees that any such Confidential Information disclosed to it/him/her, or to its/his/her Representatives shall be used only in connection with the legitimate purposes of the Study, shall be disclosed only to those who have a need to know (including but not limited to each Party’s Representatives, the REB and, in the case of a multi-site study, other sites and their respective REBs) and are obligated to keep the same in confidence, and shall safeguard it with reasonable care.
   2. The Parties shall ensure that their Representatives in receipt of another Party’s Confidential Information are made aware of the conditions of confidentiality herein or are bound by similar conditions, but not less stringent, than the conditions herein.
   3. The foregoing confidentiality and non-use obligations shall not apply when, after, and to the extent the Confidential Information disclosed:
      1. is at the time of disclosure, or thereafter becomes, generally available to the public through no breach of this Agreement by the Receiving Party;
      2. was already in possession of the Receiving Party without restriction as to confidentiality at the time of disclosure by Disclosing Party as documented by written records;
      3. is subsequently received by the Receiving Party from a third party without breaching any apparent confidential obligation between the third party and the Disclosing Party hereunder that the Receiving Party is aware of;
      4. is the subject of a valid subpoena or compelled by order of a court or regulatory agency of competent jurisdiction or is otherwise required by law to be disclosed, provided that the Receiving Party making such disclosure shall give maximum practical advance written notice of same to Disclosing Party, to the extent legally permissible, and Receiving Party shall take all reasonable steps to limit the scope of such disclosure to only include that portion that is required by law to be disclosed, and cooperate reasonably with Disclosing Party in its efforts to so limit such disclosure;
      5. is published in accordance with this Agreement; or
      6. is independently developed by the Receiving Party, without reliance on or use of the Disclosing Party’s Confidential Information, as documented by written records.
   4. The Parties may disclose Confidential Information: (i) to potential Study Participants, or to their lawful representatives throughout the conduct of the Study as required to obtain and maintain informed consent and/or as the Confidential Information relates to their health, safety or diagnosis; (ii) to regulatory authorities, or any implicated REB or other site participating in the Study, as required under Applicable Laws; and (iii) as may be otherwise permitted by this Agreement.
   5. All obligations of confidentiality and non-disclosure created under this Agreement shall terminate five (5) years from the completion of the Study or earlier termination of this Agreement unless otherwise required in compliance with another agreement or Applicable Laws, in which case the latest date shall apply. Under no circumstances shall confidentiality and non-disclosure obligations be permanent and irrevocable.
   6. At the expiration or earlier termination of this Agreement, Receiving Party shall destroy or return to Disclosing Party (at Disclosing Party’s option) all Confidential Information in their possession, except that each Receiving Party may retain one (1) archival copy of all Confidential Information for legal record keeping purposes and to ensure their rights under this Agreement.
5. **INTELLECTUAL PROPERTY.** 
   1. **DATA OWNERSHIP:** Patient medical records, Personal Information and internal source documents shall remain at all times the property or under the custody of the Participating Institution or Site Investigator or, if the Participating Institution or Site Investigator is not the trustee or custodian of medical records, then patient medical records shall remain in the custody and control of the trustee or custodian of such medical records. However, all rights, title and interest in and to any and all Data arising out of the performance of the Study at Participating Institution, including all non-health related data collected under the Protocol, shall be the property of **[select appropriate entity : Lead Institution/Principal Investigator].** All rights, title and interest to the analyzed and aggregated data collected at all centers participating in the Study (“Results”) shall vest with the Lead Institution. Lead Institution **[and Principal Investigator]** hereby grant Participating Institution and Site Investigator a [**worldwide, perpetual, irrevocable,]** non-exclusive, royalty free, fully paid up, non-transferable and non-sub-licensable license to use **[select appropriate: Results** or **de-identified Data arising out of the performance of the Study at Site]** for non-commercial, academic, educational, quality improvement, clinical and research purposes or to generate site specific publications in accordance with this Agreement. The Parties acknowledge that, to the extent that any Data constitutes Personal Information, the Participating Institution does not own such Personal Information and cannot grant Lead Institution ownership thereof.
   2. **Intellectual Property Ownership. [NTD: select the appropriate option for you, but leave the deleted item in tracked changes so that, if the other party wants an alternative option, they can simply choose the alternative language. In the final draft, make sure to delete all non-used terms].**

**Joint Ownership.** .  Intellectual Property jointly developed shall be owned jointly by the inventing Parties in accordance with any institutional policies and/or collective agreements of the inventing Parties, where such policies and agreements exist.  The inventing Parties agree to negotiate in good faith a revenue-sharing agreement which reflects the respective contributions of the Parties to the creation of the Intellectual Property. The Parties hereby grant each other a limited right of use of the Intellectual Property arising from the Study without cost and without geographical or temporal limitation for the purposes of teaching, training, quality improvement, clinical and non-commercial research, provided that the protection or marketing of Intellectual Property arising from the Study is not undermined.

**Or**

**Lead Site Ownership.** All Intellectual Propertyarising from the Study shall be owned by Lead Site in accordance with Lead Site’s institutional policies and collective agreements, where such policies and agreements exist. The Site and Site Investigator hereby transfers and assigns to Lead Site, and shall cause the Site Representatives working on the Study to assign, all their rights, title and interest in and to all Intellectual Property and agrees to undertake such actions reasonably requested by Lead Site to give effect to such ownership. Lead Site hereby grants to the Site and Site Investigator a world-wide, irrevocable, royalty-free, fully-paid up non-exclusive licence to use the Intellectual Property arising only from the Study for internal, non-commercial research, clinical, quality improvement, and educational purposes only, and with no right to grant sub-licences.

**And/Or**

**Third Party Intellectual Property Terms.** The Funder or other Study partner (including industry supporter) who is a third party to this Agreement requires the following language regarding Intellectual Property:

**[NTD: insert language]**

* 1. **Background Intellectual Property.** Notwithstanding article 8.1**, [and in accordance with any terms or conditions of the Funder,]** any Intellectual Property that was already conceived, owned or created before the Study by a Party or developed by a Party outside of the Study remains the property of the Party that developed it.

1. **PUBLICATION RIGHTS**
   1. The Participating Institution and the Site Investigator agree that the first publication or presentation of the Results of the Study (including methodology) shall be made by the Lead Site in conjunction with the Results from all site investigators and participating institutions participating in the Study. The Site Investigator shall be included as an author provided that the Site Investigator meets the criteria for authorship in accordance with the International Committee of Medical Journal Editors (“ICMJE”) and published in its Uniform Requirements for Manuscripts submitted to Biomedical Journals. At the earlier of: a) no multi-center publication or presentation being published or presented within twelve (12) months after the Principal Investigator has provided written notice of data lock for the Study at all sites; (b) the multi-center manuscript being published; or (c) the Principal Investigator and Lead Institution providing written permission that the Site is free to publish or present Data collected at Site, **[select appropriate: Results or de-identified Data arising out of the performance of the Study at Site]**and methodology in accordance with the article herein, provided the Site Investigator or Participating Institution provides a copy of the proposed manuscript, for publication or presentation, to the Principal Investigator for review and comment at least thirty (30) days before submission (“Review Period”) for consideration. **[NTD to include if relevant: Principal Investigator may, due to contractual obligations, also provide the manuscript to the Funder for review.]** After such Review Period, but subject to the remainder of this article, the Site Investigator and the Participating Institution shall be free to publish or present without further input from the Lead Institution and Principal Investigator. Upon written request from Principal Investigator, **[or]** Lead Institution, **[or any Funders,]** during the Review Period, Site shall remove from any proposed publication or presentation any other entity’s Confidential Information (for the purposes of this article, “Confidential Information” shall exclude any Data, Study Results, Study methods, or any other information the removal of which would compromise the integrity of the publication or presentation). Upon written request from the Principal Investigator, **[Funder,]** orLead Institution during the Review Period, Site shall further provide an additional sixty (60) days for Principal Investigator or Lead Institution to seek protection of any Intellectual Property that may be affected by such publication or presentation.
   2. The Lead Institution, Principal Investigator, Site Investigator, and Participating Institution will be acknowledged in any publications generated by the Site Investigator or Participating Institution for their contribution to the Study.    **[Participating Institution and Site Investigator agree that it/he/she will acknowledge and credit the contribution of the Funders to the Study in a form and manner suitable to the Funder, in any public disclosure, including, without limitation, scientific publications of whatever nature or kind, and in any communications materials or publications supported by the Funders.]**
   3. **[Site will advise Lead Site of all anticipated public disseminations, publications, media announcements or other events relating to research findings supported by the Funders, and acknowledge that the Lead Site has an obligation to collaborate with Funders in formulating and releasing such research findings.]** A copy of any publications and presentations relating to the Study shall be provided to Principal Investigator and Lead Institution upon publication or presentation, and subject to a publisher’s copyright, Lead Institution and Principal Investigator will be granted such rights or licenses as may be required to enable it to make copies of and distribute the publication or presentation as it considers necessary.
   4. To the extent applicable, Principal Investigator represents that, in accordance with requirements of the International Committee of Medical Journal Editors (ICMJE) for publication of Study results, he/she has registered the Study in a public registry.
   5. However, notwithstanding the provisions of this Agreement, including the other provisions of article 9, publication of a master’s thesis or doctorate’s dissertation shall not be delayed by publication restrictions in this Agreement and may at any time be communicated in confidence to persons responsible for the correction or defence of the thesis or dissertation, so long as such persons are under obligations of confidentiality to the discloser that are at least as restrictive as those confidentiality obligations set forth in this Agreement.
   6. **Use of Name.** Notwithstanding anything in this Agreement to the contrary and without further notice, the Parties acknowledge and agree that each of the Parties may disclose the existence of this Agreement, the title of the Protocol, the duration of the Study and the amount of funding actually received pursuant to this Agreement, and identify the Parties to this Agreement, including but not limited to in any annual public reports, institutional reports or newsletters, in conflict of interest reports, or in any publication or presentation relating to the results of the Study as provided herein, in grant submissions, and the Site Investigator (including sub-investigators) may reference same in his/her curriculum vitae. However, no Party shall use the name, logo, or mark of another Party in any publication, news release, promotion, advertisement, or other public announcement, whether written or oral, that endorses, advertises or promotes services, organizations or product (including Study Product) without the prior written approval of the Party whose name, logo or mark is to be used.
2. **RECORD RETENTION**
   1. Participating Institution and Site Investigator shall maintain a copy of all records, data results and medical notes relating to this Study for the minimum period that is required by Health Canada regulations following completion or termination of the Study, or for other period of time as required either by the REB, Site’s policies, Applicable Laws in the Site’s jurisdiction **[or by the Funder ][NTD: add amount of time required by Funder, if relevant]**, whichever is longer. The Parties shall specify reimbursement of record retention costs within the Study budget, if applicable.
3. **REPRESENTATIONS** 
   1. Each Party represents and confirms that it/he/she has full right, power, and authority to enter into this Agreement.
4. **RELATIONSHIP OF PARTIES**
   1. Any work performed by a Party or its Representatives under this Agreement shall be considered performed as independent contractors and not as partners, joint venturers, employees or agents of any other Party. Each Party agrees that it/he/she or its Representatives, shall not have the power to bind or designate another Party.
5. **LIABILITY & DISCLAIMER** Only selected terms apply. **[NTD: select the appropriate option for you, but leave the deleted item in tracked changes so that, if the other party wants an alternative option, they can simply choose the alternative language. In the final draft, make sure to delete all non-used terms].**
   1. Each Party hereto agrees to be responsible and shall assume liability for any direct costs, suits or claims on account of losses, injuries (including death) to persons or damage to property to the extent that such losses, injuries or damages arise out of its/his/her activities in the course of or arising out of the conduct of the Study including but not limited to those caused by or arising directly from:
      1. its/his/her performance of this Agreement or breach of any term or condition of this Agreement;
      2. its/his/her design (if applicable) of the Protocol, implementation, and operation of the Study which, in the case of Site, is not in accordance with the Protocol;
      3. its/his/her negligent acts or omissions or wilful misconduct; and

* + 1. any negligent acts or omissions or wilful misconduct of another entity or a person for whom in law it/he/she is responsible in the performance of the Study.

**[NTD: delete section 13.1.5 if there is no Study Product].**

* + 1. For clarity, the Participating Institution **[NTD add if Site Investigator is a party: and Site Investigator]** will not be liable for the manufacture of the Study Product, nor for the administration and/or use of the Study Product under instructions provided by the Lead Institution **[NTD: add or adapt as appropriate: [and/or Principal Investigator]]** in the Protocol.
  1. No Party or its/his/her trustees, directors, officers, and Representatives (the ‘first’ Party) shall be liable to any other Party (the ‘second’ Party) for any costs claimed, or suits or claims made by the second Party or made against the second Party arising from this Agreement, except to the extent caused by negligence or wilful misconduct or breach of this Agreement on the part of the first Party.
  2. Lead Institution shall, within Canada, defend, indemnify and hold harmless **[NTD add if necessary: [Site Investigator and]]** Participating Institution, and its/his/her respective Representatives **[NTD add in exclusions or clarifications to “Representatives” if necessary, i.e.:** (including [affiliated hospital] and [affiliated REB])], directors, officers, medical and professional staff, investigators **[NTD add if necessary [(explicitly including Site Investigator)]]**, affiliates, successors, heirs and assigns (each a “Participating Institution Indemnitee”) from and against any and all third party liabilities, claims, actions, suits, damages, costs and expenses (including reasonable legal fees and expenses) (“Claim”) to the extent arising in connection with or arising out of the negligence, willful misconduct or breach of the Agreement by the Lead Institution including its Representatives, officers and directors **[NTD add if necessary [(explicitly excluding Principal Investigator, sub-investigator and any other physician investigators)]]** specifically including any breaches of the privacy or intellectual property provisions herein. This indemnification will apply to each Participating Institution Indemnitee as if a separate indemnification had been provided to each. To the extent applicable and for the purpose of making the Lead Institution’s promise to indemnify enforceable, the Parties hereto acknowledge that the Participating Institution is acting as the agent and trustee for the Participating Institution Indemnitees.
  3. Participating Institution shall, in Canada, defend, indemnify and hold harmless Lead Institution, **[NTD add if necessary: [Principal Investigator]]** and its/his/her respective Representatives **[NTD add in exclusions or clarifications to “Representatives” if necessary, i.e.:** (including [affiliated hospital] and [affiliated REB])], directors, officers, medical and professional staff, investigators **[NTD add if necessary [(explicitly including Site Investigator)]]**, affiliates, successors, heirs and assigns (each a “Lead Institution Indemnitee”) from and against any and all Claims to the extent arising in connection with or arising out of the negligence, willful misconduct or breach of the Agreement (including failure to adhere to the Protocol) by the Participating Institution including its Representatives, officers, and directors **[[NTD add if necessary: [(explicitly excluding Site Investigator, sub investigator and any other physician investigators)]]**, specifically including any breaches of the privacy or intellectual property provisions herein. This indemnification will apply to each Institution Indemnitee as if a separate indemnification had been provided to each. To the extent applicable and for the purpose of making the Participating Institution’s promise to indemnify enforceable, the Parties hereto acknowledge that the Lead Institution is acting as the agent and trustee for the Lead Institution Indemnitees
  4. The Lead Institution has obtained an indemnity from **\_\_\_\_\_\_\_\_\_[NTD: insert name of third party]** related to the Study as follows:

**[NTD: LANGUAGE TO BE INSERTED]**

* 1. At the reasonable request of Participating Institution, Lead Institution agrees to take reasonable steps to enforce any such indemnity obtained or reasonably assist Participating Institution **[[NTD add if necessary: [and Site Investigator]]** in enforcing this indemnity.
  2. Notwithstanding articles 13.3 and 13.4 herein (if applicable), the indemnifying party shall have no obligation to defend, indemnify and hold harmless a particular indemnitee in respect of a Claim to the extent that such Claim is found to have been caused by the negligence, willful misconduct, breach of statutory duty or breach of the Agreement by that indemnitee.
  3. An indemnified party shall reasonably cooperate with the indemnifying party in the defense of any third party action arising out of the performance of the Study, including providing each other with prompt written notice of any such action and copies of all material documents, provided however, that failure by an indemnitee to provide prompt written notice shall not relieve the indemnifying party of its obligations hereunder, except to the extent that the indemnifying party is prejudiced by such failure. The indemnified parties shall each have the right to retain their own legal counsel to defend any such action at their own cost. The indemnifying Party shall not admit fault or liability on behalf of an indemnitee in the defense or settlement of such claim without the written consent of that indemnitee, not to be unreasonably withheld, conditioned, or delayed.
  4. To the extent that he/she/they are Parties to this Agreement, **[Principal Investigator] [and Site Investigator]** each agree to be responsible and assume liability for his/her breach of this Agreement, negligence, wilful misconduct, and breach of this Agreement, negligence, wilful misconduct by those for whom he/she is in law responsible.

[**NTD: select the appropriate option for you, but leave the deleted item in tracked changes so that, if the other party wants an alternative option, they can simply choose the alternative language. In the final draft, make sure to delete all non-used terms].**

* 1. Except for damages arising from a Party's gross negligence or wilful misconduct, no Party shall be liable for any lost profits, lost opportunities, or other indirect or consequential damages suffered by another Party as a result of the conduct of the Study or the performance of this Agreement. This limitation of liability does not apply to claims from participants in the Study.

**OR**

The Parties agree to remain silent on indirect damages.

* 1. Notwithstanding the above stated in this article 13, medically necessary deviations from the Protocol for reasons of Study Participant safety, as reasonably determined by the Site Investigator, as the case may be, shall not nullify or minimize the Lead Institution's indemnification obligations, as long as such deviations are consistent with prevailing standards of medical care. Such deviations shall not constitute a breach of this Agreement or a failure to follow the Protocol.
  2. **Subject Injury**

No subject injury compensation is provided hereunder.

**Or**

Lead Institution offers subject injury compensation as follows:

**[NTD: LANGUAGE TO BE INSERTED]**

**Or**

Participating Institution shall provide subject injury compensation as follows:

**[NTD: LANGUAGE TO BE INSERTED]**

**Or**

A third party has offered subject injury compensation as follows:

**[NTD: LANGUAGE TO BE INSERTED]**

* 1. **Institutional Insurance.** During the term of this Agreement and for the duration of their obligations surviving expiration or premature termination of this Agreement, Lead Institution and Participating Institution will each obtain and maintain a policy(ies) of insurance, including general liability insurance, at levels sufficient to support their obligations assumed herein, in amounts no less than ten million dollars ($10,000,000 CAD) per occurrence (or for Quebec’s site: five million dollars ($5,000,000)) and ten million dollars ($10,000,000 CAD) in the annual aggregate (or for Quebec’s site: five million dollars ($5,000,000)). This article 13.13 shall survive the completion or termination of the Agreement. If any such insurance is on a claims made basis and that insurance is cancelled or non-renewed, it must contain at least a 24-month extended reporting period. The amount of insurance is not a limit on the indemnification or liability obligations set out herein. Each of Institution and Participating Institution shall notify all Parties to this Agreement in the case of a material change to or cancellation of the above insurance. Upon request, Participating Institution and Lead Institution shall provide to any requesting Party or Parties, evidence of its insurance.
  2. **Cybersecurity Insurance.** In addition to the above, both Lead Institution and Participating Institution shall each obtain and maintain policy(ies) of cybersecurity insurance in amounts no less than one million dollars ($1,000,000).
  3. **Investigator Membership in CMPA. [NTD insert and adapt as appropriate: Each of [Principal Investigator] and [Site Investigator] shall, and shall require that any other physicians assisting her/him in connection with the Study is obligated to, maintain active membership in good standing with the Canadian Medical Protective Association (“CMPA”). Upon request, [Principal Investigator] and [Site Investigator] shall provide to any requesting Party or Parties, evidence of its insurance or membership in CMPA as described above.] [[Principal Investigator] and/or [Site Investigator] are not parties to this Agreement and do not have independent insurance obligations hereunder.]**

1. **DEFAULT**
   1. The following shall constitute an event of default:
      1. If a Party, or one of its Representatives, has committed a material breach of this Agreement or the Study including, without restricting the generality of the foregoing, a failure either (i) to provide payment or (ii) to provide any information or report as required under the Agreement that is reasonably satisfactory; or
      2. If a Party has knowingly submitted false or misleading information or has knowingly made misrepresentations.
   2. Upon an event of default, other than under article 14.1.2, a Party shall provide a notice of the default in writing by email to the defaulting Party allowing it thirty (30) days to remedy the event of default.
   3. If the defaulting Party does not remedy the default within thirty (30) days after provision of the notice or promptly in the case of a default under article 14.1.2, the other Party may, without restricting any remedies otherwise available in law, on written notice:
      1. terminate this Agreement;

[**NTD: Delete the below provisions if there is no funding exchanged hereunder]**

* + 1. in the case that the defaulting Party is the recipient of Study Funds from Lead Site, terminate Lead Site’s obligation to provide any further Study Funds to that Party;
    2. cease payments of Study Funds under the Agreement even if already due, except to the extent that the Study results remain usable;
    3. demand repayment of any unspent or uncommitted Study Funds paid under this Agreement that remain in the possession or under the control of the defaulting Party that are not required by the defaulting Party to pay the costs of winding down the Study at its location, except to the extent that the Study results remain usable; and
    4. despite article 14.3.3, if the defaulting Party has spent any amount of the Study Funds paid under this Agreement in material breach of any of the provisions of this Agreement, Lead Site may (in the case that the defaulting Party is the recipient of Study Funds from Lead Site) demand from the defaulting Party the immediate repayment of such amount.
  1. If the defaulting Party is the Lead Site, then the Site, as applicable, may on written notice terminate the Agreement and the Lead Institution shall pay the Site for any costs incurred up to the date of termination (including non-cancellable costs) in accordance with article 15.4.

1. **TERMINATION**
   1. Lead Institution, acting reasonably, shall have the right to terminate this Agreement and/or terminate the Study prior to the end date of the Agreement or the completion of the Study on thirty (30) days’ written notice. In such event and save as provided in article 15.4 below, Site will incur no expenses beyond the effective date of such termination except as detailed herein and in the budget.
   2. Lead Institution shall have the right to immediately terminate this Agreement by providing written notice of its intent to terminate to the other Parties (1) for reasons of Study Participants safety, (2) if REB or regulatory approval for the Study are withdrawn, or (3) if Lead Institution ceases to receive support from the Funder, if applicable.
   3. Participating Institution may terminate this Agreement at any time upon thirty (30) days’ prior written notice all other Parties. In addition, Participating Institution may terminate this Agreement immediately (1) for reasons of Study Participant safety, (2) if REB or regulatory approval for the Study is withdrawn, or (3) if the Site Investigator is no longer willing or able to perform the Study, at any time upon written notice to all other Parties.

Upon written notice of termination, each of the Parties will reasonably co-operate to ensure an orderly transfer of responsibilities and phase-out of activities. The Parties shall use reasonable efforts to minimize any inconvenience or harm to the Study Participants caused by the premature termination of the Study and shall do all that is reasonably necessary for the safe wind-down of the Study. Without limiting the generality of the foregoing, if required for the health, safety or welfare of the enrolled Study Participants: (i) The Site Investigator shall continue monitoring or performing follow-up activities set out in the Protocol beyond the termination date of this Agreement until they are no longer required, as determined by Site Investigator in consultation with the Study Participant's physician; and (ii) The Lead Institution shall continue supply of the Study Product, if applicable, to the extent required to safely withdraw each Study Participant from the Study, as agreed in good faith by the Parties

[**NTD: Delete the below provisions if there is no funding exchanged hereunder]**

* 1. Upon the termination of the Agreement, Site shall promptly provide Lead Site with a full account of all unused and uncommitted funds or overpayments advanced to the Site under this Agreement and shall repay such amounts to the Lead Site within forty-five (45) days of such termination. If the Agreement is terminated, all costs properly incurred in the conduct of the Study, including non-cancellable costs, pursuant to the budget, up to the effective termination date, will be paid to the Participating Institution at the next payment date according to the budget attached in the schedules herein. Any budgetary changes required due to the early termination of this Agreement shall be agreed to in writing between the Parties.
  2. Upon the termination of the Agreement, Site will no longer be eligible to receive Study Funds under this Agreement except for any amounts owing under article 15.4.

1. **GOVERNING LAW AND ATTORNMENT**
   1. This Agreement shall be governed, construed and interpreted pursuant to and in accordance with the laws of the Province of the Party defendant in litigation, and the laws of Canada applicable herein. The provincial or federal courts having jurisdiction in the Province of the Party defendant in litigation shall have exclusive jurisdiction over all matters pertaining to this Agreement.
2. **NOTICES**
   1. All notices or other communications which are required or permitted hereunder shall be in writing and delivered personally, sent by prepaid courier, or email transmission. Notices shall be deemed to have been received (i) upon receipt in the case of personal delivery; (ii) two (2) days after being deposited in the case of messenger, express or air courier or similar courier; and (iii) the day it is sent, or the next business day if sent between 4pm and midnight based on the time zone of the recipient in the case of transmittal by email. Unless and until notified of a change of address, notices and other communications shall be sent to the following addresses:

**Lead Institution**

**[NTD: Principal Investigator]**

**Participating Institution**

**[NTD: Site Investigator]**

1. **ENTIRE AGREEMENT**
   1. This Agreement represents the entire understanding of the Parties with respect to the subject matter hereof.  In the event of any inconsistency between this Agreement and the Protocol, the Protocol shall govern in matters of medicine or science to extent of such inconsistency, and this Agreement will govern for all other matters.
2. **CONFLICT OF INTEREST AND RESEARCH MISCONDUCT**
   1. Each Party shall ensure that conflicts of interest shall be mitigated in accordance with institutional policies and shall be disclosed to the Lead Institution and Principal Investigator if it materially impacts their conduct of the Study **[and in accordance with Funder requirements]**.
   2. Any allegation of scientific misconduct shall be investigated and dealt with in accordance with the internal policies and collective agreements of the Party whose employee, contractor or agent is the subject of the allegation.
   3. Parties involved shall disclose to Lead Site without delay any actual situation materially related to the Study that may be reasonably interpreted as a real conflict of interest or as a scientific misconduct.
3. **SEVERABILITY**
   1. If any provision of this Agreement shall be determined by an arbitrator or court of competent jurisdiction to be unenforceable, invalid or illegal for any reason, or inapplicable as a result of force majeure, the Parties shall meet to discuss such provision(s) and shall reasonably attempt to substitute it with a lawful and enforceable provision which, so far as possible, results in the same intended effects. If the Parties fail to negotiate a resolution within thirty (30) days, the unenforceable, invalid or illegal provision shall be stricken and the balance of the Agreement shall continue in full force and effect.
4. **NO ADVERSE CONSTRUCTION**
   1. This Agreement shall be construed neutrally and with no presumption favoring or disfavoring any Party by virtue of its involvement in authorship of this Agreement.
5. **NO WAIVER**
   1. No waiver by any Party of a breach, failure of condition, or any right or remedy contained in or granted by the provisions of this Agreement shall be effective unless it is in writing and signed by the Party waiving the breach, failure, right or remedy. No such waiver by any Party shall be deemed a waiver of any other breach, failure, right or remedy, whether or not similar, nor shall any waiver constitute a continuing waiver unless the writing so specifies.
6. **SURVIVAL**
   1. Articles 5-10, 13, 15.4, 15.6, and 16-20, 22, 23, and 26 shall survive any termination or expiration of this Agreement, as well as any other terms, which by their intent or meaning are intended to survive. No termination, expiration or completion hereunder shall constitute a waiver of any rights or causes of action that any Party may have based upon events occurring prior to the termination, expiration or completion date.
7. **INDEPENDENT LEGAL ADVICE**
   1. Each Party confirms that it has had the opportunity to seek independent legal advice with respect to this Agreement, and no Party has relied on another Party to this Agreement for legal advice with respect to this Agreement, and it is signing this Agreement voluntarily.
8. **EXECUTION AND COUNTERPARTS**
   1. This Agreement may be executed in any number of counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each Party, it being understood that the Parties need not sign the same counterpart. Each Party acknowledges that a signed copy of this Agreement or a signature generated by industry standard electronic signature software, delivered by e-mailed portable document format file or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.
9. **AMENDMENTS, ASSIGNMENT AND ENUREMENT**
   1. No part of this Agreement may be modified except in writing signed by all of the Parties. No Party may assign this Agreement or any obligation hereunder without the prior written consent of the other Parties, which may not be unreasonably withheld. This Agreement binds and enures to the benefit of the Parties and their respective successors, heirs and permitted assigns.
10. **FORCE MAJEURE**
    1. A Party shall not be liable for any failure to perform as required by this Agreement (except payment obligations), to the extent such failure to perform is due to circumstances reasonably beyond its/her/his control, such as inclement weather, fire, flood, earthquake, disease, epidemic, pandemic, labour disturbances or labour disputes of any kind, accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression (including cyber aggression), acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, or other such occurrences. In the event of any such failure, the Parties may revise the Agreement by changing the performance period and other provisions, as appropriate, by mutual written agreement. When such cause(s) of non-performance are removed or cease to exist the delayed Party shall promptly resume performance.
11. **LANGUAGE** 
    1. In accordance with the Québec’s *Charter of the French Language, RLRQ. c. C-11*, this Agreement can be written in the English language only. *En conformité avec les dispositions de la Charte de la langue française, RLRQ. c. C-11 du Québec, ce contrat peut être rédigé en anglais uniquement*

***Remainder of page intentionally left blank****.*

***The signatures are on the following page****.*

**IN WITNESS WHEREOF**, the Parties hereto have executed this Agreement on the dates indicated below their respective signatures, with effect as of the Effective Date.

|  |  |  |
| --- | --- | --- |
| **LEAD INSTITUTION**  Name :  Title :  Date :  Name :  Title :  Date : |  | **[NTD include as appropriate: read and acknowledged by:] PRINCIPAL INVESTIGATOR**  Name :  Title :  Date : |

|  |  |  |
| --- | --- | --- |
| **PARTICIPATING INSTITUTION**  Name :  Title :  Date : |  | **[NTD include as appropriate: read and acknowledged by:] SITE INVESTIGATOR**  Name :  Title :  Date : |

**SCHEDULE A**

**PROTOCOL**

*(As already provided to the Parties under separate cover, as amended from time to time, and as approved by the applicable REB)*

**Schedule B**

**Budget**

**[NTD: insert or remove as appropriate]**