GOVERNING PARTICIPATING SITE AGREEMENT
FOR TRI-COUNCIL FUNDED STUDIES: NON-REGULATED

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

WHEREAS, the Parties receive funding from Tri-Council Agencies within Canada;

WHEREAS, the Parties wish to formalize an Agreement with terms and conditions that are consistent with the requirements of Tri-Council Agencies within Canada for non-Health Canada regulated studies;

WHEREAS, the Parties shall enter into individual Study Letters for each Study entered pursuant to this Agreement;

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

1. DEFINITIONS, LIST OF PARTIES

1.1. "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 herein).

1.2. "Confidential Information" means (i) Study-related materials, records and information; or (ii) any other Study related information that has been gathered or developed pursuant to this Agreement or any Study Letter 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.

1.3. "Data" means all data collected through the conduct of a Study in accordance with the REB Approval, and specifically excluding original medical records and source documents.

1.4. "Data/Samples" means Data and/or Samples, as applicable.

1.5. "**Disclosing Party**" means the Party providing Data/Samples and/or Confidential Information to Receiving Party as outlined herein.

1.6. "**Effective Date**" means September 1, 2025.

1.7. **"Funder(s)"** means the funder(s) specified in each Study Letter.

1.8. **"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.

1.9. **"ICF"** means the informed consent in a form and content approved by the REB;

1.10. **"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, trade secrets, 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.

1.11. **"Joinder Letter"** shall mean the joinder letter attached hereto as Schedule C, as fully completed and delivered as specified therein.

1.12. **"Lead Site"** means a party or number of parties collectively referred to as Lead Site as specified on each Study Letter.

1.13. **"Lead Institution"** means the Lead Institution as specified on each Study Letter.

1.14. **"Participating Institution"** means the Participating Institution as specified on each Study Letter.

1.15. **"Participating Investigator"** means the lead investigator in the Study at the Participating Institution as specified on each Study Letter.

1.16. **"Participating Site" or "Site"** means parties collectively referred to as Participating Site as specified on each Study Letter.

1.17. **"Party"** shall mean each institution listed in Schedule A herein, or any institution who joins this Agreement via a Joinder Letter, and "**Parties"** shall mean all of the institutions listed in Schedule A herein, as well as any institution who joins this Agreement via a Joinder Letter.

1.18. **"Personal Information"** means any identifying information of an individual, which may include personal health information, as defined by the Privacy Laws.

1.19. **"Principal Investigator"** means the lead investigator in the Study at the Lead Institution as identified on each Study Letter.

1.20. **"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,* RSO 1990, c. F.31 (Ontario), *Personal Health*

Information Protection Act, 2004, SO 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*, CCSM c. P33.5 ("Manitoba PHIA") (Manitoba), *The Freedom of Information and Protection of Privacy Act,* CCSM c. F175 ("Manitoba FIPPA"), the *Health Information Protection Act*, SS 1999, c H-0.021 (Saskatchewan) ("HIPA"); the *Freedom of Information and Protection of Privacy Act*, RSBC 1996, c 165 ("FIPPA") (British Columbia); the *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.

1.21. "**Protocol"** means the REB-approved protocol incorporated into each Study Letter, by reference, which may be amended from time to time.

1.22. **"REB"** means Research Ethics Board.

1.23. **"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.

1.24. "**Receiving Party"** means the Party receiving Data/Samples and/or Confidential Information from Disclosing Party.

1.25. **"Representatives"** means any of a Party's employees, students, volunteers, agents, appointees, trustees, directors, officers, contractors and any other individual involved in the conduct of the Study other than physicians appointed to the medical staff of the institution.

1.26. **"Samples"** means biological samples derived from human subjects that are collected by Disclosing Party for the Study and/or provided by Disclosing Party to Receiving Party for the purpose of carrying out the Study in accordance with REB Approval.

1.27. **"Study"** means the Study identified in each Study Letter.

1.28. **"Study Activities"** means the governing, administrative, coordinating and related activities conducted by the Parties to a Study Letter 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.

1.29. **"Study Funds"** means funds provided to Lead Institution by Funder for the Study and conduct of Study Activities, as identified in each Study Letter.

1.30. **"Study Letter"** means the fully executed Study Letter for each Study, including any attachments thereto, signed by each signing authority of the requisite Parties, as applicable. Each Study Letter shall be in a format substantially similar to the form of the Study Letter attached hereto as Schedule B (or in such other form as agreed to between the Parties from time to time).

1.31. "**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.

1.32. **"Tri-Council Agency"** shall mean one or more of the Canadian government funding agencies, including the Canadian Institute of Health Research ("CIHR"), the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council.

2. PERFORMANCE OF STUDY

2.1. Responsibilities

2.1.1. The Study is not a Health Canada Regulated Study and, as such, is not subject to Health Canada regulations. 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 and supervision of the Study at all participating centres. The Principal Investigator and/or Lead Institution, as applicable, shall obtain and maintain all applicable government and/or regulatory approvals for the Study in Canada, as may be required, prior to and during the Study. Participating Investigator shall obtain and maintain any additional institutional approvals pertaining to Study Activities to be conducted only at Participating Site. The Parties agree to conduct the Study in compliance with this Agreement, the applicable Study Letter and its attached schedules, any Funder guidelines as specified within the Study Letter, Applicable Laws, the Protocol, REB Approvals and generally accepted ethical, medical and scientific practice standards, their own institutional policies and procedures, and the signed Study Participant's ICF (as applicable). Participating Institution and the Participating Investigator may deviate from the Protocol to the extent required to address a medical emergency. Participating Investigator shall promptly record any such deviations from 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 or a Study Letter.

2.1.2. The Principal Investigator and Participating 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 Participating Investigator shall provide Principal Investigator with a copy of each annual renewal of REB approvals, if applicable and as requested, for inclusion in yearly reports to the Funder by the Lead Institution.

2.2. The Study will be carried out at the Participating Site under the oversight, direction and supervision of the Participating Investigator, who will have responsibility for the scientific and technical conduct of the Study at the Participating Institution. The Participating 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 or a Study Letter.

2.3. 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 and the Study Letter. The Participating Institution and Participating Investigator will perform their functions and devote the time and attention required to carry out the Study in accordance with the Protocol, this Agreement, and the Study Letter. Participating Investigator shall disclose conflicts of interest that materially impact their conduct of the Study to the Lead Site.

2.4. The Participating Institution and Participating 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.

2.5. The Intellectual Property, Data, Samples, and Results (as defined in article 8.1 hereof) are provided on an "as-is" basis and the Participating Institution and Participating Investigator make no representations or warranties whatsoever, express or implied, including as to the usefulness, efficacy, or suitability of the Intellectual Property, Data, Samples, or Results for any purpose, or that the use of the Intellectual Property, Data, Samples, or Results will not infringe any patents, copyrights, trademarks, trade secrets or other proprietary rights with respect thereto. The Participating Institution and the Participating Investigator also make no representations or warranties whatsoever, express or implied: (1) that 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, Samples, and Results provided by the Participating Institution and Participating Investigator or its Representatives or affiliates under this Agreement or a Study Letter.

2.6. The Participating Investigator shall report to the Principal Investigator all adverse events affecting any Study Participant at the Participating Institution, in accordance with the Protocol. The Participating Investigator will promptly (within twenty-four (24) hours of becoming aware) and in accordance with the Protocol, report all Study-related serious 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 Participating 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.

2.7. Participating Investigator will provide to Principal Investigator written progress reports on the Study in accordance with the Protocol or as reasonably requested by Principal Investigator in writing during the term of the Study. Following the completion or

premature termination of the Study at the Participating Institution, Participating Investigator shall promptly furnish Principal Investigator and/or Lead Institution with the final Data/Samples of the Study prepared by the Participating Investigator, as well as all reports and other information generated in direct relation to the Study in accordance with the Protocol. The timeline for submission of final reports, Data/Samples, shall be established by the Principal Investigator and communicated to the Participating Investigator in writing either via email or as set out in the Study Letter.

2.8. The Parties acknowledge that any Samples exchanged under a Study Letter 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.

2.9. All other matters regarding the transfers of Samples or warranties from third parties shall be addressed in each Study Letter. No drugs regulated by Part C, Division 5 of the *Food and Drug Regulations (*C.R.C., c. 870) or devices regulated by Part 3 of the *Medical Devices Regulations* (SOR/98-282) may be distributed or administered under this Agreement.

3. MANAGEMENT OF FUNDS AND PAYMENT

3.1. Funding. The Lead Institution has received Study Funds from a Tri-Council Agency for the purposes of conducting the Study and may provide a portion of the Study Funds to the Participating Institution in accordance with the terms herein and the budget and particulars of which shall be documented in the Study Letter. The term of each grant is specified in the corresponding Study Letter, which describes the Study being supported by the grant.

3.2. Financial Reporting. The Parties shall address any financial reporting, including but not limited to the preparation and submission of Tri-Council Form 300 if applicable, in each Study Letter.

3.3. Ongoing payment of Study Funds is conditional on continued material compliance with the terms and conditions of this Agreement, applicable Study Letter, and continued funding from the Funder. If, at any time, Lead Site reasonably determines that: (1) the Study Activities were not conducted in material accordance with this Agreement and the applicable Study Letter, (2) the Study Funds provided by Lead Institution were not used in compliance with this Agreement and applicable Study Letter, (3) the Study Participants were not properly enrolled under the terms of the Protocol, (4) the Study Activities were not conducted in material compliance with 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.

4. TERM AND PERIOD OF PERFORMANCE OF THE AGREEMENT

4.1. Term of the Agreement. This Agreement shall be effective as of the Effective Date and shall continue in full force and effect for a period of five (5) years, unless otherwise extended, renewed, or amended by mutual written consent of the Parties or unless terminated earlier in accordance with the terms hereof.

4.2. Term and Period of Performance of a Study Letter. Each individual Study Letter shall specify a term within that Study Letter.

4.3. Change of Participating Investigator. If the Participating Investigator specified on a Study Letter is unable to participate or complete a Study at Participating Site, Participating Institution shall make reasonable effort to find another Participating Investigator acceptable to the Lead Institution and Principal Investigator. In the event that a suitable alternative is not found, any Party may terminate the Study Letter in accordance with the termination provisions herein.

5. AUDIT AND MONITORING

5.1. Financial Audit. Lead Institution and Funder, 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 at Participating Site. 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 and 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.

5.2. Upon reasonable advance written notice and at mutually agreeable times and in accordance with the Study Participant ICF and Applicable Laws, the Participating Institution and the Participating 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, audit records, study case report forms ("CRFs"), source documents, and any other data relating to the Study, to verify the Participating Institution's and the Participating 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 medical records, source documents or other records and information containing Personal Information from the Participating Institution. All source documents and medical records shall remain the property of the Participating Institution. The Lead Institution shall ensure that all such auditing and/or monitoring is in compliance with the Participating Institution's: (i) institutional policies and procedures governing access to its facilities, electronic systems and records, and attendance on site; and (ii) institutional privacy, security, confidentiality and health and safety requirements. 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 Participating 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.

5.3. Upon request by any regulatory authority having oversight over the Study, the Participating Institution and/or the Participating Investigator shall permit such regulatory authority's officer(s) to inspect the conduct of the Study at the Participating Site in accordance with Applicable Laws. To the extent permitted by law, Participating Institution and/or Participating Investigator shall promptly notify Lead Institution and Principal Investigator of the regulatory audit of the Study occurring at the Participating Institution.

6. TRANSFER OF DATA/SAMPLES AND PROTECTION OF PERSONAL INFORMATION.

6.1. Compliance. If Disclosing Party wishes to share the Data/Samples with Receiving Party under a specific Study Letter, the Parties shall comply with all Applicable Laws. Disclosing Party will collect and furnish the Data/Samples in accordance with the Study Protocol and executed ICF, Applicable Laws and this Agreement. 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 Study 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 or a Study Letter 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. Disclosing Party retains the right, acting on reasonable grounds, to refuse the transfer of the Data/Samples requested hereunder.

6.2. 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 and Study Letter 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:

6.2.1. maintain the Data/Samples in confidence, and not disclose the Data/Samples except as permitted by this Agreement and Study Letter for the conduct of the Study;

6.2.2. use the Data/Samples solely for the purposes of the Study or other expressly consented purposes, in compliance with:

6.2.2.1. the REB Approval;

6.2.2.2. any written conditions imposed by Disclosing Party's or Receiving Party's REB;

6.2.2.3. the Study ICF executed by the Study Subject 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;

6.2.2.4. 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 or Study Letter; and

6.2.2.5. Applicable Laws.

6.2.3. not use the Data/Samples to identify or attempt to re-identify or directly contact any individuals from whom such Data/Samples were collected, unless expressly permitted by the applicable REBs and/or the Study ICFs, if applicable;

6.2.4. if applicable, use any Data/Samples transferred hereunder exclusively for the purposes of the Study and in accordance with this Agreement, applicable Study Letter, and Applicable Laws;

6.2.5. not disclose, transfer, update, distribute, market, sell, or make any other use of the Personal Information to any third parties without the prior written consent of Disclosing Party. Notwithstanding the foregoing, Receiving Party may transfer the Data/Samples:

6.2.5.1. to regulatory authorities, provided that Receiving Party gives prior written notice of such intended disclosure to Disclosing Party;

6.2.5.2. as otherwise permitted by the applicable ICF or waiver of consent; or

6.2.5.3. 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.

6.2.6. 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,

6.2.7. 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 or any additional terms specified in a Study Letter, 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 be 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.

6.3. 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 also 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.

6.4. 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.

6.5. 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.

6.6. The provisions of this article 6 regarding the protection of Data/Samples shall survive the completion or earlier termination of this Agreement or applicable Study Letter.

7. CONFIDENTIALITY

7.1. All Confidential Information exchanged amongst the Parties 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 conduct 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.

7.2. 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.

7.3. The foregoing confidentiality and non-use obligations shall not apply when, after, and to the extent the Confidential Information disclosed:

7.3.1. is at the time of disclosure, or thereafter becomes, generally available to the public through no breach of this Agreement or Study Letter by the Receiving Party;

7.3.2. 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;

7.3.3. 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;

7.3.4. 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;

7.3.5. by written agreement from the Disclosing Party is released from confidential status;

7.3.6. is published in accordance with this Agreement or applicable Study Letter; or

7.3.7. is independently developed by the Receiving Party, without reliance on or use of the Disclosing Party's Confidential Information, as documented by written records.

7.4. 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 or Study Letter.

7.5. All obligations of confidentiality and non-disclosure created under this Agreement or a Study Letter shall terminate five (5) years from the completion of the Study or earlier termination of the Study Letter 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.

7.6. At the expiration or earlier termination of a Study Letter, 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 and compliance with their obligations under this Agreement or any Study Letter. Notwithstanding the foregoing, Receiving Party shall not be required to destroy any electronic files created during automatic system backup, provided, however, that such copy remains subject to the confidentiality obligations set forth herein.

8. INTELLECTUAL PROPERTY

8.1. DATA OWNERSHIP: Study Participant medical records, Personal Information and internal source documents shall remain at all times the property or under the custody of the Participating Institution or Participating Investigator or, if the Participating Institution or Participating Investigator is not the trustee or custodian of medical records, then Study Participant 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 Lead Institution. 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 hereby grants Participating Institution and Participating Investigator a world-wide, non-exclusive, , royalty free, fully paid up, non-transferable and non-sub-licensable license to use Results and de-identified Data arising out of the performance of the Study at Participating Site for non-commercial, academic, educational, quality improvement, clinical and research purposes in accordance with this Agreement or Study Letter. 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.

8.2. Lead Site Ownership. All Intellectual Property to the extent arising from the Study shall be owned by Lead Site in accordance with Lead Site's institutional policies. The Participating Institution and Participating Investigator hereby transfers and assigns to Lead Site, and shall direct the Participating 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, at Lead Site's full expense, to give effect to such ownership. Lead Site hereby grants to the Participating Institution and Participating Investigator a world-wide, royalty-free, fully-paid up, non-exclusive, , non-transferable and non-sub-licensable 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. The license will remain in effect until terminated by Lead Institution upon thirty (30) days' prior written notice to the affected Parties.

8.3. Background Intellectual Property. Notwithstanding article 8.1 and 8.2, and in accordance with any additional terms set out in the Study Letter, any Intellectual Property that was already conceived, owned or created before the Study or developed outside of the Study remains the property of the person or legal entity that developed it.

8.4. Further Intellectual Property terms may be specified within each Study Letter.

9. PUBLICATION RIGHTS

9.1. The first publication of the Results of the Study shall be made by means of a multi-centre publication of the Results from all participating institutions contributing data, analyses and comments, including the Participating Institution and the Participating Investigator, and coordinated by the Principal Investigator. Authorship of all publications resulting from the Study shall be in accordance with the guidelines established by the International Committee of Medical Journal Editors. All publications shall comply with CIHR's publication policies. All publications funded by CIHR shall specify the grant number. Any publication or oral presentation of the de-identified Data or Results of the Study, including scientific articles, news releases, news conferences, public lectures and media interviews shall acknowledge the contribution of CIHR or any other Funders, as applicable.

9.2. Following the multi-centre publication, or eighteen (18) months after conclusion, abandonment or termination of the Study at all sites, or after Lead Institution or Principal Investigator confirms there will be no multi-centre Study publication, whichever is earlier, the Participating Institution and Participating Investigator may publish or publicly present the clinical research methods and de-identified Data collected by the Participating Institution and Participating Investigator's site, provided the Participating 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. 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 Participating 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, Lead Institution, or any Funders, during the Review Period, Participating 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, or Lead Institution during the Review Period, Participating 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.

9.3. Participating Site will advise Lead Site of all anticipated public disseminations, media announcements or other events relating to research findings supported by the Study. To the extent applicable and if so required, Principal Investigator represents that he/she has registered the Study in a public registry.

9.4. However, notwithstanding the provisions of this Agreement, including the other provisions of article 9, nor any additional provisions specified in a Study Letter, 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 and Study Letter.

9.5. Use of Name. Notwithstanding anything in this Agreement or Study Letter to the contrary and without further notice, the Parties acknowledge and agree that each of the Parties may disclose the existence of this Agreement or any Study Letter, the title of the Protocol, the duration of the Study and the amount of funding actually received pursuant to this Agreement or any Study Letter, and identify the Parties to this Agreement or any Study Letter, 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 Participating 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 without the prior written approval of the Party whose name, logo or mark is to be used.

9.6. Further Publication terms may be specified within each Study Letter.

10. RECORD RETENTION

10.1. Participating Institution and Participating 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 the applicable REB or institutional policies, following completion or termination of the Study, or for other period of time as required either by Participating Site's policies, Applicable Laws in the Participating Site's jurisdiction, or as otherwise specified within the Study Letter, whichever is longer. The Parties shall specify reimbursement of record retention costs within the Study budget, if applicable.

11. REPRESENTATIONS

11.1. Each Party represents and confirms that it/he/she has full right, power, and authority to enter into this Agreement and any subsequent Study Letter.

12. RELATIONSHIP OF PARTIES

12.1. Any work performed by a Party or its Representatives under this Agreement or any Study Letter 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.

13. LIABILITY & DISCLAIMER

13.1. Except as otherwise agreed to in this Agreement or in a Study Letter, each Party hereto agrees to be responsible and shall assume its/his/her own 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 damage arise out of its/his/her activities in the course of the Study including but not limited to those caused by or arising directly from:

13.1.1. its/his/her performance of this Agreement or Study Letter or breach of any term or condition of this Agreement or Study Letter ;

13.1.2. its/his/her design (if applicable) of the Protocol, implementation, and operation of the Study which, in the case of Participating Site, is not in accordance with the Protocol;

13.1.3. its/his/her negligent acts or omissions or wilful misconduct; or

13.1.4. 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.

13.2. 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 or Study Letter. This limitation of liability does not apply to claims from Study Participants.

13.3. 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 Participating Investigator, as the case may be, shall not nullify or minimize the Lead Institution's liability 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 any Study Letter or a failure to follow the Protocol.

13.4. **Institutional Insurance.** During the term of this Agreement, the term of each Study Letter, and for the duration of their obligations surviving expiration or premature termination of this Agreement or each Study Letter, 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 CAD)) and ten million dollars ($10,000,000 CAD) in the annual aggregate (or for Quebec's site: five million dollars ($5,000,000CAD)). This article 13.4 shall survive the completion or termination of the Agreement or any Study Letter. If any such insurance is on a claims made basis and that insurance is cancelled or non-renewed, it must contain at least a twenty-four (24) month extended reporting period. The amount of insurance is not a limit on the indemnification or liability obligations set out herein or in the Study Letter. Each of Lead Institution and Participating Institution shall notify all Parties to every applicable Study Letter in the case of a material change to or cancellation of the above insurance at any point before the end of the twenty-four (24) month period following the end of the term of a Study Letter. Upon request, Participating Institution and Lead Institution shall provide to any requesting Party or Parties, evidence of its insurance.

13.5. **Investigator Membership in CMPA.** To the extent that each of Principal Investigator and Participating Investigator are physicians, each shall, and shall require that any other physicians assisting her/him in connection with the Study are obligated to, maintain active membership in good standing with the Canadian Medical Protective Association ("CMPA"). Upon request, Principal Investigator and Participating Investigator shall provide to any requesting Party or Parties, evidence of its insurance or membership in CMPA as described above.

13.6. Unless otherwise specified in a Study Letter, the Parties agree that no subject injury compensation is provided for any Study.

14. DEFAULT

14.1. The following shall constitute an event of default:

14.1.1. If a Party, or one of its Representatives, has committed a material breach of this Agreement, a Study Letter, 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 or Study Letter that is reasonably satisfactory.

14.2. 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.

14.3. If the defaulting Party does not remedy the default within thirty (30) days after provision of the notice, the other Party may immediately, without restricting any remedies otherwise available in law, on written notice:

14.3.1. terminate any relevant Study Letters;
14.3.2. 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 incurred beyond the termination date to that Party ;
14.3.3. cease payments of Study Funds under any applicable Study Letter even if already due, except to the extent that the Study Data remain usable;

14.3.4. demand repayment of any unspent or uncommitted Study Funds paid under any relevant Study Letter 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

14.3.5. despite article 14.3.4, if the defaulting Party has spent any amount of the Study Funds paid under a Study Letter in material breach of any of the provisions of that Study Letter, 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.

14.4. If the defaulting Party is the Lead Site, then the Participating Site, as applicable, may on written notice terminate all applicable Study Letters and the Lead Institution shall pay the Participating Site for any costs incurred up to the date of termination (including non-cancellable costs) in accordance with article 15.

15. TERMINATION

15.1. Termination of this Agreement.

15.1.1. Any Party may terminate its participation in this Agreement upon thirty (30) day's written notice to the other Parties.

15.1.2. In the case that this Agreement reaches the end of its term, or is terminated by a Party, during the ongoing term of any Study Letter(s) or the performance of any Study under a Study Letter, then the terms of this Agreement shall continue to apply to those Study(ies) and Study Letter(s) as if the Agreement had never expired or terminated.

15.2. Termination of a Study Letter.

15.2.1. Lead Institution shall have the right to immediately terminate a Study Letter by providing written notice of its intent to terminate to the other Parties to the Study Letter (1) for reasons of Study Participants safety, (2) if REB or regulatory approval for the Study are withdrawn, (3) if Lead Institution ceases to receive support from the Funder, if applicable, or (4) if the Participating Investigator is no longer willing or able to perform the Study, and no suitable replacement may be found. Lead Institution may also terminate a Study Letter at any time upon thirty (30) day's prior written notice to all other Parties.

15.2.2. Participating Institution may terminate a Study Letter at any time upon thirty (30) days' prior written notice to all other Parties. In addition, Participating Institution may terminate a Study Letter immediately at any time upon written notice to all other Parties (1) for reasons of Study Participant safety, (2) if REB or regulatory approval for the Study is withdrawn, or (3) if the Participating Investigator is no longer willing or able to perform the Study, and no suitable replacement may be found.

15.2.3. 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, the Participating Investigator shall continue monitoring or performing follow-up activities set out in the Protocol beyond the termination date of the Study Letter until they are no longer required, as determined by Participating Investigator in consultation with the Study Participant's physician..

15.2.4. Upon the termination of a Study Letter, Participating Site shall promptly provide Lead Site with a full account of all unused and uncommitted funds or overpayments advanced to the Participating Site under the Study Letter and shall repay such amounts to the Lead Site within forty-five (45) days of such termination. If the Study Letter 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. Any budgetary changes required due to the early termination of the Study Letter shall be agreed to in writing between the Parties.

15.2.5. Upon the termination of a Study Letter, Participating Site will no longer be eligible to receive Study Funds under that Study Letter except for any amounts owing under this article 15.

15.2.6. Termination shall not relieve any Party of any obligation accrued prior thereto.

16. GOVERNING LAW AND ATTORNMENT

16.1. This Agreement and all Study Letters 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 and all Study Letters.

17. NOTICES

17.1. 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 addresses specified under each Party’s information at Schedule A, or as specified within a Joinder Letter or Study Letter as applicable. For clarity, this section 17.1 shall not apply to any legal proceedings.

18. ENTIRE AGREEMENT

18.1. 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, a Study Letter, and the Protocol, the Protocol shall govern in matters of medicine or science, and this Agreement and Study Letter will govern for all other matters. In the event of any

inconsistency between this Agreement and a Study Letter, the terms and obligations in the Study Letter shall prevail.

19. CONFLICT OF INTEREST AND RESEARCH MISCONDUCT

19.1. 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.

19.2. 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.

19.3. Parties involved in the performance of a Study 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.

20. SEVERABILITY

20.1. If any provision of this Agreement or Study Letter 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 or Study Letter shall continue in full force and effect.

21. NO ADVERSE CONSTRUCTION

21.1. This Agreement and all Study Letters shall be construed neutrally and with no presumption favoring or disfavoring any Party by virtue of its involvement in authorship of this Agreement or Study Letter.

22. NO WAIVER

22.1. 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 or any Study Letter 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.

23. SURVIVAL

23.1. Articles 2.5, 2.6, 5-10, 13, 15.1.2, 15.2.3, 15.2.4, 15.2.5, 15.2.6, and 16-26 shall survive any termination or expiration of this Agreement, as well as any other terms, in this Agreement or in any Study Letter, 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.

24. INDEPENDENT LEGAL ADVICE

24.1. 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.

25. EXECUTION AND COUNTERPARTS

25.1. 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.

26. AMENDMENTS, ASSIGNMENT AND ENUREMENT

26.1. No part of this Agreement may be modified except in writing signed by all of the Parties who were a Party to this Agreement at the time of the amendment. Each Study Letters must be amended in accordance with the terms of the Study Letter. No Party may assign this Agreement, any Study Letter or any obligation hereunder without the prior written consent of the other Parties, which may not be unreasonably withheld. This Agreement and all Study Letters bind and enure to the benefit of the Parties and their respective successors, heirs and permitted assigns.

27. FORCE MAJEURE

27.1. A Party shall not be liable for any failure to perform as required by this Agreement or any Study Letter (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 applicable Study Letter 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.

28. LANGUAGE

28.1. 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.

Name of legal entity:
Name of signatory:
Title :
Date :

Attachments:

Schedule A : the list of all Parties
Schedule B: the draft Study Letter
Schedule C: Joinder Letter

STUDY LETTER

Pursuant to the GOVERNING PARTICIPATING SITE AGREEMENT FOR TRI-COUNCIL FUNDED STUDIES: NON-REGULATED

This Study Letter constitutes an integral part of the Governing Tri-Council Participating Site Agreement for Tri-Council Funded Studies: Non-Regulated effective as of September 1, 2025 (the "Governing Agreement") and is entered between **[NTD: please adjust the parties as much as required to meet your circumstances, including removing any investigators as needed]** _____ ("Participating Institution"), Dr. _____, an investigator[ ] with Participating Institution ("Participating Investigator"), the _____ ("Lead Institution"), and Dr. _____, an investigator[ ]with Lead Institution ("Principal Investigator"), and is effective as of the last signature date below ("Study Letter Effective Date"). The Parties agree that terms used in this Study Letter not otherwise defined will have the same meaning as set forth in the Governing Agreement and is effective as of the last signature date below ("Study Letter Effective Date"). The Parties agree that terms used in this Study Letter not otherwise defined will have the same meaning as set forth in the Governing Agreement.

WHEREAS, Lead Institution has received Tri-Council Agency funding ("**Study Funds**") from the Canadian Institute of Health Research **[NTD: if there is another funder you want to include whose terms are similar, then amend the above and please further specify** ("**Funder**") for the purposes of a study titled "_____" (hereinafter the "**Study**"), as detailed in the protocol attached hereto as Attachment A;

WHEREAS, the Study is an interventional/observational, study that is not subject to Health Canada regulations, led by **[NTD: insert Lead Institution]**.

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

[NTD: If Participating Investigator is <u>not</u> a Party, add: WHEREAS, the principal investigator at Participating Institution is [insert Participating Investigator] ("Participating Investigator);]

[NTD: include additional recitals as needed, including the grant number][WHEREAS [. . .]]

The Parties hereby agree as follows:

1. Definitions

1.1.1 "Lead Site" means Lead Institution **[together with] [NTD: the term "Lead Site" is meant to include all collective parties at the lead site who should be party to this agreement, potentially including the PI, universities, hospitals, health authorities, or other multiple parties depending on the structure of your**

institution. If Lead Institution is the only party involved, then only say "Lead Institution"] [however their rights, obligations, and liabilities under this Agreement shall be several and not joint].

1.1.2 "Participating Site" or "Site" means Participating Institution **[together with] [NTD: the term "Participating Site" is meant to include all collective parties at the participating site who should be party to this agreement, potentially including the Participating Investigator , universities, hospitals, health authorities, or other multiple parties depending on the structure of your institution. If Participating Institution is the only party involved, then only say "Participating Institution"] [however their rights, obligations, and liabilities under this Agreement shall be several and not joint]**.

2. **Scope.**

2.1 This Study Letter constitutes a "Study Letter" as defined at section 1.30 of the Governing Agreement. The performance of the Study, in accordance with the Protocol, attached as Attachment A to this Study Letter, is to be conducted, in accordance with the terms and conditions of the Governing Agreement and this Study Letter. **[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 you have multiple Parties to this Agreement and you want them to be bound by all obligations of the Participating Institution in the Governing Agreement, add the following: [Each of [name the institutional parties who are not "Participating Institution"] agrees to follow all obligations and liabilities of the Principal Institution in the Governing Agreement as if they were defined as "Principal Institution" in this Study Letter]].**

2.2 Attachments to this Study Letter:

Attachment A: Protocol
[Attachment B: Payment Schedule and Budget [NTD: also include payment schedule and invoicing information at this attachment]
[Attachment C: Additional Funder terms]
[Attachment D: Notice information]

3. **Study Details**

3.1 **Data and Samples.** **[NTD: delete whichever provisions are not applicable]**

☐ No Samples shall be transferred under this Study Letter. Data shall be transferred under this Study Letter between the Parties in accordance with the terms of the Governing Agreement.

Or

☐ Samples and Data shall be transferred under this Study Letter between the Parties in accordance with the terms of the Governing Agreement.

[NTD: if third party technologies or apps are included in the Study, or if the data will be linked to a third party database (like IC/ES or CIHI) you can include details of them here]

3.2 **Funding.** **[NTD: delete whichever provisions are not applicable]**

☐ No funds transferred hereunder.

Or

☐ Payments will be made to the Participating Institution in accordance with the budget, which is attached as Attachment B, and Participating Institution agrees to be bound by all relevant provisions under article 3 of the Governing Agreement **[NTD: confirm the attachment reference and add the following only if the parties are receiving funds up front, rather than invoicing]** and Attachment B.1 herein. Any additional transfer of funds within the period covered by this Study Letter will require a duly-signed amendment of this Study Letter and may be conditional upon receipt of additional funding from Tri-Council Agencies, availability of funds at that time, the receipt of an accurate, detailed annual financial report from the Participating Institution and approval from the Principal Investigator.

3.3 **Financial Reporting.** **[NTD: delete whichever provisions are not applicable]**

☐ NA. **[NTD: to be selected when no funds are transferred under this Agreement]**

Or

☐ All amounts will be invoiced after they have been incurred, and as such no financial reporting required.

Or

☐ Financial reporting is required and shall be provided in accordance with the Governing Agreement and the appendices thereto. Financial reporting shall be provided in accordance with Attachment B hereto.

And/Or

☐ **All additional funding requirements from [name of third party funder], as outlined in Attachment C].**

4. **Liability.** **[NTD: this is the stand-in prompt, but you can replace this with an indemnification clause. See in the Drafter's Note a draft indemnification clause]** The Parties agree to the liability and disclaimer provisions set out in section 13 of the Governing Agreement without further change.

5. **Insurance.** **[NTD: delete whichever provisions are not applicable. Please note that many institutions, particularly those in Quebec, may not have cybersecurity insurance]**

☐ The Parties agree to the insurance provisions set out in section 13 of the Governing Agreement without further change.

OR

☐ Cybersecurity Insurance. In addition to the insurance provisions set out in section 13 of the Governing Agreement, 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).

6. **Modifications to Governing Agreement.**

The Parties agree to amend the following terms of the Governing Agreement as listed below:

[NTD: in particular, contemplate indemnification, record retention, governing law, intellectual property (give particular attention to whether you want the IP rights to be revocable, any third party IP rights or if you want joint ownership), indirect damages, and subject injury provisions. Contemplate if other institutional obligations may apply (i.e. collective agreements). See Drafters Note attached hereto for suggested language. If no changes are needed, simply write "No changes made to the Governing Agreement" or "NA"]

7. **Term.**

The term of this Study Letter will commence on the Study Letter Effective Date and will continue until the completion of the Study in accordance with the Protocol unless terminated in accordance with the termination terms of this Study Letter. **[NTD: consider adding language specifying the term of the grant if applicable and ensure that this is mirrored in clause 2 of Attachment B.1]**

8. **Binding on Investigators.**

[NTD: include if the Principal Investigator or Participating Investigator are a Party to the Study Letter. Adapt as needed] The Principal Investigator and Participating Investigator expressly agree to be bound by all terms and conditions of the Governing Agreement. Principal Investigator and Participating Investigator agree that he/she has had the opportunity to seek independent legal advice with respect to this Study Letter and the

Governing Agreement, has either sought such advice or has declined to do so, and is signing this Study Letter voluntarily and with a full understanding of its contents and the contents of the Governing Agreement. Principal Investigator and Participating Investigator each agree to be responsible and assume liability for: (i) his/her breach of the Governing Agreement and this Study Letter; (ii) his/her negligence, wilful misconduct; (iii) the breach of this Agreement and any Study Letter by those whom he/she is in law responsible; and (iv) the negligence, willful misconduct by those for whom he/she is in law responsible. In accordance with clause 13.5 of the Governing Agreement, Principal Investigator and Participating Investigator shall maintain membership in the CMPA.

9. Termination.

The Parties may terminate this Study Letter in accordance with the terms within the Governing Agreement. Termination or completion of this Study Letter shall be without prejudice to the accrued rights and liabilities of the Parties under this Study Letter or the Governing Agreement.

10. **Amendments; Waiver.**

Amendments to the Governing Agreement apply directly to this Study Letter. No modification, amendment, or waiver of this Study Letter shall be effective unless in writing and signed by a duly authorized representative of each Party, in accordance with the terms of the Governing Agreement.

11. Counterparts.

The Study Letter shall be executed in accordance with the applicable counterpart clauses of the Governing Agreement.

12. **Governing Agreement.** The Parties agree that except as expressly provided for in this Study Letter, the terms of the Governing Agreement remain in effect unchanged.

13. **Notices.** The Parties shall provide each other notice in accordance with the terms of the Governing Agreement. Notice information shall be provided at Attachment D herein **[NTD: confirm attachment]**.

14. Languages.
(If Applicable) In accordance with the Québec's *Charter of the French Language, RLRQ. c. C-11*, this Agreement and all related documents can be written in the English language only. *En conforvité avec les dispositions de la Charte de la langue française, RLRQ. c. C-11 du Québec, ce contrat* ***et tout documents y étant relié*** *peut être rédigé en anglais uniquement*

IN WITNESS WHEREOF, each of the Parties has caused this Study Letter to be executed as follows:

Lead Institution

By:
Name:
Title:

Date:

I have authority to bind the organization.

Principal Investigator
[NTD: adapt as needed]

By:
Dr.

Date:

[NTD: adapt as needed]
Participating Institution

By:
Name:
Title:

Date:

I have authority to bind the organization.

Participating Investigator

By:
Dr.

Date:

[NTD add the following attachments, as appropriate to your Study]

Attachment A: Study Protocol **(NTD: optional; can add as a reference)**

Attachment B: Study Budget **(NTD: optional; as required)**

- **[NTD:**
    - **please attach and reference itemized study budget with payment terms and obligations**
    - **Please specify in the budget who owns any items purchased under the grant]**

Attachment B.1: Tri-Council Sub-granting Required Specifications **(NTD: optional; as required)**

- **[NTD: See the suggested language included below**
- **If you change this language, please note that it must meet the specifications outlined at Appendix 2 of the Tri-Council Agency policies: https://www.nserc-crsng.gc.ca/InterAgency-Interorganismes/TAFA-AFTO/guide-guide_eng.asp#40]**

Attachment C: Additional Funding Terms from Additional Funder (optional, as required by non-Tri-Council Agency funders)

Attachment D: Notice Information [**NTD: insert as needed]**

Attachment B.1
Tri-Council Funding Terms

1. Participating Investigator and Participating Institution shall complete the Study within the maximum budget set forth in the Study Letter and will not commit to any expenses in excess of such maximum without prior written consent of Lead Institution and Principal Investigator. All Study Funds transferred shall constitute "Eligible Expenses" in accordance with Tri-Council Agency requirements. The Lead Institution shall have the right to withhold approval of expenses proposed by the Participating Institution and Participating Investigator if those expenses do not comply with CIHR requirements or with its own institutional policies. Any use of funds that does not fully conform to CIHR guidelines shall be repaid to the Lead Institution.
    a. Any Study Funds provided in relation to the conduct of the Study shall be detailed within each Study Letter.
    b. The Parties may agree to specify other Funders and other funding terms within each Study Letter, at their discretion.

2. The Participating Institution shall prepare a Form 300 each year and shall provide it to the Lead Institution before April 30th of each year.

3. The Lead Institution and Principal Investigator are not responsible for any amounts spent over and above the amount mentioned in any Study Letter or for any amounts spent before or after the period covered by this Agreement. Unspent funds may be carried over into the next fiscal year period to cover research expenses. **Any unused funds must be returned to the Lead Institution at the end of the Term as specified in each Study Letter.**

4. Lead Site and Participating Site shall each maintain appropriate accounting records according to generally accepted accounting practices for costs claimed as incurred in the performance of the Study as detailed in the Study Letter and shall keep these records for a minimum of seven (7) years from date of transaction, or as otherwise set out in the Study Letter. Participating Institution shall also make such accounting records available, upon request, to authorized entities for financial audit in accordance with article 5 of the Governing Agreement.

5. Lead Institution will promptly notify the Participating Site in the event that the funding from Funders is suspended or terminated. Upon such notice, the Participating Investigator agrees to immediately cease enrolling Study Participants. Payment for any outstanding amounts will be made in accordance with the Termination section of this Study Letter and the Governing Agreement.

6. The Participating Institution's execution of a Study Letter constitutes certification that the Participating Institution will comply with all the applicable policies, procedures, and assurances required by the Tri- Agency as applicable and set out at CIHR Funding policies, (accessible online via: https://cihr-irsc.gc.ca/e/204.html) including but not limited to: Tri-Agency Open Access Policy on Publications; Tri-Agency (CIHR, NSERC, & SSHRC)

Guide on Financial Administration; New CIHR requirements for registration and public disclosure of results from clinical trials; and Conflict of Interest and Confidentiality Policy of the Federal Research Funding Organization.

Drafter's Note

Alternative clauses to consider adding to the Study Letter, if applicable

Study Product (NTD: if you are involving a Study Product, you likely need to use the Regulated version of this letter, even if the study is Phase IV regulated with Health Canada and no clinical trial application is needed)

14.1 **Study Product.**

14.1.1 The Study involves the use of the Study Product _____**[NTD: insert product details, including relevant placebos and comparators]** which shall be procured by_____**[NTD: insert procurement method of the Study Product (i.e. if it is obtained via Participating Institution's pharmacy, provided by a supplier, etc. Add additional relevant terms, if any, from the product provider]**. The Participating 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. Participating Site shall ensure that the Study Product is only used for the conduct of the Study as directed in the Protocol, and shall maintain complete and accurate records relating to the Study Product.

14.1.2 **[NTD: insert the below only if Lead Institution is directly providing Participating Institution with the Study Product]** The Lead Institution shall ensure that the Participating Site is provided with sufficient quantities of the Study Product as 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. Participating Site shall receive such Study Product free of charge. The Lead Institution shall require that the Study Product shall be provided to the Participating Institution in appropriate packaging as approved by Health Canada.

Intellectual Property

Revocable Data rights. The license will remain in effect until terminated by Lead Institution upon thirty (30) days' prior written notice to the affected Parties, at which point the parties shall enter into good faith negotiations regarding such termination. Notwithstanding the foregoing, such license cannot be revoked in relation to any publication rights outlined in article 9 of the Governing Agreement.

Joint Ownership. Intellectual Property arising from the Study that is 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 such jointly developed Intellectual Property. The Parties hereby grant each other a limited right of use of the jointly developed 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 such jointly developed Intellectual Property arising from the Study is not undermined.

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]**

Indirect Damages

The Parties agree to remain silent on indirect damages.

Additional Indemnification Language

[NTD: consider if you want the below indemnity to be in addition to or to replace clause 13 of the Governing Agreement] The Parties agree to replace/add to the liability provisions set out in section 13 of the Governing Agreement with the following language.

[NTD: the below is suggested language for indemnification based on negotiations between Canadian institutions, however other language may be proposed]

Lead Institution shall, within Canada, defend, indemnify and hold harmless [NTD add if necessary: [Participating 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 Participating 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.

☐ 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 Participating 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 Participating 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

☐ 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]

☐ 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 Participating Investigator]] in enforcing this indemnity.

☐ Notwithstanding articles 4.1.1 and 4.1.2 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.

☐ 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.]

Notwithstanding the foregoing, or anything in the Agreement to the contrary, any

medically necessary deviations from the Protocol for reasons of Study Participant safety shall not constitute a breach of this Agreement or any Study Letter or a failure to follow the Protocol.

Additional Liability Language:

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 or applicable Study Letter, except to the extent caused by any liability assumed in article 13.1.

Schedule C:

Letter Joinder Agreement to
GOVERNING PARTICIPATING SITE AGREEMENT
FOR TRI-COUNCIL FUNDED STUDIES: NON-REGULATED

("Letter Joinder Agreement")

This letter is a Letter Joinder Agreement for a new party that wishes to sign onto and join the Governing Participating Site Agreement For Tri-Council Funded Studies: Non-Regulated (the "Governing Agreement").

TO: *Please return an executed copy of this Letter Joinder Agreement to: Ottawa Hospital Research Institute ("OHRI") c/o Jennifer Cox, Legal Counsel and Manager, Research Contracts at jencox@ohri.ca and to contracts@ohri.ca. OHRI will maintain signed originals and the official list of signatory organizations.*

Name of New Party: (hereinafter "New Party"),

Notice information of New Party:
Address of the New Party:
Contact Information:
Name and title:
Email:

WHEREAS, a number of research institutions and hospitals are parties to the Governing Agreement. In consideration for participating in the Governing Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the undersigned hereby declares and agrees as follows:

1. This Joinder Letter Agreement dated and effective _____ binds the New Party to all terms, conditions, rights, and obligations in the Governing Agreement as if they had been an original party to that Agreement.

2. New Party agrees that its participation as a signatory to the Governing Agreement may be made publicly available.

EXECUTED by "name of the New Party" through its duly authorized representative(s).

Per:_____
Name/Title:
Date: