

**mCTA DRAFT VERSION 8.0**

**Jan 2021**

**MODEL CLINICAL TRIAL AGREEMENT  
FOR PHARMACEUTICAL INDUSTRY SPONSORED, PHASE [II or III]  
MULTI-SITE DRUG TRIALS**

Clinical Trial Code:	
Clinical Trial Name:	
Final Protocol Date or Version or Investigational Product Number:	
Number of Clinical Trial Participants to be recruited for the Clinical Trial:	

This Clinical Trial Agreement is made as of this \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_ between and among:

**[Insert Institution's name]**, having its principal place of business at **[Insert Institution's address]**

- And -

Dr. **[Insert Principal Investigator's name and address]**

- And -

**CHOOSE CONTRACTING PARTY and delete other reference (where CRO is party consider adding Sponsor Power of Attorney or similar Exhibit):**

**[Insert Sponsor's name]** having its principal place of business at **[Insert Sponsor's address]**

OR

**[Insert CRO's name]** having its principal place of business at **[insert CRO's address]**

(Each a "Party", and collectively the "Parties")

## **BACKGROUND**

Institution is an organisation engaged in the diagnosis, treatment and prevention of disease and/or clinical research for the improvement of healthcare, and has the facilities and Study Personnel necessary to conduct the Clinical Trial.

Investigator has reviewed information regarding the Investigational Product and the Protocol for the Clinical Trial and wishes to conduct the Clinical Trial and to supervise the Study Personnel at the Clinical Trial Site.

Sponsor is a pharmaceutical company involved in the research, development, manufacture and sale of medicines for use in humans and wishes to contract with Institution and Investigator to undertake the Clinical Trial.

**[delete if not applicable:** CRO is a clinical research organization engaged by Sponsor to provide it with research support services].

**NOW THEREFORE, FOR VALUE RECEIVED**, the Parties agree as follows:

### **1. DEFINITIONS**

In this Agreement, the following capitalized words and phrases have the following meanings:

- 1.1 **"Agreement"** means this clinical trial agreement, including the attached appendices, as amended or restated from time to time;
- 1.2 **"Applicable Law"** means all of the statutes, regulations, rules and guidelines, including the *Food and Drugs Act* (Canada), the *Food and Drug Regulations*, Regulatory Authority rules and guidelines, ICH GCP, and federal and provincial privacy and data protection laws, that apply to the conduct of the Clinical Trial, all as amended or restated from time to time;

- 1.3 “**Auditor/Monitor**” means a representative of [**choose Sponsor or CRO to match contracting party**] authorised to carry out a systematic review and independent examination of Clinical Trial-related activities and Clinical Trial Documentation to determine whether the Clinical Trial-related activities, including the collection and recording of Clinical Trial Data, were conducted, analysed and accurately reported in accordance with the Protocol, and the applicable regulatory requirements, and to conduct source data verification;
- 1.4 “**Clinical Trial**” means the investigation to be conducted at the Trial Site by Investigator in accordance with the Protocol and this Agreement;
- 1.5 “**Clinical Trial Data**” means data, results, information, discoveries, inventions, processes and methods (whether patentable or not) resulting from or developed by Investigator or Study Personnel in the performance of the Clinical Trial, but excludes all Personal Information and medical records;
- 1.6 “**Clinical Trial Documentation**” means all records, accounts, notes, reports, data, ethics communications (submission, approval and progress reports) collected, generated or used in connection with the Clinical Trial that are not Clinical Trial Data, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as case report forms (“CRFs”) or electronic case report forms (“e-CRFs”), the Protocol, Investigator’s Brochure, and all other reports and records necessary for the evaluation and reconstruction of the Clinical Trial, but excludes source documents and records of Personal Information and medical records, which shall remain the confidential and proprietary property of Institution;
- 1.7 “**Clinical Trial Name**” means the acronym or short title found on the cover page of this Agreement;
- 1.8 “**Clinical Trial Participant**” means an individual who is eligible and who has consented or, where applicable, whose legal representative has consented on behalf of the Clinical Trial Participant, to participate in the Clinical Trial;
- 1.9 “**Confidential Information**” means the confidential and proprietary information of Sponsor and includes: (i) all information disclosed by or on behalf of Sponsor concerning the Clinical Trial to Institution, Investigator or Study Personnel, all pre-existing Intellectual Property of Sponsor, all Sponsor Intellectual Property; and (ii) Clinical Trial enrollment information, information pertaining to the status of the Clinical Trial, communications to and from a Regulatory Authority, and information relating to the regulatory status of the Investigational Product. Confidential Information shall not include information that: (a) can be shown by documentation to have been public knowledge prior to or after disclosure by or on behalf of Sponsor, other than through wrongful acts or omissions attributable to Institution, Investigator or Study Personnel; (b) can be shown by documentation to have been in the possession of Institution, Investigator or Study Personnel prior to disclosure by or on behalf of Sponsor, from sources other than Sponsor without restriction as to use or confidentiality; (c) can be shown by documentation to have been independently developed by Institution, Investigator or any Study Personnel without reference to the Confidential Information; or (d) can be shown by documentation to have been received from

a third party that did not have an obligation of confidentiality to Sponsor [**include if applicable:** or CRO];

- 1.10 [**include if applicable:** “CRO” means [insert name], which has been retained by Sponsor to provide research support to Sponsor];
- 1.11 “**Effective Date**” means the date of this Agreement, as set out on the first page;
- 1.12 “**ICH GCP**” means International Conference on Harmonisation-Good Clinical Practice, as amended or restated from time to time;
- 1.13 “**including**” means including without limitation;
- 1.14 “**Inspector**” means a person, acting on behalf of a Regulatory Authority, who conducts an official review of the Clinical Trial Documentation, facilities, and any other resources or records related to the Clinical Trial and located at the Clinical Trial Site that the Regulatory Authority deems appropriate;
- 1.15 “**Institution**” means [insert name];
- 1.16 “**Investigator**” means [insert name], the person primarily responsible for the conduct of the Clinical Trial at the Clinical Trial Site and the supervision of the Study Personnel;
- 1.17 “**Investigator’s Brochure**” means a document containing the nonclinical and clinical data on the Investigational Product that are described in section C.05.005(e) of the *Food and Drug Regulations (Canada)*;
- 1.18 “**Intellectual Property**” means patents, trademarks, trade names, trade secrets, service marks, domain names, copyrights, rights in and to databases (including rights to prevent the extraction or reutilization of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them, which may subsist anywhere in the world, whether or not any of them are registered, including applications for registration of any of them, and includes all and any technical and other information which is not in the public domain (other than as a result of a breach of confidence), including information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, materials, substances, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to regulatory authorities, whether or not protected by intellectual property rights or any applications for such rights;
- 1.19 “**Investigational Product**” means the drug and the control material as defined in the Protocol;
- 1.20 “**Master File**” means the file maintained by Investigator containing the documentation specified in ICH GCP;
- 1.21 “**Materials**” means any equipment, software, materials, documents, data, information (including Clinical Trial Data, Clinical Trial Documentation,

Investigator's Brochure and the Protocol, but excludes Investigational Product and biological materials) supplied by, or on behalf of, or purchased at the expense of, **[choose Sponsor or CRO to match contracting party]** in connection with the Clinical Trial;

- 1.22 **"Personal Information"** means any information that is directly or indirectly referable to an individual and protected by Applicable Law;
- 1.23 **"Protocol"** means the document describing the Clinical Trial (a copy of which is available by separate cover and is signed by Investigator and approved by the REB), and any amendments thereto to which the Parties may from time to time agree in writing and which are approved by the REB and applicable Regulatory Authority;
- 1.24 **"Publication"** means a publication, abstract or presentation, whether written, electronic, oral or audio-visual, related to the Clinical Trial;
- 1.25 **"Regulatory Authority"** means any national, supranational or other governmental or regulatory body that has power to regulate the conduct of the Clinical Trial at the Clinical Trial Site;
- 1.26 **"REB"** means an independent, institutional, regional, national or supranational research ethics board or committee authorized by Institution as the research ethics board of record for the Clinical Trial, the responsibility of which is to protect the rights, safety and well-being of Clinical Trial Participants in the Clinical Trial, including reviewing and approving the Protocol and any amendments thereto, the suitability of Investigator, the Clinical Trial Site, Clinical Trial Participant recruitment materials and informed consent forms;
- 1.27 **"Retention Period"** means 25 years following the expiry of the Term or the earlier termination of this Agreement;
- 1.28 **"Sponsor"** means **[insert name]**, which is responsible for the initiation, management and financing of the Clinical Trial;
- 1.29 **"Sponsor Intellectual Property"** means all Intellectual Property arising from and relating to the Clinical Trial, including the Clinical Trial Data and Clinical Trial Documentation, the Investigational Product (including its formulation and use alone or in combination with other drugs), the Protocol and Investigator's Brochure, but excludes: (i) any clinical procedures or other processes or procedures relating in general to the conduct of clinical trials and any improvements thereto that are the procedures of Institution; (ii) copyright in Publications made by Institution or Investigator; and (iii) patient medical records.
- 1.30 **"Study Personnel"** includes any researchers, scientists, technicians and other individuals employed by Institution, or any sub-investigators, agents, consultants or affiliates of Institution, engaged in any aspect of the Clinical Trial, but excludes Investigator;
- 1.31 **"Term"** has the meaning given to it in Subsection 12.1;

- 1.32 “**Timelines**” means the dates set out in Appendix II, as may be amended or restated from time to time in accordance with Subsection 16.1, and Timeline shall mean any one of such dates; and
- 1.33 “**Trial Site(s)**” means any premises, approved by the Parties, in which the Clinical Trial will be conducted.

## 2. INVESTIGATOR AND INSTITUTION

- 2.1 Investigator represents and warrants that Investigator holds the necessary qualifications and has the necessary expertise, time and resources to conduct the Clinical Trial, and that the terms of this Agreement are not inconsistent with any other contractual or legal obligations that Investigator may have, or with Institution’s policies or procedures, or the policies and procedures of any institution or company with which Investigator is associated. Investigator shall during the Term: (i) remain a member in good standing of the applicable College of Physicians and Surgeons (without any terms, limitations or conditions); (ii) remain a member of the Canadian Medical Protective Association, or have equivalent professional liability insurance coverage; and (iii) promptly notify the other Parties in writing if such status changes during the Term.
- 2.2 Investigator shall oversee the performance of the obligations of the Study Personnel as set out in this Agreement.
- 2.3 Each of Institution and Investigator represents and warrants that it, he or she is not currently using, and shall not knowingly use, the services of any individual in connection with the conduct of the Clinical Trial, including Investigator, who is debarred, proposed for debarment, otherwise disqualified or suspended from performing a clinical study, or otherwise subject to any restrictions or sanctions by any Regulatory Authority or research ethics board with respect to the performance of scientific or clinical investigations. Institution and Investigator, as applicable, shall notify **[choose Sponsor or CRO to match contracting party]** upon becoming aware of any such debarment, proposal for such debarment, disqualification or suspension during the Term and for three years thereafter.
- 2.4 Each of Institution and Investigator makes no representations or warranties regarding the Clinical Trial results or Clinical Trial Intellectual Property, including any representations or warranties regarding any merchantability of the Clinical Trial results or Clinical Trial Intellectual Property or fitness of the Clinical Trial results or Clinical Trial Intellectual Property for any particular purpose.
- 2.5 The compensation paid under this Agreement shall be fair market value for the services provided under this Agreement, and no payments shall be provided for the purpose of inducing a Party (including anyone in or under that Party’s employment, direction or control) to purchase or prescribe any drugs, devices or products. In addition, Institution and Investigator shall not (i) bill any patient, insurer or governmental agency for any items, visits, services or expenses provided or paid for under this Agreement, or (ii) provide any money or item of value to any government official or representative to improperly influence government actions in respect of the Clinical Trial. If at any time during the Term or during the two years thereafter, Investigator is a member of a committee that sets formularies or develops clinical guidelines, Investigator shall disclose to the

committee the nature and existence of his or her relationship with **[choose Sponsor or CRO to match contracting party]**. Institution and Investigator shall obligate any Study Personnel to do the same.

- 2.6 Institution and Investigator expressly consent, and agree to obtain express consent from any Study Personnel, to authorize the collection, processing, and transfer of such individual's personal data to countries other than that individual's own country, even though data protection may not exist or be as developed there, for the following purposes: (i) the conduct and interpretation of the Clinical Trial; (ii) review by governmental or regulatory authorities; (iii) satisfying legal or regulatory requirements; (iv) publication on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and websites and databases that serve a comparable purpose; and (v) storage in databases for use in selecting sites in future clinical trials.

### 3. CLINICAL TRIAL GOVERNANCE

- 3.1 Institution acknowledges that it has been selected for the purpose of this Agreement because of its resources. Investigator acknowledges that Investigator has been selected to conduct the Clinical Trial because of his or her experience, expertise and access to resources. Institution and Investigator each acknowledge that they have not been selected by **[choose Sponsor or CRO to match contracting party]**, in any way, as an inducement to, or in return for, past, present or future prescribing, purchasing, recommending, using, obtaining preferential formulary status for, or dispensing any of, Sponsor's products.
- 3.2 In accordance with Applicable Law, **[choose Sponsor or CRO to match contracting party]** shall:
- a. promptly notify Investigator, Institution, and the Regulatory Authority of any information that could affect adversely the safety of Clinical Trial Participants, impact the conduct of the Clinical Trial, or alter the REB's approval of the Clinical Trial; and
  - b. expedite reporting to Investigator, Institution, the data safety monitoring board (if applicable) and the Regulatory Authority of all adverse drug reactions that are both serious and unexpected in accordance with the Regulatory Authority's requirements.
- 3.3 If Institution or Investigator has concerns about information provided by **[choose Sponsor or CRO to match contracting party]** under Subsection 3.2, Institution or Investigator shall contact Sponsor. If Sponsor does not make a report under Subsection 3.2 after receiving Institution's or Investigator's concerns as set out in this Subsection 3.3, Institution or Investigator (or both of them together) may make such a report, provided that Institution or Investigator provide a copy to Sponsor at least two business days before making the report.
- 3.4 The Parties shall promptly meet to resolve any conflict between this Agreement and the Protocol; and if the conflict involves:
- a. the administration or use of the Investigational Product, the rebuttable presumption shall be that the Protocol prevails; or

- b. any other matter, the rebuttable presumption shall be that the Agreement prevails.

#### 4. OBLIGATIONS OF THE PARTIES

- 4.1 Institution and Investigator shall be responsible for the Study Personnel's compliance with the terms of this Agreement. Each of Institution and Investigator shall be liable for the negligent acts and omissions of the Study Personnel under that Party's employment, direction or control.
- 4.2 The Parties shall conduct the Clinical Trial in accordance with:
  - a. the Protocol and the Clinical Trial Participant informed consent form, as approved by the REB;
  - b. Investigator's Brochure and other prescribing information provided by **[choose Sponsor or CRO to match contracting party]**;
  - c. Clinical Trial manuals, if any, as each may be amended;
  - d. any terms and conditions imposed by the REB;
  - e. any terms and conditions imposed by the Regulatory Authority;
  - f. Applicable Law;
  - g. the terms and conditions of this Agreement; and
  - h. any other written instructions that may be provided from time to time to Institution and Investigator by **[choose Sponsor or CRO to match contracting party]** acting reasonably that are not inconsistent with the matters described in Subsections 4.2(a) through (g).
- 4.3 If Institution is in receipt of any funding from one of the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Science and Humanities Research Council of Canada, the applicable Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans" shall apply to the conduct of the Clinical Trial at Institution.
- 4.4 To the extent required for urgent medically necessary variations to the Protocol, Investigator may diverge from the Protocol to the extent required to address the medically necessary variation, and Investigator shall promptly record any such divergence in the source document, promptly report the variation to the other Parties and, as necessary to the REB, and any such variation shall not constitute a failure to follow the Protocol or, more generally, a breach of this Agreement.
- 4.5 Until **[choose Sponsor or CRO to match contracting party]** has obtained all required documentation from the Regulatory Authority and the Clinical Trial has received REB approval, it shall not supply the Investigational Product to Institution or Investigator. Investigator shall ensure that neither administration of the Investigational Product to any Clinical Trial Participant nor any other clinical intervention mandated by the Protocol takes place in relation to any Clinical Trial Participant until all relevant regulatory approvals and an approval from the REB

have been obtained, as well as **[choose Sponsor or CRO to match contracting party]**'s written confirmation of the start date for the Clinical Trial at the Clinical Trial Site.

- 4.6 **[choose Sponsor or CRO to match contracting party]** shall make available to Investigator copies of the relevant documents, such as the Protocol, Investigator's Brochure, product monograph and study manuals, and Investigator shall include such documents together with evidence of the REB approval in the Master File.
- 4.7 Investigator shall complete a financial disclosure form in a format provided by **[choose Sponsor or CRO to match contracting party]** and ensure that each Study Personnel to whom financial disclosure applies, completes the form. During the Term and for one year thereafter, Investigator shall promptly notify **[choose Sponsor or CRO to match contracting party]** of any material change in the information disclosed on a previous form.
- 4.8 **[choose Sponsor or CRO to match contracting party]** shall provide Institution and Investigator, as applicable and in accordance with the Protocol, with the Investigational Product free of charge and in quantities sufficient to complete the Clinical Trial, together with guidelines and descriptions for the safe and proper use, storage and disposal of the Investigational Product. Sponsor represents and warrants to Institution and Investigator that all Investigational Products shall be manufactured, and provided in full compliance with Applicable Law. If the Investigational Product is to be imported, Sponsor shall not list Institution or Investigator as an importer.
- 4.9 Investigator shall keep the Investigational Product in a locked, secured area at all times, within the conditions required in the Protocol, and maintain complete, up-to-date records showing receipt of shipments, administration or dispensing, and returns of the Investigational Product as required by the Protocol and Applicable Law.
- 4.10 Neither Institution nor Investigator shall permit the Investigational Product to be used for any purpose other than the conduct of the Clinical Trial and upon expiry or termination of this Agreement, all unused Investigational Product shall, at **[choose Sponsor or CRO to match contracting party]**'s option and expense, either be returned to **[choose Sponsor or CRO to match contracting party]** or disposed of in accordance with the Protocol or **[choose Sponsor or CRO to match contracting party]**'s reasonable written instructions.
- 4.11 Investigator shall use reasonable efforts to recruit the number of Clinical Trial Participants set out on the cover page of this Agreement. The Parties acknowledge and agree that the Clinical Trial will involve the participation of multiple sites and recruitment will be competitive, and Institution and Investigator acknowledge and agree that, when the enrolment goal for the Clinical Trial as a whole is reached, enrolment will be closed at all sites, including the Clinical Trial Site, regardless of whether Institution and Investigator has reached its, his or her individual enrolment goal.
- 4.12 Institution and Investigator shall permit the Auditor/Monitor or Inspector access to all relevant Clinical Trial Data of the Clinical Trial Participants for monitoring

and source data verification during normal business hours, on reasonable notice. Investigator and Study Personnel, as needed, shall make themselves available to the Auditor/Monitor or Inspector. The monitoring or verification conducted by Auditor/Monitor under this Subsection 4.12 may take any form **[choose Sponsor or CRO to match contracting party]** reasonably deems appropriate, including an inspection of the Clinical Trial Site and examination of any procedures, records or data relating to the Clinical Trial, provided that nothing entitles the Auditor/Monitor to copy any records of Personal Information compiled by or for Institution or Investigator or to exempt the Auditor/Monitor from reasonable processes that the Clinical Trial Site has in place requiring the Auditor/Monitor to sign a confidentiality statement. **[choose Sponsor or CRO to match contracting party]** shall alert Institution and Investigator promptly to significant issues, in the opinion of **[choose Sponsor or CRO to match contracting party]**, arising out of such monitoring or verification. Investigator and Institution shall take appropriate measures reasonably required by **[choose Sponsor or CRO to match contracting party]** to take corrective actions without delay in order to rectify or address all problems found during the monitoring or verification.

- 4.13 Institution shall have written procedures for investigating any research misconduct at the Clinical Trial Site. If **[choose Sponsor or CRO to match contracting party]** reasonably believes there has been any research misconduct in relation to the Clinical Trial, **[choose Sponsor or CRO to match contracting party]** shall promptly notify Institution and request Institution's procedures for making a research misconduct complaint. Institution and Investigator shall provide reasonable assistance in a timely manner to any investigation into same in accordance with Institution's research misconduct procedure. If Institution or Investigator reasonably believes there has been any research misconduct in relation to the Clinical Trial, Institution or Investigator, as applicable, shall notify the Auditor/Monitor and **[choose Sponsor or CRO to match contracting party]** promptly. Institution shall provide **[choose Sponsor or CRO to match contracting party]** with a confidential report of the results of any research misconduct investigation it conducts in relation to the Clinical Trial.
- 4.14 To the extent permitted by Applicable Law, Institution and Investigator shall promptly inform **[choose Sponsor or CRO to match contracting party]** of any intended or actual inspection, written inquiry or visit to the Clinical Trial Site by any Regulatory Authority in connection with the Clinical Trial and forward promptly to **[choose Sponsor or CRO to match contracting party]** copies of any correspondence from any such Regulatory Authority relating to the Clinical Trial. Institution or Investigator shall use reasonable efforts to obtain the consent of the Regulatory Authority to have a representative of Sponsor present during any visit. If a representative of Sponsor is unable to be present during a visit, Institution and Investigator shall, to the extent permitted by Applicable Law, provide **[choose Sponsor or CRO to match contracting party]** with a detailed written report of the visit promptly following the visit.
- 4.15 Institution and Investigator shall keep complete and accurate records of the conduct of the Clinical Trial and all relevant Clinical Trial Data in accordance with generally accepted industry standards and practices and Applicable Law. At **[choose Sponsor or CRO to match contracting party]**'s expense, Institution and Investigator shall retain all such records for the Retention Period. At **[choose Sponsor or CRO to match contracting party]**'s request and expense,

Institution or Investigator shall retain the required records after the expiry of the Retention Period. Institution shall use reasonable efforts to give **[choose Sponsor or CRO to match contracting party]** notice before destroying the Clinical Trial Documentation and Clinical Trial Data.

- 4.16 Institution and Investigator shall ensure that any clinical biological samples required to be tested during the course of the Clinical Trial are tested in accordance with the Protocol and at a laboratory approved by **[choose Sponsor or CRO to match contracting party]** and with the Clinical Trial Participant's informed consent. The Parties shall treat all clinical biological samples as Personal Information.
- 4.17 Investigator shall not, during the Term, conduct any other clinical trial using the same eligibility criteria which might hinder the recruitment of the required cohort of Clinical Trial Participants or otherwise hinder the performance of the Clinical Trial in accordance with the Protocol.
- 4.18 The Parties acknowledge that equipment provided by or on behalf of **[choose Sponsor or CRO to match contracting party]** to Institution shall be inspected and approved by **[choose Sponsor or CRO to match contracting party]**, either directly or through a third party, to ensure compliance with applicable laws, regulations, standards and guidelines as well as Institution's policies and procedures, and Institution shall facilitate access to its premises for this purpose.

## 5. INDEMNIFICATION, INSURANCE, LIMITATION OF LIABILITY

- 5.1 Sponsor shall indemnify, defend, and hold harmless Institution and its directors, officers, employees and agents, Investigator and the Study Personnel, (each the "Indemnitee" and collectively, the "Indemnitees") from and against any and all liabilities, damages, losses, claims and expenses, including court costs and reasonable legal fees ("Losses") resulting from or arising out of any third-party claims, actions or proceedings arising out of (i) personal injury to or death of any Clinical Trial Participant enrolled in the Clinical Trial, which injury or death is caused by (a) the Investigational Product used in accordance with the Protocol and this Agreement; or (b) the performance of any procedure required by the Protocol (that would not occur but for the participation in the Clinical Trial) or Sponsor's written instructions;(ii) Sponsor's **[include if applicable: or CRO's]** use or publication of Clinical Trial Data; or (iii) Sponsor's or Sponsor's employees', contractors' or agents' acts, omissions or negligence related to the Clinical Trial or Sponsor's obligations under this Agreement, in each case to the extent that such Losses do not arise out of any Indemnitee's: (A) failure to comply with this Agreement; or (B) negligence or willful misconduct.

Notwithstanding the above, medically necessary deviations from the Protocol for reasons of Clinical Trial Participant safety shall not nullify or minimize Sponsor's indemnification obligations, as long as such deviations are consistent with prevailing standards of medical care. The above indemnity shall apply separately to each Indemnitee in such manner and to the same extent as though a separate indemnity had been given to each.

- 5.2 An Indemnitee claiming a right of indemnification or defense under this Agreement shall provide Sponsor with prompt written notice of any such claim,

including a copy thereof, served upon it, and shall cooperate with Sponsor and its legal representatives in the investigation of any matter regarding the subject of indemnification, at Sponsor's expense; provided, however, that failure by an Indemnitee to provide prompt notice shall not relieve Sponsor of its obligations hereunder except to the extent that Sponsor is prejudiced by such failure. Sponsor shall have the right to exercise sole control over the defense and settlement of any claim for which indemnification or defense is sought, including the sole right to select defense counsel and to direct the defense or settlement of any such claim; provided that Sponsor shall not enter into any non-monetary settlement or admit fault or liability on behalf of any Indemnitee without the prior written consent of such Indemnitee, which consent shall not be unreasonably withheld, conditioned or delayed. An Indemnitee shall have the right to select and to obtain representation by separate legal counsel at the Indemnitee's sole expense.

- 5.3 No Party shall be liable to any other Party in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues or anticipated savings for any indirect or consequential damage of any nature.
- 5.4 Sponsor shall procure and maintain, or self-insure, at its sole expense, policies of general liability insurance in amounts of not less than \$.....[please insert amount] per occurrence, \$.....[please insert amount] in the aggregate. Such insurance shall include clinical trial liability, broad form contractual liability, completed operations and product liability coverage. The obligation to maintain the insurance shall survive the completion or termination of this 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 obligations of Sponsor. Institution and Investigator shall maintain appropriate and sufficient liability protection in respect of their respective obligations to third parties under this Agreement. For Investigator, this may include membership in the Canadian Medical Protective Association, evidence of which shall be provided upon request. Each of Sponsor and Institution shall produce, upon request of the other, a copy of insurance certificates attesting to the insurance coverage described in this Subsection.

## 6. CLINICAL TRIAL PARTICIPANT INJURY

- 6.1 If a Clinical Trial Participant suffers an adverse reaction, illness, or injury that was caused by the Investigational Product or any procedure performed in accordance with the Protocol (one that would not have been performed but for the Clinical Trial Participant's participation in the Clinical Trial), or as the result of any actions taken at the written instruction of **[choose Sponsor or CRO to match contracting party]**, **[choose Sponsor or CRO to match contracting party]** shall pay for the reasonable and necessary costs of medical diagnosis and treatment of such illness or injury, except to the extent that such expenses are covered by government-sponsored insurance. Notwithstanding the foregoing, **[choose Sponsor or CRO to match contracting party]** shall not be liable for expenses that arise as a result of: (i) negligence or willful misconduct on the part of Investigator, Institution or Study Personnel; or (ii) the natural progression of

an underlying or pre-existing condition, unless exacerbated by participation in the Clinical Trial.

## 7. CONFIDENTIALITY AND DATA PROTECTION

- 7.1 Each of Investigator and Institution shall not: (i) use Confidential Information for any purpose other than the performance of the Clinical Trial, aggregate and de-identified (as to Sponsor and Clinical Trial) metric reporting to third parties, and for internal training and quality assurance purposes; or (ii) disclose Confidential Information to any third party, except as permitted by this Section and Section 9 (Publication Rights), as required by Applicable Law or by a Regulatory Authority, or as authorized in writing by **[choose Sponsor or CRO to match contracting party]**, which authorization shall not be unreasonably withheld. To protect Confidential Information, Investigator and Institution shall: (i) limit dissemination of Confidential Information to only those Study Personnel and other personnel having a "need to know"; (ii) advise all Study Personnel and other personnel who receive Confidential Information of the confidential nature of such information; and (iii) protect Confidential Information from disclosure. Nothing herein shall limit the right of Institution and Investigator to disclose Clinical Trial Data as required during the informed consent process.
- 7.2 If Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide **[choose Sponsor or CRO to match contracting party]** with notice as promptly as possible so that Sponsor may seek a protective order or other appropriate remedy, unless prohibited by Applicable Law. If such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for the Confidential Information.
- 7.3 Upon expiry of this Agreement or upon any earlier written request by **[choose Sponsor or CRO to match contracting party]** at any time, Institution and Investigator shall return to **[choose Sponsor or CRO to match contracting party]**, or destroy, at **[choose Sponsor or CRO to match contracting party]**'s option and expense, all Confidential Information other than as may be permitted by Section 9 (Publication Rights) or as required by Applicable Law, except that Institution and Investigator may retain one copy of such Confidential Information in a secure location for archival purposes and ongoing compliance under this Agreement, and thereafter make no use of Confidential Information whatsoever, other than to protect its rights and interests under this Agreement. Any Confidential Information retained in computer backups shall be maintained in accordance with this Agreement.
- 7.4 (i) Where applicable, Sponsor **[insert if applicable: or CRO]** may have access to Clinical Trial Participant Personal Information. This information is required to be protected under Canadian and provincial laws and Sponsor **[insert if applicable: and CRO]** shall treat all Clinical Trial Participant Personal Information it may come in contact with as confidential.
- (ii) Sponsor **[insert if applicable: and CRO]** shall comply with the applicable requirements of both **[insert applicable province of Institution]** and Canadian privacy and data protection laws, including the **[insert applicable provincial**

**personal health information law]** and the *Personal Information Protection and Electronic Documents Act* (“PIPEDA”), and shall limit the use, transfer or disclosure of Clinical Trial Participant Personal Information strictly for the purposes of the Clinical Trial and in compliance with the REB-approved informed consent document and Applicable Law.

(iii) Sponsor shall keep confidential and secure any Personal Information, regardless of format, obtained or accessed by Sponsor or any agent, contractor, third-party service provider or employee of Sponsor. Sponsor shall ensure appropriate administrative, technological and physical safeguards are put in place, using current industry best practices, to protect the Personal Information against risks such as unauthorized access, use, disclosure, copying, modification, disposal, loss or theft.

(iv) Sponsor confirms that, for those accessing Personal Information, it has a program of education for its employees, contractors and agents on privacy, confidentiality and security of information. Sponsor shall ensure that its employees, contractors and agents are aware of their privacy and confidentiality obligations, and that employees, contractors and agents who resign or are terminated return all Personal Information to Sponsor, are reminded of their continued responsibility to maintain the information’s confidentiality, and no longer have access to the Personal Information.

(v) Sponsor represents and warrants that if it engages any third-party service providers who will have access to Personal Information that: (a) they are subject to obligations of confidentiality and privacy substantially similar to those contained herein, and (b) they will not share Clinical Trial Participant Personal Information with Sponsor or any other third party, except as explicitly provided for in the REB-approved informed consent document.

(vi) Sponsor agrees that Institution retains custody and control of Clinical Trial Participant Personal Information.

(vii) **[choose Sponsor or CRO to match contracting party]** shall, working with Institution and Investigator, ensure that any Clinical Trial Participant Personal Information is removed from any equipment or devices that were brought into Institution for the purposes of the Clinical Trial, prior to the equipment leaving Institution.

(viii) Sponsor shall notify Institution within one day and in writing if it becomes aware of a privacy, confidentiality or security breach relating to Personal Information. In the event of a breach, Sponsor shall consult with Institution and Investigator to identify the root cause of the breach and the affected information, to undertake and implement possible mitigation measures, and to determine appropriate measures to prevent the recurrence of such a breach.

(ix) Upon expiry or termination of this Agreement, or upon request, Sponsor shall cease any and all use of the Clinical Trial Participant Personal Information and shall at no cost return it to Institution, including any copies, or shall destroy it in a manner designated by Institution with proof of destruction.

- 7.5 With respect to any biological materials to be transferred to Sponsor or any Sponsor-designated representative for testing or analyses, as required by the Protocol and permitted by Clinical Trial Participants' informed consents, such biological materials shall: (i) be transferred via a secure mode; (ii) be stored in a secure location with limited access; and (iii) only be used for the purpose of the Clinical Trial for which the biological materials were collected and in accordance with the informed consents, REB-approved Protocol, and Applicable Law, including privacy and data protection laws. Sponsor shall not make any attempt to re-identify Clinical Trial Participants with the biological materials or contact any such Clinical Trial Participants. Sponsor shall require any Sponsor-designated representative receiving biological materials to comply with all Applicable Law and the terms of this Agreement applicable to such biological materials, and Sponsor shall be liable for any breach of the foregoing by any of its representatives. Sponsor acknowledges that the biological materials transferred under this Agreement are experimental in nature and may have infectious and/or hazardous properties and that Sponsor and any Sponsor-designated representatives have the necessary facilities and expertise to safely handle such biological materials. Promptly following conclusion of the Clinical Trial, Sponsor shall and shall cause its designated representatives to destroy such biological materials in a secure fashion and in compliance with Applicable Law except to the extent the REB-approved Protocol and informed consent permits or requires otherwise.
- 7.6 This section 7 shall survive expiry or termination of this Agreement for seven years, excepting the provisions related to Personal Information and biological materials, which shall survive indefinitely.

## 8. USE OF NAME

- 8.1 No Party shall use, or authorize others to use, the name, symbols, trademark, trade name or logo of another Party or refer to the terms of this Agreement in any publication, press release or promotional material with respect to the Clinical Trial, without the prior written approval of the Party whose name, symbols, trademarks, trade name or logo are to be used or, with respect to the terms of this Agreement, without the prior written approval of all of the other Parties. Notwithstanding the foregoing and subject to Subsection 8.2:
- a. Sponsor [*insert as applicable*: and CRO] may name Institution as the site at which the Clinical Trial was conducted and to name Investigator and Study Personnel in connection with activities relating to the Clinical Trial as well as any consideration and compensation and its amount or value, the recipient, purpose and date of payments;
  - b. Institution may use Sponsor's [*insert as applicable*: and CRO's] name, the Clinical Trial Name, the Term, and the annual aggregate amount of funding provided to Institution for the Clinical Trial for financial reporting purposes, as required by Institution's policies;
  - c. Institution may name Sponsor [*insert as applicable*: and CRO] as a financial supporter of clinical studies conducted at Institution, and may include the funding for the Clinical Trial in an annual aggregate number which represents all funding received by Institution for all clinical trials funded by private

industry conducted at Institution, to a public funding agency requesting such information from Institution;

- d. Investigator may, in his or her *curriculum vitae*, list Sponsor's [insert as applicable: and CRO's] name, the Clinical Trial Name and the Term;
- e. if required by a funding agency as part of a submission for a grant, Investigator may list the total amount of funding received under this Agreement for the purpose of making the grant submission; and
- f. Institution and Investigator shall acknowledge Sponsor's role in the Clinical Trial in any Publication permitted under this Agreement.

- 8.2 No Party shall make any form of representation or statement in relation to the Clinical Trial that would constitute an express or implied endorsement of any other Party or any of its products or services.

## 9. PUBLICATION RIGHTS

- 9.1 Institution and Investigator shall have the right to publish or present the results of Institution's and Investigator's activities conducted under this Agreement, including Clinical Trial Data, only in accordance with the requirements of this Section 9. Institution and Investigator, as the case may be, shall submit any proposed Publication to **[choose Sponsor or CRO to match contracting party]** for review at least 45 days prior to submitting any such proposed Publication to a publisher or proceeding with such proposed presentation. Within 45 days of such receipt, **[choose Sponsor or CRO to match contracting party]** shall advise Institution or Investigator, as the case may be, in writing of any information contained therein which is Confidential Information or which may be required for the protection of Sponsor Intellectual Property and the Parties shall discuss the use of such information in the Publication. **[choose Sponsor or CRO to match contracting party]** shall have the right to require Institution and/or Investigator, as applicable, to remove specifically identified Confidential Information (other than data, results and methods of the Clinical Trial sufficient for publication in a peer reviewed journal) and/or to delay the proposed Publication for an additional 75 days to enable Sponsor to seek protection of Sponsor Intellectual Property.
- 9.2 If the Clinical Trial is a multi-centre study, Institution and Investigator each agree that it, he or she shall not, without **[choose Sponsor or CRO to match contracting party]**'s prior written consent, publish, present or otherwise disclose any results of, or information pertaining to, Institution's or Investigator's activities conducted under this Agreement until a multi-centre publication is published; provided, however, that if a multi-centre publication is not published within 18 months after completion of the Clinical Trial and lock of the database at all research sites or any earlier termination or abandonment of the Clinical Trial, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Clinical Trial Data, in accordance with the provisions of Subsection 9.1 above.

- 9.3 For all Publications relating to the Clinical Trial or including any Clinical Trial Data, each of the Parties shall comply with all ethical standards concerning publications and authorship as established by the International Committee of Medical Journal Editors (“ICMJE”) (found at <http://www.icmje.org>).
- 9.4 Sponsor shall register the Clinical Trial with one or more public clinical trial registry(ies) in accordance with Applicable Law and will report the results of the Clinical Trial publicly when and to the extent required by Applicable Law.

## 10. INTELLECTUAL PROPERTY

- 10.1 Ownership of Intellectual Property existing as of the Effective Date is not affected by this Agreement, and no Party shall have any claims to or rights in any pre-existing Intellectual Property of another Party, except as may be otherwise expressly provided in a separate written agreement between the Parties.
- 10.2 All Sponsor Intellectual Property shall vest exclusively in Sponsor.
- 10.3 Investigator and Institution shall, and shall ensure that its Study Personnel, disclose all Sponsor Intellectual Property promptly and fully to **[choose Sponsor or CRO to match contracting party]** in writing, and Investigator and Institution, hereby assign, and shall ensure that their respective Study Personnel assign, to Sponsor all of its rights, title and interest in and to all Sponsor Intellectual Property, including all patents, copyrights and other intellectual property rights contained therein (but excludes patient medical records) and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights.
- 10.4 Institution and Investigator shall cooperate and assist Sponsor, at Sponsor's expense, by executing, and ensuring that their respective Study Personnel execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in Sponsor Intellectual Property.
- 10.5 Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use the Clinical Trial Data, subject to the obligations set forth in Section 7 (Confidentiality and Data Protection), for its own internal research and educational purposes (all of which must be non-commercial purposes), and for Publications, presentations and public disclosures in accordance with Section 9 (Publication Rights).
- 10.6 Institution and Investigator shall reasonably cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Sponsor Intellectual Property.

## 11. FINANCIAL ARRANGEMENTS

- 11.1 **[choose Sponsor or CRO to match contracting party]** shall pay Institution in accordance with the budget and payment schedule described in Appendix 1. Unless otherwise specified in Appendix 1, all references to monetary amounts shall be to Canadian dollars.

- 11.2 If amendments to the Protocol require changes to the Clinical Trial financing arrangements, an amended financial schedule will be agreed upon by the Parties in accordance with Subsection 16.1 below.
- 11.3 Within 60 days of the close-out of the Trial Site, Institution and **[choose Sponsor or CRO to match contracting party]** shall reconcile any outstanding amounts due in accordance with Appendix 1, unless there is a written agreement between the Parties to extend the time.

## 12. TERM

- 12.1 This Agreement shall commence on the Effective Date and remain in effect until completion of the Clinical Trial and close-out of the Clinical Trial Site (“Term”), unless terminated earlier in accordance with this Agreement.

## 13. EARLY TERMINATION

- 13.1 Any Party (the “**Terminating Party**”) may terminate this Agreement with immediate effect, at any time, if another Party (the “**Defaulting Party**”) is in breach of any of the Defaulting Party’s obligations hereunder (including a material failure without just cause to meet a Timeline) and fails to remedy such breach, where it is capable of remedy, within 30 days of a written notice from the Terminating Party specifying the breach and requiring its remedy.
- 13.2 **[choose Sponsor or CRO to match contracting party]** may terminate this Agreement upon 30 days’ prior written notice to Institution and Investigator, or such shorter notice period as required by a Regulatory Authority, for any reason whatsoever.
- 13.3 Without limiting the generality of the foregoing, **[choose Sponsor or CRO to match contracting party]** may terminate this Agreement:
- a. upon reasonable prior written notice to Institution and Investigator, if Investigator is no longer able (for whatever reason) to act as the investigator and no replacement mutually acceptable to Institution and **[choose Sponsor or CRO to match contracting party]** can be found; and
  - b. immediately upon written notice to Institution or Investigator if, at any time, in Sponsor’s sole judgment, an adverse safety concern with respect to the Investigational Product makes continuing the Clinical Trial inadvisable.
- 13.4 If Institution or Investigator has a concern about the health, safety or welfare of the Clinical Trial Participants in connection with the Clinical Trial, Institution or Investigator shall give prompt notice to **[choose Sponsor or CRO to match contracting party]** and to the REB of such concerns, and may suspend the Clinical Trial, including the enrolment of Clinical Trial Participants, for a period deemed appropriate by the REB. Within 30 days of **[choose Sponsor or CRO to match contracting party]**’s receipt of notice of the suspension, **[choose Sponsor or CRO to match contracting party]** shall evaluate the concern raised by Institution or Investigator to determine if the Agreement should be terminated pursuant to this Section 13. Institution and Investigator shall continue monitoring and follow-up of enrolled Clinical Trial Participants during any suspension period

in strict adherence to the Protocol, unless otherwise directed by the REB. If the health, safety or welfare concern has not been fully resolved by **[choose Sponsor or CRO to match contracting party]** within the 30-day evaluation, Institution or Investigator may terminate this Agreement immediately upon written notice to **[choose Sponsor or CRO to match contracting party]** and the other Party, as applicable.

- 13.5 Any Party may terminate this Agreement immediately upon written notice to the other Parties in response to the loss of Regulatory Authority or REB approval for the Clinical Trial.
- 13.6 If **[choose Sponsor or CRO to match contracting party]** assigns this entire Agreement in accordance with Section 14.1, Institution and Investigator, acting reasonably, may terminate this Agreement upon 30 days' written notice to **[choose Sponsor or CRO to match contracting party]** and assignee.
- 13.7 Upon giving or receiving notice of termination of this Agreement under this Section 13, Institution and Investigator shall immediately cease enrolment of Clinical Trial Participants, and promptly return, at **[choose Sponsor or CRO to match contracting party]**'s request and expense, all copies of Confidential Information, except that Institution and Investigator are permitted to retain archival copies of Confidential Information to the extent required to exercise their rights and monitor compliance with their obligations hereunder and, where required, by Applicable Law.
- 13.8 Any Materials that are in the possession, care or control of Institution or Investigator upon expiry or termination of this Agreement shall be dealt with in accordance with Appendix III.
- 13.9 Where supported by the recipient institution, if the Clinical Trial Participants are to be transferred to another trial site, Institution and Investigator shall provide, at **[choose Sponsor or CRO to match contracting party]**'s sole expense, such reasonable assistance as is necessary to facilitate a smooth and orderly transition of the Clinical Trial with minimal disruption of the Protocol.
- 13.10 The Parties shall use reasonable efforts to minimize any inconvenience or harm to Clinical Trial Participants caused by the premature termination of the Clinical Trial and shall do all that is reasonably necessary for a safe winding up of the Clinical Trial. Without limiting the generality of the foregoing, if required for the health, safety or welfare of the enrolled Clinical Trial Participants:
  - a. 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 Investigator in consultation with the Clinical Trial Participant's physician; and
  - b. **[choose Sponsor or CRO to match contracting party]** shall continue supply of the Investigational Product as required to safely withdraw each Clinical Trial Participant or Clinical Trial Participants from the Clinical Trial.
- 13.11 In the event of the early termination of this Agreement, **[choose Sponsor or CRO to match contracting party]** shall pay all costs incurred and falling due for

payment up to the date of termination and, subject to an obligation on Institution and Investigator to mitigate any losses, any non-cancellable, non-refundable expenditure falling due for payment after the date of termination which arose from commitments reasonably and necessarily incurred by Institution or Investigator for the performance of the Clinical Trial prior to the date of termination in accordance with this Agreement.

- 13.12 Within 30 days after the termination of this Agreement, Investigator shall deliver to **[choose Sponsor or CRO to match contracting party]** in writing a final accounting of:
- a. all Clinical Trial Participants that participated in the Clinical Trial;
  - b. the Clinical Trial Participant visits completed in accordance with the Protocol during the Term; and
  - c. all reasonable direct costs incurred in connection with any transfer of the Clinical Trial to another trial site.
- 13.13 Within 45 days of delivery or receipt of the final accounting, Institution shall repay unearned monies paid by **[choose Sponsor or CRO to match contracting party]**, or **[choose Sponsor or CRO to match contracting party]** shall pay any additional amounts owed to Institution under the terms of this Agreement, as the case may be.
- 13.14 Termination of this Agreement shall be without prejudice to the accrued rights and liabilities of the Parties under this Agreement.

#### **14. ASSIGNMENT AND SUB-CONTRACTING AND ENUREMENT**

- 14.1 Neither Investigator nor Institution may assign this Agreement without the prior written consent of **[choose Sponsor or CRO to match contracting party]**. Sponsor may assign any or all of its rights and obligations under this Agreement at any time, provided that Sponsor ensures the assignee is bound by the terms hereof. Sponsor shall provide Institution and Investigator with prompt written notice of any assignment.
- 14.2 Investigator and Institution shall not subcontract the whole or any part of the performance of the Clinical Trial without the prior written consent of **[choose Sponsor or CRO to match contracting party]**.
- 14.3 This Agreement enures to the benefit of and binds the Parties and their respective successors and permitted assigns, and with respect to Investigator, administrators, heirs and executors.
- 14.4 ***Keep if contracting with Sponsor or remove if contracting with CRO:*** [Sponsor may retain one or more clinical research organizations to assist Sponsor in managing, monitoring and otherwise assisting with the Clinical Trial. Institution and Investigator acknowledge Sponsor's right to delegate, in whole or in part, without the consent of Institution or Investigator, any of its rights or obligations under this Agreement to any such clinical research organizations or to designate any such clinical research organizations to exercise such rights or

perform such obligations on behalf of Sponsor. Institution shall permit any clinical research organizations to perform any obligation(s), and to exercise any right(s), of Sponsor that have been assigned, transferred or delegated, as the case may be, to such clinical research organizations by Sponsor. Sponsor shall notify Institution or Investigator, from time to time, of the identity of any clinical research organizations and their roles with respect to the Clinical Trial to the extent reasonably necessary for Institution and Investigator to perform their responsibilities hereunder. Sponsor confirms that each clinical research organizations, by assuming any or all of Sponsor's obligations, as applicable, shall comply with the terms and conditions of this Agreement and shall be subject to the same regulatory action as Sponsor for failure to comply with any obligations under this Agreement. Notwithstanding the foregoing, Sponsor remains liable to Institution and Investigator should any clinical research organization fail to perform any of Sponsor's obligations under this Agreement, and for any negligence or willful misconduct of any such clinical research organization.]

## **15. RELATIONSHIP OF THE PARTIES**

- 15.1 Each of the Parties to this Agreement is an independent contractor. Nothing in this Agreement shall be deemed or construed to constitute a relationship of agency or employment, a partnership or joint venture between or among any of the Parties for any purpose whatsoever. No Party shall have the authority to act on behalf of another Party or to assume or create any obligation or make any commitment on behalf of another Party.

## **16. AGREEMENT AND MODIFICATION**

- 16.1 Any change in the terms of this Agreement shall be valid only if the change is made in writing, agreed to and signed by the Parties.
- 16.2 This Agreement contains the entire understanding between and among the Parties in respect of the Clinical Trial, and supersedes all other agreements, negotiations, representations and undertakings, whether written or oral, of prior date between or among the Parties relating to the Clinical Trial. Nothing in this Agreement shall, however, operate to limit or exclude any liability for fraud.

## **17. DISPUTE RESOLUTION**

- 17.1 The Parties shall attempt in good faith to resolve any dispute arising out of or relating to this Agreement promptly by negotiation between officials or representatives who have authority to settle the controversy and who are at a higher level of management or responsibility than the persons with direct responsibility for administration of this Agreement. Any Party may give the other Parties written notice of any dispute not resolved in the normal course of business.
- 17.2 Within 15 days after delivery of the notice, the receiving Party shall submit to the other Parties a written response. The notice and the response shall include:
- a. a statement of that Party's position and a summary of arguments supporting that position; and

- b. the name of the title of the official or representative who will represent that Party and any other person that will accompany the official representative.
- c. Within 30 days after delivery of the disputing Party's notice, the Parties shall meet at a mutually acceptable time and place and thereafter as often as they reasonably deem necessary to attempt to resolve the dispute. All reasonable requests for information made by one Party to the other Party or Parties shall be honoured.

17.3 All negotiations pursuant to this Section 17 are confidential and shall be treated as compromise and settlement negotiations and; therefore, deemed to be off the record and without prejudice.

## 18. FORCE MAJEURE

18.1 No Party shall be liable to any other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, terrorist activity, revolution, civil commotion, strike, epidemic, fire, and flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Parties in writing when such circumstances cause a delay or failure in performance and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible. In the event of a delay lasting for four weeks or thirty (30) working days or more, the non-affected Parties shall have the right to terminate this Agreement in accordance with Section 13 of this Agreement.

## 19. NOTICES

19.1 Any notices under this Agreement shall be in writing, signed by the relevant Party, and delivered personally, by courier, by registered mail or by facsimile or email transmission to the addresses set out below (or such other addresses as a Party may designate from time to time in writing).

Notices to **[choose Sponsor or CRO to match contracting party]** shall be addressed to:

Name:  
Title:  
Address:  
Fax:  
E-mail:

Notices to Institution shall be addressed to:

Name:  
Title:  
Address:  
Fax:  
E-mail:

Notices to Investigator shall be addressed to:

Name:

Title:

Address:

Fax:

E-mail:

Any notice delivered on a business day before 4:00 p.m. shall be deemed to have been given on that business day and after 4:00 p.m. shall be deemed to have been given on the next business day. Any notice delivered on any day that is not a business day shall be deemed to have been given on the next business day.

## **20. RIGHTS OF THIRD PARTIES**

- 20.1 Nothing in this Agreement is intended to confer on any person that is not a Party to this Agreement any right to enforce any term of this Agreement.

## **21. WAIVER**

- 21.1 A waiver of any default, breach or non-compliance of or with this Agreement is not effective unless in writing and signed by the Party or Parties to be bound by the waiver. No waiver shall be inferred from or implied by any failure to act or delay in acting by a Party in respect of any default, breach or non-observance or by anything done or omitted to be done by any other Party. The waiver by a Party of any default, breach or non-compliance under this Agreement shall not operate as a waiver of that Party's rights under this Agreement in respect of any continuing or subsequent default, breach or non-observance (whether of the same or any other nature).

## **22. SURVIVAL [REQUIRES REVIEW ONCE AGREEMENT IS COMPLETE TO ENSURE ACCURACY AND COMPLETENESS]**

- 22.1 All provisions of this Agreement which, by their nature, ought reasonably to survive the expiry or termination of this Agreement, including Section 1 (Definitions), Subsection 2.3 (Debarment), Subsection 3.2 (Notice), Subsection 4.4 (Variation of Protocol), Subsection 4.8 (Warranty regarding Investigational Products), Subsection 4.9 (Investigational Product Storage), Subsection 4.10 (Use of Investigational Product), Subsection 4.12 (Audit/Inspection), Subsection 4.13 (Research Misconduct), Subsection 4.14 (Notice of Inspection), Subsection 4.15 (Records), Subsection 4.16 (Biological Samples), Section 5 (Indemnification, Insurance Limitation of Liability), Section 6 (Clinical Trial Participant Injury), Section 7 (Confidentiality and Data Protection), Section 8 (Use of Name), Section 9 (Publication Rights), Section 10 (Intellectual Property), Section 11 (Financial Arrangements), Section 13 (Early Termination), Section 17 (Dispute Resolution), this Section 22, and Section 23 (Governing Law), shall survive any such expiry or termination.

## **23. GOVERNING LAW**

- 23.1 The interpretation and construction of this Agreement and the rights and obligations of the Parties hereunder shall be governed by the laws of the

Province of **[INSERT APPLICABLE PROVINCE]** and the laws of Canada applicable therein, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. Each of the Parties irrevocably consents to the exclusive jurisdiction of the federal and provincial courts located in **[INSERT APPLICABLE PROVINCE]**.

## **24. COUNTERPARTS**

24.1 This Agreement may be executed in two or more counterparts, which may be delivered by facsimile or electronic format, each of which shall be deemed to be an original and all of which shall together be deemed to constitute one agreement. If a paper copy with original signatures is required, the Parties will provide it in a timely manner.

## **25. LANGUAGE [ONLY INCLUDE IF A PARTY IS BASED IN QUEBEC]**

25.1 The Parties confirm that they accept that this Agreement as well as all other documents relating to this Agreement, including notices, be drawn up in English only. Les Parties aux présentes confirment qu'elles acceptent que la présente convention de même que tous les documents, y compris les avis s'y rattachant, soient rédigés en anglais seulement.

## **26. LEGAL ADVICE**

26.1 The Parties acknowledge that their legal counsel has reviewed and participated in settling the terms of this Agreement and that any rule of construction to the effect that any ambiguity is to be resolved against the drafting party shall not be applicable in the interpretation of this Agreement.

26.2 Investigator confirms that he or she has read, understands and agrees with the terms of this Agreement, that he or she has been afforded a reasonable opportunity to consult with independent legal counsel with respect to this Agreement, and that he or she signs this Agreement freely and voluntarily and without any pressure, duress or undue influence.

**IN WITNESS WHEREOF**, the Parties have executed this Agreement.

**[INSERT LEGAL NAME OF SPONSOR or CRO  
to match contracting party]**

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Name:

Title:

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Name:

Title:

**[INSERT LEGAL NAME OF INSTITUTION]**

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Name:

Title:

**[INSERT LEGAL NAME OF INVESTIGATOR]**

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Name:

Title:

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Witness Name:

Address:

Telephone Number:

**APPENDIX 1**

**FINANCIAL ARRANGEMENTS**

**BUDGET AND PAYMENTS' SCHEDULE**

**[To be inserted by the Parties]**

**APPENDIX II**

**TIMELINES**

**[To be inserted by the Parties]**

**APPENDIX III**

**MATERIALS AND THEIR DISPOSTION ON EXPIRY/TERMINATION OF AGREEMENT**

**[Parties to insert: (1) a description of any Materials (as defined in the Agreement); and (2) direction as to the disposition of the Materials upon expiry or termination of this Agreement.]**