[MODEL] CLINICAL TRIAL AGREEMENT

FOR PHARMACEUTICAL INDUSTRY SPONSORED, PHASE [II OR III],

MULTI-SITE DRUG TRIALS

COVER PAGE

Clinical Trial Code:	
Clinical Trial Name:	
Final Protocol Date or Version:	
Title:	
Number of Clinical Trial Subjects to be recruited by Institution:	

This Clinical Trial Agreement made this day of , 20___ between:

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

(hereinafter known as the "Institution")

- and -

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

(hereinafter known as the "Investigator")

- and -

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

(hereinafter known as "Sponsor")

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

BACKGROUND

The Institution is a health care organisation engaged in the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare, and has the facilities and personnel necessary to conduct the clinical trial described on the cover page of this Agreement;

The Investigator has reviewed information regarding the Sponsor's drug and the protocol for the proposed clinical trial and wishes to conduct the trial and to supervise the team members at the 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 the Institution and the Investigator to undertake the clinical.

NOW THEREFORE, in consideration of the mutual covenants and promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by each Party, the Parties agree and covenant as follows:

1. DEFINITIONS

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

1.1 "**Agent**" means any person providing services in connection with the Clinical Trial on a Party's behalf, whether or not the person is an employee of the Party;

1.2 "**Agreement**" means this Clinical Trial Agreement including the appendices attached hereto and any agreements or documents to be executed hereunder;

1.3 "**Applicable Law**" means all of the statutes, regulations, rules and guidelines, including without limitation, Regulatory Authority rules and guidelines relating to the conduct of the Clinical Trial, ICH GCP, and data protection laws that apply to the conduct of the Clinical Trial by the Institution, the Investigator and Sponsor;

1.4 "**Auditor/Monitor**" means a representative of the Sponsor authorised to carry out a systematic review and independent examination of Clinical Trial-related activities and documents to determine whether the Clinical Trial-related activities, including the collection and recording of data, were conducted, analysed and accurately reported in accordance with the Protocol, the Sponsor's standard operating procedures, ICH GCP and the applicable regulatory requirements and to conduct source data verification;

1.5 "**Clinical Trial**" means the investigation to be conducted at the Trial Site by the Investigator in accordance with the Protocol and this Agreement;

1.6 "**Clinical Trial Data**" means data, results, information, documents, discoveries, inventions, processes and methods (whether patentable or not) resulting from or developed by Investigator and/or the Institution, its employees and/or collaborators in the performance of the Clinical Trial;

1.7 "**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 CRFs, the Protocol, the Investigator Brochure, and all other reports and records necessary for the evaluation and reconstruction of the Clinical Trial, but excluding source documents and records of patient personal health information which shall remain the confidential and proprietary property of the Institution;

1.8 "**Clinical Trial IP**" has the meaning attributed thereto in Section 10.3 of this Agreement;

1.9 "**Clinical Trial Name**" means the acronym or short title found on the cover page of this Agreement;

1.10 "**Clinical Trial Subject**" means a person who is eligible and who has consented to participate in the Clinical Trial;

1.11 "**Confidential Information**" means information about Sponsor or about the Clinical Trial, that reveals scientific, technical, commercial, financial or similar information, if the disclosure of the information could reasonably be expected to,

a. prejudice significantly the competitive position of Sponsor;

b. interfere significantly with the contractual or other negotiations of any of the Parties; or

c. result in undue loss to Sponsor or undue gain to a third party,

and includes any such information exchanged between any of the Parties before the effective date of the Agreement, whether or not the information was the subject of a confidentiality agreement;

1.12 "**Food and Drugs Act**" or "**FDA**" means the *Food and Drugs Act*, R.S.C. 1985, c. F-27;

1.13 "**FDA Regulations**" means the Food and Drugs Regulations, C.R.C., c. 870, made under the FDA;

1.14 "**ICH GCP**" means the ICH Harmonised Tripartite Guideline for Good Clinical Practice, as amended from time to time;

1.15 "**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 Trial Site that the Regulatory Authority deems appropriate;

1.16 "**Intellectual Property Rights**" means patents, trade marks, trade names, service marks, domain names copyrights, trade secrets, rights in and to databases (including rights to prevent the extraction or reutilisation 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 and including applications for registration of any of them;

1.17 "**Investigational Medicinal Product**" means the drug or comparator material (including placebos used in the Clinical Trial) that is the subject of the Clinical Trial as defined in the Protocol;

1.18 "**Master File**" means the file maintained by the Investigator containing the documentation specified in ICH GCP;

1.19 "**Materials**" means any equipment, materials (excluding Investigational Medicinal Product), documents, data, software and information supplied by or on behalf of, or purchased at the expense of Sponsor, in connection with the Clinical Trial as described in Appendix III;

1.20 "**Personal Information**" means any information that is directly or indirectly referable to a natural person and protected by privacy legislation;

1.21 "**Protocol**" means the document describing the Clinical Trial (a copy of which is available by separate cover and is signed by the Investigator and approved by the REB) and all amendments thereto to which the Parties may from time to time agree in writing;

1.22 "**Regulatory Authority**" means any national, supranational or other governmental or regulatory body which has power to regulate the conduct of the Clinical Trial at the Trial Site;

1.23 "**Research Ethics Board**" or "**REB**" means an independent body, institutional, regional, national or supranational committee or review board, the responsibility of which is to ensure the protection of rights, safety and well-being of human subjects in a clinical study, including reviewing, providing direction and approving the Protocol, the suitability of the investigator(s), facilities, subject recruitment materials, methods and informed consent forms;

1.24 "**Retention Period**" has the meaning attributed thereto in Subsection 4.17;

1.25 "**Timelines**" means the dates set out in Appendix II hereto, as may be amended from time to time in accordance with Subsection 16.1 herein, and Timeline shall mean any one of such dates;

1.26 "**Trial Site(s)**" means any premises, approved by the Institution and Sponsor and listed on the cover page of this Agreement, as may be amended from time to time in accordance with subsection 16.1 herein, in which the Clinical Trial will be conducted; and

1.27 "**Trial Site Team Members**" means the persons who will undertake the conduct of the Clinical Trial at the Trial Site on behalf of the Institution or Investigator and under the supervision of the Investigator.

2. INVESTIGATOR AND INSTITUTION

2.1 The Investigator represents and warrants that he or she holds the necessary qualifications and has the necessary expertise, time and resources to perform the Clinical Trial and that the terms of this Agreement are not inconsistent with any other contractual or legal obligations that the Investigator may have, or with the Institution's policies or procedures or the policies and procedures of any institution or company with which the Investigator is associated. The Investigator shall through the duration of the Clinical Trial: (i) remain a member in good standing of the applicable College of Physicians and Surgeons or such other health profession regulatory body with which the Investigator is registered or of which the Investigator is a member; (ii) remain a member of the Canadian Medical Protective Association, or have equivalent professional liability insurance

coverage; and (iii) immediately notify the other Parties in writing if such status changes during the term of this Agreement.

2.2 The Institution and the Investigator shall recruit and ensure the performance of the obligations of the Trial Site Team Members as set out in this Agreement.

2.3 The Institution and the Investigator shall be responsible and liable for the acts and omissions of their own employees and Agents in connection with the Clinical Trial, as if such acts and omissions were those of the Institution or the Investigator.

2.4 The Institution and the Investigator represent and warrant that they are not currently using, and shall not knowingly use the services of any person, including the Investigator, who is debarred, proposed for debarment or otherwise disqualified or suspended from performing a clinical study or otherwise subject to any restrictions or sanctions by any Regulatory Authority or REB with respect to the performance of scientific or clinical investigations. The Institution and the Investigator will immediately notify Sponsor if either of them becomes aware of any such debarment, proposal for such debarment, disqualification or suspension.

3. CLINICAL TRIAL GOVERNANCE

3.1 The Institution and the Investigator acknowledge that they have been selected to conduct the Clinical Trial because of their experience, expertise and resources and not, 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, Sponsor shall:

a. promptly notify the Investigator, the Institution, and the Regulatory Authorities of any findings that could affect adversely the safety of Clinical Trial Subjects, impact the conduct of the Clinical Trial, or alter the REB's approval of the Clinical Trial; and without limiting the generality of the foregoing; and

b. expedite reporting to the Investigator, the Institution, the data safety monitoring board (if applicable) and the Regulatory Authorities of all adverse drug reactions that are both serious and unexpected.

3.3 If the Institution or the Investigator has concerns about a decision made by Sponsor under Subsection 3.2, the Institution and/or the Investigator shall contact the Sponsor's Drug Safety Representative, and if that person is not able to resolve the concerns within a reasonable period, escalate the matter to Sponsor's Medical Officer or where Sponsor's Drug Safety Representative is the Medical Officer, to Sponsor's Chief Operating Officer. In the event that Sponsor does not make a report under Subsection 3.2 after receiving the Institution or the

Investigator's concerns as set out in this Subsection 3.3, the Institution and/or Investigator may make such a report, provided that the Institution or the 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 Study Product, the rebuttable presumption shall be that the Protocol prevails; or

b. the relationship of the Parties, intellectual property, record keeping, insurance, indemnification and finances, the rebuttable presumption shall be that the Agreement prevails.

4. OBLIGATIONS OF THE PARTIES

4.1 The Investigator shall be responsible for obtaining and maintaining all approvals from the appropriate REB for the conduct of the Clinical Trial and the Investigator shall keep Sponsor and the Institution fully apprised of the progress of REB submissions and directions, and provide Sponsor and the Institution with all correspondence relating to such submissions. Sponsor shall be responsible for obtaining and maintaining authorization for the Clinical Trial from Health Canada in accordance with Part C, Division 5 of the FDA Regulations. The Investigator shall be responsible for obtaining a signed informed consent form from each Clinical Trial Subject prior to the Clinical Trial Subject's participation in the Clinical Trial. The Investigator shall be responsible for performing the services in relation to the Clinical Trial with reasonable care, diligence and skill and shall ensure that the Trial Site Team Members are competent and have appropriate professional qualifications, training and experience.

4.2 Sponsor shall submit the Clinical Trial for listing in a free, publicly accessible clinical trial registry prior to initiation of Clinical Trial Subject enrolment and give the Institution and the Investigator notice of same. For greater certainty, neither the Institution nor the Investigator shall register either the Clinical Trial or the results of the Clinical Trial on any publicly accessible clinical trial registry. Sponsor shall ensure that a non-promotional summary of the results of the Clinical Trial or a citation or link to a peer-reviewed article in a medical journal where one exists, shall be posted on a free publicly accessible clinical trial results database within one year after the Investigational Medicinal Product is first approved and made commercially available in any country or, if the Clinical Trial is under review by a peer-reviewed journal that prohibits disclosure of results pre-publication, as soon as practicable after publication.

4.3 The Parties shall conduct the Clinical Trial in accordance with:

a. the Protocol and the Clinical Trial Subject informed consent form, as approved by the REB;

b. the Investigator's Brochure and other prescribing information provided by Sponsor;

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 and GCPs;

g. the terms and conditions of this Agreement; and

h. any other written instructions that may be provided from time to time to the Institution by Sponsor.

4.4 Sponsor acknowledges that, if the Institution is in receipt of 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 Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans" (2010) shall apply to the conduct of the Clinical Trial at the Institution.

4.5 Where allowance is made for medically necessary variations to the Protocol by the REB, or as required for ethical medical practice, (including without limitation in connection with any required variation in the dates on which or the frequency with which the Investigative Medicinal Product is administered), the Investigator may diverge from the Protocol to the extent required to address the medically necessary variation or ethical medical practice, and the Investigator shall immediately record any such divergence in the source document, promptly report the variation to Sponsor and, as necessary the REB, and any such variation shall not constitute a failure to follow the Protocol or more generally, a breach of this Agreement.

4.6 Until Sponsor has obtained all required documentation from the Regulatory Authority and REB approval, it shall not supply the Investigational Medicinal Product to the Institution. The Investigator shall ensure that neither administration of the Investigational Medicinal Product to any Clinical Trial Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any Clinical Trial Subject until the Investigator is satisfied that all relevant regulatory approvals and an approval from the REB have been obtained as well as Sponsor's written confirmation of the start date for the Clinical Trial at the Clinical Trial Site.

4.7 Sponsor shall make available to the Investigator copies of the Protocol and the Investigator's Brochure, and the Investigator shall include such documents together with evidence of the approval of the REB in the Master File.

4.8 The Investigator shall complete a financial disclosure form in a format provided by Sponsor and ensure that each Trial Site Team Member to whom financial disclosure applies, completes the form.

4.9 Sponsor shall provide the Institution and the Investigator, as applicable and in accordance with the Protocol, with the Investigational Medicinal 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 Medicinal Product. Sponsor represents and warrants to the Institution and the Investigator that all Investigational Medicinal Products shall be manufactured and provided in full compliance with Applicable Law and specifications. If the Investigational Medicinal Product is to be imported, Sponsor shall not list the Institution or Investigator as an importer.

4.10 The Investigator shall keep the Investigational Medicinal Product in a locked, secured area at all times, within the temperatures required in the Protocol and maintain, complete, up-to-date records showing receipt of shipments, dispensing and returns of the Investigational Medicinal Product as required by the Protocol and Applicable Law.

4.11 Neither the Institution nor the Investigator shall permit the Investigational Medicinal Product to be used for any purpose other than the conduct of the Clinical Trial and upon termination or expiration of this Agreement, all unused Investigational Medicinal Product shall, at Sponsor's option, either be returned to Sponsor or disposed of in accordance with the Protocol or Sponsor's written instructions. Notwithstanding the preceding, subject to any necessary regulatory approval being granted, the Sponsor shall, on the written request of and in consultation with the Investigator, assess its ability to continue to supply the Investigational Medicinal Product for a particular Clinical Trial Subject, free of charge to the Clinical Trial Subject and the Institution, on specified terms and conditions and for an established period of time. The Parties shall take into consideration the following and any additional factors that the Parties consider relevant to the assessment in regard to the Clinical Trial Subject:

a. the nature of his or her illness and more particularly, whether it is considered life-threatening or likely to result in serious residual disability;

b. the availability of other therapeutic options;

c. the degree of clinical benefit he or she derived from the Investigational Medicinal Product;

d. the availability of the Investigational Medicinal Product in Canada;

e. any extension protocol approved by the REB; and

f. any government-administered program under which the Investigational Medicinal Product may be administered prior to receiving regulatory approval.

Any agreement reached under this Subsection 4.10 shall be set out in writing and the written instrument executed by each Party prior to the delivery of the Investigational Medicinal Product.

4.12 The Investigator shall use reasonable efforts to recruit the agreed upon number of Clinical Trial Subjects (as set out on the cover page of this Agreement) on a timely basis and the Parties shall use reasonable efforts to conduct the Clinical Trial in accordance with the Timelines.

4.13 The Parties acknowledge and agree that the Clinical Trial will involve the participation of multiple sites and recruitment will be competitive and the Institution and the 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 Trial Site, regardless of whether the Institution has reached its individual enrolment goal.

4.14 The Institution shall permit the Auditor/Monitor or Inspector access to all relevant clinical data of the Clinical Trial Subjects for monitoring and source data verification during normal business hours, on reasonable notice. The Investigator, and members of the Clinical Trial Team as needed, shall make themselves available to the Auditor/Monitor. The monitoring or verification conducted under this Subsection 4.13 may take any form Sponsor reasonably deems appropriate, including an inspection of the 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 health information compiled by or for the Institution or to exempt the Auditor/Monitor from any processes that the Trial Site has in place requiring the Auditor/Monitor to sign a confidentiality statement. Sponsor shall alert the Institution and the Investigator promptly to significant issues, in the opinion of the Sponsor, arising out of such monitoring or verification.

4.15 The Institution shall have written procedures for investigating any research misconduct at the Trial Site. If Sponsor reasonably believes there has been any research misconduct in relation to the Clinical Trial, Sponsor shall promptly notify the Institution and request the Institution's procedures for making a research misconduct complaint. The Institution and the Investigator shall provide all reasonable assistance in a timely manner to any investigation into same in accordance with the Institution's research misconduct procedure. In the event that the Institution or the Investigator reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Institution or the Investigator shall notify the Auditor/Monitor and Sponsor promptly. The Institution agrees to provide the Sponsor with a confidential report of the results

of any research misconduct investigation it conducts in relation to the Clinical Trial.

4.16 To the extent permitted by law, the Institution and the Investigator shall immediately inform Sponsor of any intended or actual inspection, written inquiry or visit to the Trial Site by any Regulatory Authority in connection with the Clinical Trial and forward promptly to Sponsor copies of any correspondence from any such Regulatory Authority relating to the Clinical Trial. The Institution or the Investigator shall use all reasonable efforts to obtain the consent of the Regulatory Authority to have a representative of Sponsor present during any a visit. If a representative of Sponsor is unable to be present during a visit, the Institution and the Investigator shall provide Sponsor with a detailed written report of the visit promptly following the visit.

4.17 The Institution and the Investigator shall keep complete and accurate records of the conduct of the Clinical Trial and of all Clinical Trial Data in accordance with generally accepted industry standards and practices and Applicable Law. The Institution and the Investigator agree to retain all such records for a period of not less than twenty-five (25) years from the date of termination of this Agreement (the "**Retention Period**"). At Sponsor's request and expense, the Institution or the Investigator shall retain the Clinical Trial Documentation and Clinical Trial Data after the expiry of the Retention Period. The Institution shall use reasonable efforts to give Sponsor notice before destroying the Clinical Trial Documentation and Clinical Trial Data.

4.18 The Institution and the 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 Sponsor and with the Clinical Trial Subject's informed consent. The Parties shall treat all clinical biological samples as Personal Information as defined in this Agreement.

4.19 The Investigator shall not, during the term of this Agreement, conduct any other clinical trial using the same eligibility criteria which might hinder the recruitment of the required cohort of Clinical Trial Subjects or otherwise hinder the performance of the Clinical Trial in accordance with the Protocol.

5. Indemnification, limitation of liability, insurance

5.1 Sponsor agrees to defend, indemnify and hold harmless the Institution and the Investigator and their respective directors, officers, employees, Agents, and Trial Site Team Members (the **"Indemnitees"**), against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a third party against an Indemnitee for harm:

a. arising out of or relating to the administration of the Investigational Medicinal Product in accordance with the Protocol or any clinical intervention or

procedure provided for or required by the Protocol to which the Clinical Trial Subjects would not have been exposed but for their participation in the Clinical Trial;

b. arising out of errors or omissions by Sponsor;

c. arising out of or relating to the negligence or wilful misconduct of Sponsor in performing its obligations under this Agreement;

d. arising out of or relating to the violation of Applicable Law related to the conduct of the Clinical Trial by Sponsor; or

e. arising out of or relating to the breach of any provision of this Agreement by Sponsor.

5.2 The Institution agrees to defend, indemnify and hold harmless the Sponsor, the Investigators and their respective directors, officers, employees and Agents (the **"Indemnitees"**) against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a third party against an Indemnitee for harm:

a. arising out of or relating to the negligence or wilful misconduct of the Institution, its employees and Agents in performing their obligations under this Agreement;

b. arising out of errors or omissions by Institution;

c. arising out of or relating to the failure of the Institution, its employees and Agents to comply with the provisions of this Agreement, the Protocol, or any written instructions of Sponsor concerning the Clinical Trial; or

d. arising out of the violation of Applicable Law related to the conduct of the Clinical Trial by the Institution, its employees or Agents.

5.3 The indemnities set out in 5.1 and 5.2 shall not apply to a claim or proceeding:

a. if the Indemnitee has made any admission or taken any action relating to the claim or proceeding that is prejudicial to the defence of it without the written consent of the indemnifying party;

b. to the extent that the claim or proceeding is caused by a breach of this Agreement, by a negligent, reckless or wrongful act or omission, or by a breach of a statutory duty, by an Indemnitee;

c. to the extent that the claim or proceeding is caused by the failure of an Indemnitee to conduct the Clinical Trial in accordance with the Protocol;

d. if the Indemnitee fails to notify the indemnifying party in writing of the claim or proceeding as soon as reasonably practicable (but no more than 10 business days after the Indemnitee becomes aware of it or, if there is no prejudice to the indemnifying party, within a reasonable period thereafter); or

e. if, after a request by the indemnifying party, the Indemnitee fails to cooperate with the indemnifying Party in the defence of any claim or proceeding, including providing prompt notice of any such claim or proceeding and the provision of all material documentation. The Indemnitee has a right, however, to retain its own counsel to conduct a full defence of any claim or proceeding.

5.4 The Investigator shall be liable for all claims and proceedings made or brought by a third party against an Indemnitee for harm:

a. arising out of or relating to the negligence or wilful misconduct of the Investigator, his or her employee or any person for whom the Investigator is responsible at law in performing their obligations under this Agreement;

b. arising out of or relating to the failure of the Investigator, his or her employees and any person for whom the Investigator is responsible at law to comply with the provisions of this Agreement, the Protocol, or any written instructions of Sponsor concerning the Clinical Trial; or

c. arising from a violation of Applicable Law related to the conduct of the Clinical Trial by the Investigator, his or her employees or any person for whom the Investigator is responsible at law.

5.5 Each Party shall use reasonable efforts to inform the other Parties promptly of any circumstances of which it is aware that are reasonably likely to give rise to a claim or proceeding and shall keep the other Parties reasonably informed of developments in relation to any claim or proceeding, even where a Party decides not to make a claim for indemnification under this Section 5. The Parties further agree that they have a right to retain their own counsel to conduct a full defence of any such claim or proceeding.

5.6 The Institution, the Investigator and Sponsor shall each give to the others such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding concerning the Clinical Trial.

5.7 The Institution and the Investigator shall not be liable for any claim or loss arising out of Sponsor's use of the results of the Clinical Trial or any Clinical Trial IP.

5.8 The Institution and the Investigator make no representations or warranties regarding any merchantability of the Clinical Trial results or Clinical Trial IP, or fitness of the Clinical Trial results or Clinical Trial IP for any particular purpose.

5.9 No settlement or compromise of a claim or proceeding subject to indemnification under this Section 5 shall be binding on a Party without the prior written consent of the other affected Party(s). A Party shall not unreasonably withhold such consent of a settlement or compromise. Without limiting the generality of the preceding, no Party shall admit fault on behalf of an Indemnitee or enter into a non-monetary settlement that places future obligations on an Indemnitee without the written approval of the Indemnitee.

5.10 With the exception of a Party's obligations under an indemnifying provision in this Agreement, or under the provisions concerning confidentiality and use of name found in Articles 5 and 7 and in Subsection 8.2, 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 special, indirect or consequential damage of any nature,.

5.11 Each of Sponsor, the Institution and the Investigator shall maintain appropriate and sufficient liability protection in respect of their respective obligations to third parties under this Agreement. For the Investigator, this may include membership in the Canadian Medical Protective Association, evidence of which shall be provided upon request. Each of Sponsor and the Institution shall produce, upon request of the other, a copy of insurance certificates attesting to the insurance coverage described in this Subsection. For greater certainty, the terms of any insurance or the amount of cover shall not relieve any Party of its liabilities under this Agreement.

6. SUBJECT INJURY

6.1 Sponsor shall reimburse the Institution for all reasonable expenses incurred as a result of an injury or illness caused as a direct result of a Clinical Trial Subject's participation in the Clinical Trial, except to the extent that such expenses are covered by government sponsored insurance or to the extent that such injury or illness is a direct result of:

a. A breach of this Agreement,

b. A negligent, reckless or wrongful act or omission or a breach of a statutory duty by the Institution, the Investigator or a Trial Site Team Member; or

c. Without limiting the generality of a) and b), the failure of the Institution or Investigator to conduct the Clinical Trial in accordance with the Protocol.

7. CONFIDENTIALITY, DATA PROTECTION

7.1 The Institution and the Investigator shall ensure that only those of its directors, officers, employees and Agents directly concerned with the carrying out of this Agreement who have a "need to know" and the REB, as required by the terms of this Agreement, shall have access to Confidential Information, provided all such persons are obligated to deal with Confidential Information in a manner consistent with the terms of this Agreement.

7.2 The Institution and the Investigator undertake to treat as strictly confidential and not to disclose to any third party, any Confidential Information. Notwithstanding the foregoing, nothing in this Agreement shall prevent:

a. (i) the Institution or the Investigator from disclosing Confidential Information as required by a Regulatory Authority, by Applicable Law or court order, provided that in each case, the Institution or the Investigator give Sponsor prompt written notice in order to allow Sponsor to take whatever actions it deems necessary to protect its Confidential Information;

b. (ii) the Investigator from complying with his or her professional obligations, including the standards of practice of his or her profession including the obligation to disclose information to actual or prospective Clinical Trial Subjects for the purposes of obtaining and maintaining informed consent; and

c. (iii) the REB from complying with its requirements, including the ability to coordinate reviews of ethical and safety concerns with REBs of other trial sites participating in the Clinical Trial.

7.3 The Institution and the Investigator undertake not to make use of any Confidential Information other than in accordance with this Section 7, without the prior written consent of Sponsor.

7.4 The obligations of confidentiality set out in this Section 7 shall not apply to Confidential Information which is:

a. (i) published or becomes generally available to the public other than as a result of a breach of the undertakings hereunder by the Institution or the Investigator;

b. (ii) in the possession of the Institution or the Investigator prior to its receipt from Sponsor, as evidenced by contemporaneous written evidence, and is not subject to a duty of confidentiality;

c. (iii) obtained by the Institution or the Investigator from a third party not subject to a duty of confidentiality; or

d. (iv) expressly permitted to be disclosed under this Agreement.

7.5 If the Investigator decides not to proceed with a Clinical Trial prior to any Clinical Trial Documentation being provided to the REB or the Institution, the Investigator shall return all Confidential Information to Sponsor at Sponsor's request.

7.6 The Institution and the Investigator shall maintain Confidential Information and Clinical Trial Subject Personal Information in a secure facility, taking commercially reasonable steps to protect such information from unauthorized use, access and disclosure.

7.7 Subject to Subsection 7.8, unless otherwise expressly set out in this Agreement, the obligations of the Institution and the Investigator under this Section 7 shall remain in force for a period of ten (10) years commencing on the date of the termination or expiry of this Agreement. In addition, if requested by the Sponsor in writing before the expiry of the ten (10) year period, the Institution and Investigator shall maintain an identified subset of the Confidential Information as confidential under the terms herein for an additional ten (10) years commencing on the date on which the Sponsor's request was received by the Institution and Investigator.

7.8 The Parties agree to abide by Applicable Law relating to the protection of Clinical Trial Subject Personal Information and where Confidential Information is also Personal Information, the obligations in this Section 7 shall remain in force for the period required under such law. The Party that received Personal Information hereunder shall only use or disclose the Personal Information as set out in the Clinical Trial Subject's consent form or as required by Applicable Law. Each Party shall give prompt notice to the other Parties of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

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 the Agreement, without the prior written approval of all of the other Parties. Notwithstanding the foregoing and subject to Subsection 8.2:

a. Sponsor shall have the right to identify the Institution as the site at which the Clinical Trial was conducted and to identify the Investigator and the

responsible Trial Site Team Members in connection with activities relating to the Clinical Trial;

b. the Institution may use Sponsor's name, the name of the Clinical Trial, the duration of the Agreement, and the annual aggregate amount of funding provided by Sponsor to the Institution for clinical trials conducted at the Institution for financial reporting purposes, as required by the Institution's policies;

c. the Institution may name Sponsor as a financial supporter of clinical studies conducted at the Institution, and may include the funding for the Clinical Trial in an annual aggregate number which represents all funding received by the Institution for all clinical trials funded by private industry conducted at the Institution, to a public funding agency requesting such information from the Institution;

d. the Investigator may in his or her *curriculum vitae* list Sponsor's name, the name of the Clinical Trial, and the duration of the Agreement;

e. if required by a funding agency as part of a submission for a grant, the Investigator may list the total amount of funding received from Sponsor solely for the purpose of making the grant submission; and

f. the Institution and the 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 of its commercial products or services by another Party.

9. PUBLICATION

9.1 In the case of a Phase III trial, Sponsor shall submit the results of the Clinical Trial for publication.

9.2 Sponsor shall submit Clinical Trial results for publication, as set out in Subsection 9.1 above:

a. within eighteen (18) months after obtaining regulatory approval of the Investigational Study Drug or a decision to discontinue development of the Investigational Study Drug;

b. if publication is based on results obtained at the Trial Site (or a group of trial sites), after the date of the first Clinical Trial publication based on the results from all sites; or

c. as otherwise agreed to by the Parties in writing.

9.3 The Institution and the Investigator shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, methods and results of the Clinical Trial from the Trial Site, in accordance with this Section 9 and any publication policy described in the Protocol. The Institution or the Investigator may prepare material for publication or presentation derived from the Clinical Trial Data and Clinical Trial Documentation. Except for data, results and methods of the Clinical Trial, no such publication or presentation may include Confidential Information without Sponsor's prior written approval. Proposed publications and presentations shall be submitted to Sponsor for review and comment at least ninety (90) calendar days prior to submission for publication, public dissemination, or review by a publication committee.

9.4 Where Sponsor indicates that the proposed publication or presentation contains Confidential Information, the Institution or Investigator shall remove such information from the publication or presentation, provided that Sponsor shall not request the removal of, and the Institution and Investigator shall not be required to remove data, results or methods of the Clinical Trial.

9.5 Where Sponsor indicates that the proposed publication or presentation contains information for which Sponsor wishes to obtain intellectual property protection, the Institution or the Investigator shall have the option to either:

a. remove such information from the proposed publication or presentation in order to proceed immediately with the publication, or

b. delay publication until the earlier of:

9.5.b.1 the date on which Sponsor has obtained the applicable intellectual property protection; and

9.5.b.2 one-hundred and eighty (180) calendar days from the date of receipt by Sponsor of the proposed publication or presentation for its review and comment.

9.6 The Institution and the Investigator shall give serious consideration to incorporating comments of Sponsor in relation to proposed publications and presentations. However, Sponsor is not granted any right to edit such publications and presentations and the final analysis of the results published by the Institution or Investigator lies with the Investigator.

9.7 The Institution and the Investigator acknowledge that Sponsor shall have the right to independently present as to the methods and results of the Clinical Trial at symposia, national or regional professional meetings, and publish in journals, theses or dissertations, or otherwise at its discretion, provided that it duly acknowledges the intellectual contribution made by the Institution and the Investigator in accordance with standard scientific practice. In the event that

Sponsor coordinates a multi-centre publication, the participation of the Investigator or other representative of the Institution as a named author shall be determined in accordance with Sponsor's publication policy and International Committee of Medical Journal Editors (ICMJE) standards for authorship.

10. INTELLECTUAL PROPERTY

10.1 All Intellectual Property Rights owned by or licensed to Sponsor prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the Clinical Trial, are and shall remain the exclusive property of Sponsor.

10.2 All Intellectual Property Rights owned by or licensed to the Institution or the Investigator prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the Clinical Trial, are and shall remain the exclusive property of the Institution or the Investigator, as applicable.

10.3 All Intellectual Property Rights (including Clinical Trial Data and Clinical Trial Documentation) arising from and relating to the Clinical Trial, the Investigational Medicinal Product or the Protocol (the "**Clinical Trial IP**") shall be the exclusive property of Sponsor and for this purpose, the Institution and the Investigator hereby assign and transfer, and shall cause the Trial Site Team Members to assign and transfer, without additional consideration, to Sponsor (or its nominate designee), all their rights and title in and to the Clinical Trial IP throughout the world. The Institution and the Investigator shall execute and deliver, and shall cause the Trial Site Team Members to execute and deliver, all such documents and, at Sponsor's expense, do all such other acts as Sponsor may reasonably require in order to vest fully and effectively all Clinical Trial IP in Sponsor or its nominate designee.

10.4 The Institution and the Investigator shall promptly disclose to Sponsor any Clinical Trial IP generated pursuant to this Agreement and shall treat the Clinical Trial IP as Confidential Information.

10.5 Sponsor hereby grants to the Institution and the Investigator a non-exclusive, perpetual, royalty-free license, without the right to grant sub-licenses, to use the Clinical Trial Data generated in the performance of this Agreement for its own non-commercial, internal research or educational purposes, on the condition that the Institution and the Investigator comply with the restrictions relating to Confidential Information and publication in Sections 7 and 9 of this Agreement and that the use of such license does not result in the infringement of any Intellectual Property Right of Sponsor. For the avoidance of doubt, this grant does not include any rights to use any inventions related to or derived from the Investigational Medicinal Product.

10.6 The Institution and the Investigator shall make it a condition of participation in the Clinical Trial, that the Investigator and each Trial Site Team Member waive their moral rights in their works in respect of the Clinical Trial for the benefit of

Sponsor and its successors, assigns and licensees, and sign all required documentation to effect the waiver. Sponsor shall maintain the accuracy of the data, results and interpretations of the Investigator and shall not modify such data, results and interpretations in any way that harms the reputation of the Investigator or any Trial Site Team Member. Notwithstanding the preceding:

a. the waiver of moral rights under this Subsection 10.6 does not apply to publications of the Institution or Investigator approved under Section 9; and

b. Sponsor is not prevented from using the name of the Investigator or Trial Site Team Member in accordance with Section 8.

11. FINANCIAL ARRANGEMENTS

11.1 Sponsor shall pay Institution in accordance with the arrangements relating to the financing of this Clinical Trial by Sponsor as set out in Appendix 1 hereto. Unless otherwise specified in Appendix 1 hereto, all references to monetary amounts shall be to Canadian dollars.

11.2 In the event that amendments to the Protocol require changes to the Clinical Trial financing arrangements, an amended financial schedule will be signed by the Parties in accordance with Subsection 16.1 below.

11.3 Within 45 days of the close-out of the Trial Site, the Institution and Sponsor shall reconcile any outstanding amounts due in accordance with Appendix 1, unless there is a written agreement between the Institution, the Investigator and Sponsor to extend the time.

12. TERM

12.1 This Agreement shall remain in effect until completion of the Clinical Trial and close-out of the Trial Site, 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 thirty (30) days of a written notice from the Terminating Party specifying the breach and requiring its remedy.

13.2 Sponsor may terminate this Agreement upon thirty (30) days prior written notice to the Institution and the 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, Sponsor may terminate this Agreement:

a. upon reasonable prior written notice to the Institution and the Investigator, if the Investigator is no longer able (for whatever reason) to act as the investigator and no replacement mutually acceptable to the Institution and Sponsor can be found; and

b. immediately upon written notice to the Institution or the Investigator if, at any time, in Sponsor's sole judgment, an adverse safety concern with respect to the Investigational Medicinal Product makes continuing the Clinical Trial inadvisable.

13.4 If the Institution or the Investigator have concerns about the health, safety or welfare of the Clinical Trial Subjects in connection with the Clinical Trial, the Institution or the Investigator shall give prompt notice to Sponsor and to the REB of such concerns, and may suspend the Clinical Trial, including the enrolment of Clinical Trial Subjects, for a period deemed appropriate by the REB. Within thirty (30) days of Sponsor's receipt of notice of the suspension, Sponsor shall evaluate the concerns raised by the Institution or the Investigator to determine whether the Agreement should be terminated pursuant to this Section 13. The Institution and the Investigator shall continue monitoring and follow-up of enrolled Clinical Trial Subjects during any suspension period in strict adherence to the Protocol, unless otherwise directed by the REB. If the health, safety and welfare concerns have not been fully resolved by Sponsor within the thirty (30) day evaluation, the Institution or the Investigator may terminate this Agreement immediately upon written notice to Sponsor.

13.5 Any Party may terminate this Agreement immediately upon written notice to the other Parties in response to the loss of regulatory or REB approval for the Clinical Trial.

13.6 Upon giving or receiving notice of termination of this Agreement under this Section 13, the Institution and the Investigator shall immediately cease enrolment of Clinical Trial Subjects, and promptly return, at Sponsor's request and expense all copies of Confidential Information, except that the 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.

13.7 Any Materials which are in the possession, care or control of the Institution or the Investigator upon termination of this Agreement shall be dealt with in accordance with Appendix III.

13.8 If the Clinical Trial Subjects are to be transferred to another trial site, the Institution and the Investigator agree to provide, at Sponsor's sole expense, such reasonable assistance as is necessary to ensure a smooth and orderly transition

of the Clinical Trial with no disruption of the Protocol. The Parties shall use reasonable efforts to minimize any inconvenience or harm to Clinical Trial Subjects 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 Subjects,

a. the Institution or the 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 the Investigator in consultation with the Clinical Trial Subject's physician; and

b. Sponsor shall continue supply of the Investigational Product as required to safely withdraw each Clinical Trial Subject from the Clinical Trial.

13.9 In the event of the early termination of this Agreement, Sponsor shall pay all costs incurred and falling due for payment up to the date of termination and, subject to an obligation on the Institution and the Investigator to mitigate any losses, also any non-cancellable, non-refundable expenditure falling due for payment after the date of termination which arose from commitments reasonably and necessarily incurred by the Institution or the Investigator for the performance of the Clinical Trial prior to the date of termination, as agreed with Sponsor.

13.10 Within thirty (30) days after the termination of this Agreement, the Investigator shall deliver to Sponsor in writing a final accounting of:

a. all Clinical Trial Subjects that participated in the Clinical Trial;

b. the Clinical Trial Subject visits completed in accordance with the Protocol during the term of this Agreement; and

c. all reasonable direct costs incurred in connection with any transfer of the Clinical Trial to another trial site.

13.11 Within forty-five (45) days of delivery or receipt of the final accounting, the Institution shall repay unearned monies paid by Sponsor, or Sponsor shall pay any additional amounts owed to the Institution under the terms of this Agreement, as the case may be.

13.12 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 the Investigator nor the Institution may assign this Agreement without the prior written consent of Sponsor. 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 the Institution and the Investigator with prompt written notice of any assignment.

14.2 The Investigator and the Institution shall not subcontract the whole or any part of the performance of the Clinical Trial without the prior written consent of Sponsor.

14.3 This Agreement enures to the benefit of and binds the Parties and their respective administrators, successors and permitted assigns, and with respect to the Investigator, heirs and executors.

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 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 obligations or make any commitments 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 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 the Parties, or between any two of the Parties, relating to the Clinical Trial. Nothing in this Agreement shall, however, operate to limit or exclude any liability for fraud.

17. FORCE MAJEURE

17.1 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, 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 (4) weeks or more, the non-affected Parties shall have the right to terminate this Agreement in accordance with Section13 of this Agreement.

18. NOTICES

18.1 Any notices under this Agreement shall be in writing, signed by the relevant Party to this Agreement and delivered personally, by courier or by registered mail.

Notices to the Sponsor shall be addressed to:

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

Notices to the Institution shall be addressed to:

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

Notices to the Investigator shall be addressed to:

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

19. RIGHTS OF THIRD PARTIES

19.1 Nothing in this Agreement is intended to confer on any party that is not a Party to this Agreement, any right to enforce any term of this Agreement.

20. WAIVER

20.1 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 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).

21. SURVIVAL

21.1 All provisions of this Agreement which, by their nature, ought reasonably to survive the termination or expiry of this Agreement, including without limitation, Subsection 1.1 (Definitions), Subsection 2.4 (Debarment), Subsection 3.2 (Notice), Subsection 4.4 (Variation of Protocol), Subsection 4.8 (Warranty regarding Investigational Medicinal Products), Subsection 4.9 (Investigational

Medicinal Product Storage), Subsection 4.10 (Use of Investigational Medicinal Product), Subsection 4.13 (Audit/Inspection), Subsection 4.14 (Research Misconduct), Subsection 4.15 (Notice of Inspection), Subsection 4.16 (Records), Subsection 4.17 (Biological Samples), Section 5 (Indemnification, Limitation of Liability, Insurance), Section 6 (Confidentiality, Data Protection), Section 7 (Use of Name), Section 9 (Publication), Section 10 (Intellectual Property), Subsection 13.8 (Transfer of Clinical Trial), this Section 21, and Section 22 (Governing Law), shall survive any such termination or expiry.

22. GOVERNING LAW

22.1 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.

23. COUNTERPARTS

23.1 This Agreement may be executed in two or more counterparts, which may be delivered by facsimile, each of which shall be deemed to be an original and all of which shall together be deemed to constitute one agreement.

24. LANGUAGE – [ONLY INCLUDE IF CLINICAL TRIAL BEING CONDUCTED IN QUEBEC]

24.1 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.

IN WITNESS WHEREOF, the Parties have executed this Agreement.

[INSERT LEGAL NAME OF SPONSOR]

_____
Name:
Title:

_____
Name:
Title:

[INSERT LEGAL NAME OF

INSTITUTION]

Name:
Title:

Name:
Title:

[INSERT LEGAL NAME OF INVESTIGATOR]

Name:
Title:

Witness Name:
Address:
Telephone Number:

TOR01: 4612309: v5

APPENDIX 1

FINANCIAL ARRANGEMENTS

[To be inserted by the Parties]

APPENDIX II

TIMELINES

[To be inserted by the Parties]

APPENDIX III

MATERIALS AND THEIR DISPOSTION ON TERMINATION/EXPIRY OF AGREEMENT

[Parties to Insert: (1) a description of any equipment, materials (excluding Investigational Medicinal Product), documents, data, software and information supplied by or on behalf of, or purchased at the expense of Sponsor in connection with the Clinical Trial; and (2) direction as to the disposition of the equipment and other materials upon termination or expiry of the Agreement.]