CLINICAL TRIALS AGREEMENT

THIS AGREEMENT IS MADE on _____, 2016 (the "Effective Date").

BY AND BETWEEN:

QUEEN'S UNIVERSITY AT KINGSTON, in the style and cause of the CANADIAN CANCER TRIALS GROUP, having an office at 10 Stuart Street, Kingston, Ontario, K7L 3N6 CANADA (hereinafter "**CCTG**");

and

XXXXX, having an office at [ADDRESS] (hereinafter called "**Company**").

WHEREAS:

A) CCTG desires to conduct a clinical research study, referred to as CCTG [INSERT TRIAL ID], (hereinafter the "Study") in accordance with the protocol entitled "[INSERT PROTOCOL NAME]" (the "Protocol");

B) Company is interested in the scientific outcome of the Study and the clinical testing of Company's drug, known as xxxx (the "Study Drug"); and,

C) Company is willing to support the Study by providing supplies and funding for the Study as set forth in this Agreement.

THE PARTIES THEREFORE AGREE as follows:

1. Definitions

1.1 In this Agreement the following words and phrases shall have the following meanings unless the context requires otherwise:

(1) "Affiliate" means any corporation or other business entity controlled by, controlling or under common control of Company. Control for the purposes of this definition shall mean direct or indirect beneficial ownership of fifty percent (50%) or more of the voting interest in an entity, or such other relationship as, in fact, constitutes actual control.

(2) "cGCP" means current Good Clinical Practices as established pursuant to the regulations and guidelines of the Regulatory Authority or Regulatory Authorities having jurisdiction.

(3) "cGMP" means the standards of the relevant Regulatory Authorities relating to Manufacturing practices for active pharmaceutical ingredients, viral therapeutics and vaccines, intermediates or bulk products, including those established by the principles detailed in 21 CFR 210/211: "Good Manufacturing Practice Regulations" and 21 CFR 600, 601, 610: "Biologics Regulations" and including those established by the European Medicines Agency and Health Canada.

(4) "ICH" means the International Conference on Harmonisation of Technical Requirements

for Registration of Pharmaceuticals for Human Use.

(5) "Participating Centres" means any Study sites participating in the Study including those sites with investigators and institutions located in Canada.

(6) "Participating Investigator" means the clinician investigators at each Participating Centre who are conducting the Study at that site.

(7) "Regulatory Authority" means the European Medicines Agency, the United States Food and Drug Administration, the Health Products and Food Branch of Health and Welfare Canada, or other agency having authority for the evaluation, approval or regulation of medicinal products.

(8) "Research Results" means all data, information and results arising from the Study.

(9) "Biological Samples" means all clinical specimens, including, but not limited to tumour, normal tissues, extracted DNA/RNA, urine, plasma, serum, blood cells and other human tissue received by Company from CCTG under this Agreement.

2. PARTIES' RESPONSIBILITIES

2.1 CCTG will conduct the Study in accordance with the Protocol attached to this Agreement as Appendix A.

2.2 CCTG, shall use Study Drug only for the purpose of conducting the Study pursuant to the Protocol, and shall not release any Study Drug(s) to a third party other than a Participating Centre.

2.3 As consideration for CCTG's service, Company agrees to the budget and payments as detailed in Appendix B.

2.4 In performing this Study and their respective obligations under this Agreement, each party will follow and comply with all applicable laws, rules, and regulations relating to the conduct of such Study including, without limitation, those related to privacy and protection of personal information, those promulgated by Health Canada, ICH/GCP, the FDA, and the Tri-Council Policy Statement, "*Ethical Conduct for Research Involving Humans*" as amended from time to time, as well as generally accepted clinical practices and conventions such as the Declaration of Helsinki ("Applicable Laws").

2.5 Both parties agree to perform the responsibilities related to the Study as are detailed in Appendix C.

2.6 The parties recognize that Company is not the sponsor of the Study in Canada. CCTG shall have the responsibilities of a sponsor for this Study in Canada, including, but not limited to, the submission and maintenance of the CTA application and the initiation of the Study. Notwithstanding this, Company retains the following sponsor responsibilities as indicated in Appendix C:

- Manufacturing and labeling of the Study Drug;
- Supply of the Study Drug to CCTG designated Drug Warehouse;
- Providing CCTG with a summary of the Study every 6 months, including accrual and safety;
- Supplying CCTG with a current copy of the Investigators Brochure for the Study Drug and any relevant non-clinical updates in a timely manner;
- Supplying CCTG with clinical safety updates in the following manner:
    - Serious, related and unexpected adverse events from this Protocol from non-Canadian sites as CIOMS reports to enable CCTG to meet its reporting requirements to Health Canada;
    - Serious, related and unexpected adverse events from other trials with TH-302 which require immediate modification of the informed consent, protocol or conduct of the Study will be provided as CIOMS reports;
    - All other serious, related and unexpected adverse events will be provided as a 3 monthly line listing (corresponding CIOMS report upon request.

If and to the extent required by any regulatory authority with jurisdiction over the Study, Company agrees to:

- permit representatives of CCTG to examine Company's facilities at reasonable times, and
- use reasonable efforts to facilitate representative of CCTG to examine facilities of Company's contractors,

to determine the adequacy of the facilities related to the handling and storage of the Study Drug; as indicated in Appendix C.

CCTG shall permit representatives of Company to audit CCTG providing advance notice is provided, and audit is conducted at mutually acceptable times.

2.7 CCTG will provide the required Biological Samples to Company for any Protocol specified and planned assays, testing or other analyses agreed to be conducted by Company (the "Project"). Company shall comply, and shall be responsible for ensuring that any approved third party performing all or part of the Project on behalf of Company shall comply, with the applicable terms of this Agreement, the Protocol, Applicable Laws and with the following additional requirements:

a. Biological Samples may be used only for the approved Project and shall not be used outside the scope of the work specified;

b. Biological Samples will be provided in a de-identified condition and may not be connected with any patient identifying information;

c. Biological Samples shall be kept in an appropriate and secured environment;

d. Biological Samples shall be returned at the completion of the Project or immediately, upon request by CCTG;

e. Company (or approved third party) will ensure CCTG is provided with digitized images of stained slides as required; and,

f. CCTG shall be permitted to enter, in a reasonable manner, any facilities where the Biological Samples are located or analyzed to review and or audit the results and the maintenance and use of the Biological Samples.

2.8 Company will provide CCTG with the full results of the Project in a format acceptable to CCTG. The parties acknowledge that the results of the Analyses are considered part of the Research Results; are the Confidential Information of CCTG; and are subject to the publication requirements under section 5.

3. STUDY DRUG

3.1 Company shall provide CCTG with sufficient amounts of the Study Drug, free of charge, to enable CCTG to carry out the Study. CCTG shall only use the Study Drug for the purposes of carrying out the Study and shall not permit any third party to use the Study Drug except as set out in the Protocol.

3.2 Company represents and warrants to CCTG that all Study Drug provided pursuant to this Agreement by Company shall be in full compliance with cGMP, cGCP and all applicable requirements and specifications of Health Canada. For all imported Study Drug, Company agrees that it shall have a designated importer as required by the Health Canada Regulation and that neither CCTG nor Participating Centres nor Participating Investigator shall be the importer. Company will supply to CCTG copies of all such documents required to document such compliance, upon request.

CCTG allows Company or its designee to provide the Study Drug on its behalf to the designated Drug Warehouse.

Both parties agree that packaging, labeling and distribution of Study Drug will be done according to Health Canada regulations and be approved by both parties. Parties' responsibilities are specified in Appendix C.

4. CONFIDENTIALITY

4.1 Company may disclose to CCTG certain confidential and proprietary information and materials relating to the Study Drug and CCTG may disclose to Company certain confidential and proprietary information relating to the Study for the purpose of facilitating, supporting or conducting such Study. Confidential Information includes any information related to the Study, the Study Drug or Company's technology, research or business plans that Company provides to CCTG. All such confidential and proprietary information exchanged by Company and CCTG (whether verbal, written, electronically transmitted or machine reproduced) shall constitute "Confidential Information".

4.2 In consideration of Company's and CCTG's disclosure of Confidential Information to each other, each recipient agrees that, during the Study and for a period of five (5) years from the expiration or termination of the Study, it shall retain in confidence the Confidential Information belonging to the other, and will prevent disclosure of such Confidential Information to third parties. These restrictions shall not apply to Confidential Information which:

(1) was known to, or was otherwise in the possession of the receiving party or its Affiliate prior to receipt from the other party;

(2) at the time of disclosure is or thereafter becomes part of the public domain without breach of this Agreement;

(3) is obtained from third parties which have no confidentiality obligations to the contracting parties;

(4) is developed by or on behalf of the receiving party or its Affiliates independently of any disclosure hereunder; or,

(5) must be disclosed to potential subjects during the recruitment process or to subjects who are or were enrolled in the Study, or their lawful representatives, in order to obtain and maintain written informed consent or as the information relates to their health, safety or diagnosis.

4.3 Notwithstanding anything else in this Agreement, neither CCTG nor Company will be bound by any obligations of confidentiality where maintaining confidentiality could prejudice patient safety or welfare, or where they are obliged by law or regulation to disclose such information. If a party is compelled by a court, government regulatory agency or stock exchange order to disclose any Confidential Information, such party will provide the other party with prompt written notice in order to permit the other party to seek a protective order, or other appropriate remedy, or to waive compliance with the provisions of this Agreement. The party will furnish only that portion of the Confidential Information required by the court, government regulatory agency or stock exchange order.

4.4 For the purposes of this Agreement CCTG, Participating Centres, Participating Investigators and their respective personnel, Research Ethics Board members reviewing the Study for the Participating Centres, and the CCTG independent Data Monitoring Committee are <u>not</u> considered third parties.

4.5 CCTG and Company shall ensure that their respective employees, subcontractors, and agents, the Participating Centers and any other persons assisting in the conduct of the Study, including the Participating Investigators, and the CCTG independent Data Monitoring Committee to whom Confidential Information is disclosed are informed of the obligations of confidentiality under this Agreement and are made subject to the same or substantially similar obligations of confidentiality as set out herein.

5. PUBLICATION

5.1 CCTG shall publish the Research Results in the scientific literature. CCTG will submit for Company's review its manuscripts or presentations utilizing data generated from this Study intended for publication or other public disclosure and utilizing data generated from this Study at least thirty days prior to the date of submission for publication or of public disclosure. Abstracts will be submitted for Company's review at least ten (10) days prior to the date of submission for publication or public disclosure. This review is in no way intended to influence or restrict the content or conclusions of any such publication. Company may wish to publish secondary analyses after the primary research results have appeared in print in the scientific literature. Company will submit abstracts and publications to CCTG for review and approval at least thirty days prior to the date of submission for publication.

5.2 During its review period, Company may request that CCTG delete from its publication any reference to Company's Confidential Information. Company may also notify CCTG that it desires patent applications to be filed on any inventions or discoveries disclosed or contained in the publication and CCTG will defer publication or other disclosure for a period, not to exceed sixty (60) days from the date of submission to Company, sufficient to permit Company to file any desired patent applications.

5.3 Material provided by Company for internal review at semi-annual meetings of the CCTG, their investigators as well as the independent Data Monitoring Committee is not considered a publication. Attendees at such meetings shall be subject to obligations of confidentiality.

5.4 CCTG will provide a summary of the Study to www.clinicaltrials.gov for inclusion in the clinical trials listing databases. CCTG and Company reserve the right to publish information of the existence of the Study on any relevant website on the worldwide web, including the CCTG website, and Company's website; provided, however, that such information will be limited to information about the type of drug, clinical trial design, or names of Participating Centers. The Protocol and other study specific information and tools will be posted on the members-only section of the CCTG website.

5.5 No Party shall use the name or logo of the other in any publication, news release, promotion, advertisement, or other public announcement, whether written or oral, that endorses services, organizations or products, without the prior written approval of the other.

6. ACCESS TO DATA & INTELLECTUAL PROPERTY

6.1 Data collection and specified data analysis, as detailed in the Protocol, will be performed by CCTG, and the Research Results may be made available to Participating Centres, Participating Investigators, Company and the CCTG independent data monitoring committee.

6.2 Company shall not have access to any personal identifying information. Should Company come into contact with any such information, Company shall comply with all applicable privacy laws and regulations.

6.3 Any inventions or discoveries made by CCTG during the course of this Study which directly relate

to the Company's Study Drug shall be disclosed to Company and shall become the property of Company or its designated Affiliate. CCTG assigns such inventions and discoveries and associated intellectual property rights to the Company. However, CCTG shall retain the right to use any such inventions or discoveries for its own internal research and education.

Any inventions or discoveries made by CCTG during the course of the Study which are not directly related to the Company's Study Drug shall be the property of CCTG; provided however, that if such invention or discovery relates to the known properties of the Study Drug, CCTG shall promptly disclose to Company each such invention or discovery and the terms under which CCTG would be prepared to license it and Company shall have a right of first refusal to negotiate an exclusive license to develop and commercialize such invention or discovery. Company shall have thirty (30) days after receipt of such disclosure to exercise its rights of first refusal, and if so exercised, the parties shall thereafter negotiate a mutually acceptable licensing agreement in good faith. In the event that Company does not exercise its right of first refusal within such thirty (30) day period or the parties are unable to agree on terms for a licensing agreement, (a) CCTG shall have the right to license such invention or discovery to another party; provided, however, that the terms and conditions of such license shall be no more favourable to the other party than the terms and conditions upon which such invention or discovery was offered to Company pursuant to the right of first refusal granted in this Section; and, (b) Company is hereby granted an irrevocable, non-exclusive, royalty-free, sub-licensable, worldwide licence to use such invention in connection with the development and use of the Study Drug.

6.4 A Tumour and Tissue Bank (the "**Tissue Bank**") will be created and maintained by CCTG for this Study, and will be managed in accordance with CCTG Policies and Procedures for Tissue Banking. Tissue may be provided to Company for any protocol specified and planned analyses.

6.5 Subject to Section 6.3, any inventions or discoveries made by CCTG related to the Tissue Bank shall be the property of CCTG; provided however, that if such invention or discovery relates to the known properties of the Study Drug, CCTG shall promptly disclose to Company each such invention or discovery and the terms under which CCTG would be prepared to license it and Company shall have a right of first refusal to negotiate an exclusive license to develop and commercialize such invention or discovery. Company shall have thirty (30) days after receipt of such disclosure to exercise its rights of first refusal, and if so exercised, the parties shall thereafter negotiate a mutually acceptable licensing agreement in good faith. In the event that Company does not exercise its right of first refusal within such thirty (30) day period or the parties are unable to agree on terms for a licensing agreement, CCTG shall have the right to license such invention or discovery to another party; provided, however, that the terms and conditions of such license shall be no more favourable to the other party than the terms and conditions upon which such invention or discovery was offered to Company pursuant to the right of first refusal granted in this Section.

6.6 CCTG, Participating Centres, and Participating Investigators make no warranties, express or implied, as to the merchantability or fitness for a particular purpose of the Research Results or any invention or product arising from the Study.

7. INDEMNIFICATION

7.1 CCTG shall indemnify Company, its trustee, directors and personnel and hold it harmless from any liability, cost, or expense, including legal fees, arising out of, or in connection with, any injury to a person (including death) arising from Company's Study Drug used in this Study to the extent such injury relates directly to any negligent act by CCTG and its employees pertaining to the activities to be carried out pursuant to the obligations of this Agreement.

7.2 Notwithstanding the indemnity obligations in this section, CCTG will not assume responsibility for negligent acts of Participating Centres, Participating Investigators or their personnel involved in the Study.

7.3 Company shall indemnify and hold harmless CCTG, its trustees, directors and personnel and those Participating Centres, Participating Investigators, and their respective trustees, directors and personnel (the "Indemnitee(s)") from any liability, cost, or expense, (including reasonable legal fees and expenses), including without limitation claims arising from bodily injury, including death, (individually, a "Claim") arising in connection with or arising out of: (i) the use of the Study Drug in the Study; and (ii) the use by Company or any Affiliate of the data, results, materials, any other information generated under the Study, or any products based upon or incorporating such data, results, materials, or other information; except to the extent such Claims are directly attributable to: (i) an Indemnitee's failure to conduct the Study in accordance with the Protocol (it being understood however that deviation from the Protocol where necessary to eliminate any immediate hazard to Study subjects shall not be considered non-compliance with the Protocol for the purpose of this indemnification) or with generally accepted standards for clinical trials in Canada (or in the location of the Participating Site); or (ii) the negligence or willful misconduct on the part of the Indemnitee(s), or a breach of any applicable law or regulation by the Indemnitee(s). This 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.

7.4 Each party's agreement to indemnify and hold the other harmless is conditioned on the indemnified party:

(1) providing written notice to the indemnifying party of any claim, demand, cause of action or suit arising out of the indemnified activities within thirty (30) days after the indemnifying party has knowledge of such claim, demand or action;

(2) permitting the indemnifying party to assume full responsibility to investigate, prepare for and defend against any such claim, demand, causes of action or suit;

(3) assisting the indemnifying party, at the indemnifying party's reasonable expense, in the investigation or investigation of, preparation for and defense of any such claim, demand, causes of action or suit; and,

(4) not compromising or settling such claim, demand, causes of action or suit without the indemnifying party's prior written approval. In turn, the indemnifying party will not make any settlement which adversely affects in a material manner the reputation of an indemnified party without such indemnified party's prior approval, which approval shall

not be unreasonably withheld or delayed.

7.5 Company warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed under this Agreement. Upon request, Company shall provide evidence of its insurance or self-insurance to CCTG.

7.6 Company agrees to reimburse Participating Centres for all reasonable and necessary expenses incurred for medical care received by Study subjects, including hospitalisation, in the treatment of any injury or illness sustained by a Study subject as a result of his or her participation in the Study and due to the Study Drug except to the extent that (I) such cost is covered by the Study subject's public health care system or other government sponsored insurance for as long as legally applicable (II) such injury is a direct result of failure by Participating Centre, Participating investigator, and/or their personnel, including but not limited to research staff, to comply with the Protocol or all written instructions (that do not require an amendment to the Protocol in order to be implemented) regarding the administration of the Study Drug; or, (III) such injury is a direct result of the negligence or wilful misconduct of Participating Centre, Participating Investigator, and/or their personnel, including but not limited to research staff.

7.7 CCTG will ensure all Participating Centres have in place a CCTG Participating Centre Agreement, as well as a trial specific letter agreement as detailed in Appendix D.

8. TERM & TERMINATION

8.1 This Agreement shall become effective as of the Effective Date and shall continue to be effective until either the Study is completed or terminated or the Agreement is terminated in accordance with this section. It is anticipated that this study should be completed by [DATE].

8.2 This Agreement may be terminated by either party for any reason upon a thirty (30) day prior written notice. Termination shall not relieve any party of its obligations accrued prior thereto. If the study is terminated purely for business reasons and CCTG wishes to complete the Study with its own resources, the parties agree to enter into negotiations at that time for the purpose of establishing a temporary supply of the study medication and to adjust the budget of the Study.

8.3 CCTG retains the right to terminate this study for good and sufficient reasons at any time. Such reasons could include risk to patient safety, unsatisfactory patient enrollment or a decision of a regulatory agency. In addition, the Study may be terminated, on written notice, in the following circumstances:

(a) by either party, if regulatory authorization and approval to conduct the Study is withdrawn;

(b) by either party, if any adverse reaction or side effect associated with the conduct of the Study is sufficient in the opinion of the terminating party, acting reasonably, to warrant termination of the Study;

(c) by either party, if the other party has breached any material obligations pursuant to this Agreement and has failed to remedy such breach within ten (10) days after notice in writing, or if the nature of the breach reasonably requires more than ten (10) days to

remedy, if the party in default fails to commence to remedy the breach within ten (10) days or there after fails to diligently pursue the remedy to completion.

8.4 Following termination of this Agreement:

(1) Company shall reimburse CCTG all sums due under the Payment Schedule up to the date of termination and, except in the case of termination by Company pursuant to Section 8.3(c), reimburse CCTG for any prepaid, committed or accrued expenses of CCTG incurred in accordance with the terms of this Agreement, provided that in no event shall Company be responsible for expenses in excess of those set forth in the Budget attached as Appendix B; and,

(2) Any unused and uncommitted funds previously paid by Company to CCTG shall be refunded to Company.

9. MISCELLANEOUS

9.1 Any notice or communication required or permitted to be given or made under this Agreement by one of the parties to the other shall be in writing and shall be deemed to have been sufficiently given or made for all purposes on the third business day following the date of mailing by certified mail, postage prepaid, addressed to such other party at its respective address as reference below:

For Canadian Cancer Trials Group, Queen's University at Kingston:
Cancer Research Institute
10 Stuart Street
Kingston, ON K7L 3N6
Attention: CCTG Contracts Office
FAX: 613-533-2941

With a copy to:
Queen's University Research Services
3rd Floor, Fleming Hall, Jemmett Wing
78 Fifth Field Company Lane
Kingston, ON K7L 3N6
Attention: Ms. Janice Mady, Director of Industry Partnerships

For Company:
[Address]
Attention:
FAX:

9.2 This Agreement (together with any documents referred to herein) constitutes the entire Agreement of the parties with regard to its subject matter, and supersedes all previous written or oral representations, agreements and understandings between the parties in respect of the Study. Should there be any discrepancies between this Agreement and the Protocol, the Agreement shall take precedence over the Protocol. Any other modifications and changes to

this Agreement may only be recognized by written and signed consent of both Parties.

9.3 For the purposes of this Agreement, CCTG will be deemed an independent contractor and not an employee of Company. No provision of this Agreement shall be deemed to constitute any party as the agent, employee, partner, joint venture, or legal representative of any other party for any purpose whatsoever.

9.4 This Agreement shall be governed, construed and interpreted pursuant to and in accordance with the laws of the Province of Ontario, and the laws of Canada applicable to the Province of Ontario.

9.5 This Agreement may be executed in one or more counterpart copies, each of which shall be deemed an original and all of which shall together be deemed to constitute one agreement. The parties agree that execution of this Agreement by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each party waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance or the executed Agreement electronically.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS whereof this Agreement has been executed by duly authorised officers of the parties as of the Effective Date.

APPROVED on behalf of CCTG by:

_____ _____

Ms. Janice Mady
Director of Industry Partnerships
Queen's University

Date

_____ _____

[CCTG Senior Investigator]
[TITLE] Canadian Cancer Trials Group
Queen's University

Date

APPROVED on behalf of COMPANY by:

_____ _____

Signature
Name:
Title:

Date

_____ _____

Signature
Name:
Title:

Date

APPENDIX A

[INSERT PROTOCOL]

APPENDIX B

[Insert Budget]

Expenses detailed as pass through will be invoiced regularly. Payments made under the terms of this Agreement will be paid as detailed below and *made payable to:*

Queen's University
Canadian Cancer Trials Group
10 Stuart Street
Kingston, Ontario, K7L 3N6
Attention: Diane Caverley, Finance Coordinator

Payment will be made by Company within thirty (30) days of receipt of invoices from CCTG.

APPENDIX C

[Insert Roles and Responsibilities Table]

APPENDIX D

Site Agreement and Indemnification

1. Company shall indemnify and hold harmless Participating Centre, Participating Investigator, and their respective trustees, directors and personnel (the "Indemnitee(s)") from any liability, cost, or expense, (including reasonable legal fees and expenses), including without limitation claims arising from bodily injury, including death, (individually, a "Claim") arising in connection with or arising out of: (i) the use of the Study Drug in the Study; and (ii) the use by Company or any Affiliate of the data, results, materials, any other information generated under the Study, or any products based upon or incorporating such data, results, materials, or other information; except to the extent such Claims are directly attributable to: (i) an Indemnitee's failure to conduct the Study in accordance with the Protocol (it being understood however that deviation from the Protocol where necessary to eliminate any immediate hazard to Study subjects shall not be considered non-compliance with the Protocol for the purpose of this indemnification) or with generally accepted standards for clinical trials in Canada (or in the location of the Participating Site); or (ii) the negligence or willful misconduct on the part of the Indemnitee(s), or a breach of any applicable law or regulation by the Indemnitee(s). This 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.

2. Company agrees to reimburse Participating Centres for all reasonable and necessary expenses incurred for medical care received by Study subjects, including hospitalisation, in the treatment of any injury or illness sustained by a Study subject as a result of his or her participation in the Study and due to the Study Drug except to the extent that (I) such cost is covered by the Study subject's public health care system or other government sponsored insurance for as long as legally applicable (II) such injury is a direct result of failure by Participating Centre, Participating investigator, and/or their personnel, including but not limited to research staff, to comply with the Protocol or all written instructions (that do not require an amendment to the Protocol in order to be implemented) regarding the administration of the Study Drug; or (III) such injury is a direct result of the negligence or wilful misconduct of Participating Centre, Participating Investigator, and/or their personnel, including but not limited to research staff.

   The effective date of this Letter of Indemnification is the date of the last signature.

Participating Centre	**Company**
By:_____	By:_____
Name:_____	Name:_____
Title:_____	Title:_____
Date:_____	Date:_____