

This Agreement effective (“Effective Date”) as of the ____ day of _____, 2010.

CLINICAL TRIAL AGREEMENT

AMONG:

{NAME}, a medical doctor having offices at {ADDRESS}, Vancouver, British Columbia, Canada
{POSTAL CODE}

(the “Investigator”)

AND:

VANCOUVER COASTAL HEALTH AUTHORITY, an academic based healthcare system having its research administrative offices at the Willow Chest Centre – Room 100, 2647 Willow Street, Vancouver, British Columbia, V5Z 3P1 (the “Health Authority”) and THE UNIVERSITY OF BRITISH COLUMBIA, a corporation continued under the *University Act* of British Columbia and having its administrative offices at 2075 Wesbrook Mall, Vancouver, British Columbia, V6T 1W5 (the “University”)

(the Health Authority and
University collectively referred
to as the “Institution”)

AND:

{COMPANY NAME}, a corporation incorporated under the laws of {PROVINCE/STATE}, and having its registered office at {ADDRESS}, {CITY}, {PROVINCE/STATE}, {POSTAL CODE}

(the “Sponsor”)

WHEREAS:

- A. The Investigator is a faculty member of the Faculty of Medicine of the University and carries on a clinical practice within the Health Authority;
- B. The Sponsor wishes the Investigator and the Institution to participate in a Study entitled “{STUDY TITLE}” (hereinafter referred to as the “Study”) to be conducted under the direction and supervision of the Investigator using the facilities of the Institution;
- C. The Investigator and the Institution are willing to participate in the Study;
- D. The Investigator will submit to the University the Protocol (hereinafter defined) and related information and the University will conduct an ethics review of the Study through its Research Ethics Board (the “REB”);

NOW THEREFORE THIS AGREEMENT WITNESSETH that in consideration of the premises and of the mutual covenants herein set forth, the parties hereto have covenanted and agreed as follows:

1. CONDUCT OF THE STUDY

1.1 The Investigator and the Institution shall perform the Study in accordance with the protocol entitled “{STUDY TITLE}” and dated {DATE} and attached hereto and marked as Schedule “A” to this Agreement (hereinafter referred to as the “Protocol”). In the event that there is a conflict between the terms of the Protocol and the terms of this Agreement, the terms of this Agreement will govern.

1.2 The Study shall be carried out under the direction and supervision of the Investigator, and the Investigator shall have responsibility for the scientific and technical conduct of the Study. The Investigator shall be responsible for ensuring that all staff and Study personnel are properly informed as to the procedures specified in the Protocol, and for the safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Study.

1.3 Where the Study involves a compound, the Sponsor shall supply the Investigator with documentation, which describes the compound(s) being tested in the Study (“Study Drug”) and its known toxicological effects. The Sponsor shall, to the best of its knowledge, answer any questions the Investigator or the Institution may have regarding the Protocol or the Study Drug, whether such questions are asked before the commencement of the Study or during its conduct.

1.4 The Investigator shall obtain written approval for the conduct of the Study and the terms of the Protocol through the Institution’s REB prior to the commencement of the Study. The Investigator shall deliver a copy of such approval to the Sponsor and the Sponsor shall not deliver Study Drug to the Investigator or the Institution until it has received a copy of such approval. Said approval must indicate the date it was given and the name of the Chairperson or Secretary of the REB.

2. FINANCIAL TERMS

2.1 The Investigator shall issue invoices to the Sponsor on behalf of the Institution and the Sponsor shall make payments to the Institution in accordance with the budget and payment schedule attached hereto and marked as Schedule “B”. The Sponsor shall pay each invoice within sixty (60) days after receipt of same. In the event that the Sponsor fails to pay any invoice within the aforementioned time period, the Investigator and the Institution reserve the right, in their sole discretion, to suspend conduct of the Study until all outstanding payments have been received, or to continue the Study but suspend the reporting of data to the Sponsor until all outstanding payments have been received, or to terminate this Agreement in accordance with Article 13.2, or to do any combination of the foregoing. In the event that Study subjects are entered into but do not complete the Study, then in respect of said Study subjects the Sponsor shall only be required to pay the Institution on a prorated basis.

The parties shall negotiate any changes to the budget that may be necessitated by amendments to the Protocol.

3. PUBLICATION

3.1 Following completion of the Study, the Investigator and the Institution shall have the right to present at symposia, national or regional professional meetings, and to publish in journals or other publications any data or information derived from the Study, provided that:

(a) where the Study is part of a multi-centre study, the Investigator and the Institution shall not present or publish data derived from the Study until the complete multi-centre study has been reported in full; however, if the full study results have not been published within twelve (12) months after the results from all of the centers have been received, then the Institution and the

Investigator may publish or otherwise disclose the results of the Study for non-commercial purposes, subject to the other conditions of this section;

(b) where the Sponsor fails to advise the Institution and Investigator within the time specified above, the Institution and Investigator shall be entitled to proceed with the presentation and/or publication of the results of the Study;

(c) the Sponsor shall be furnished copies of the submission for the proposed presentation or publication materials at least thirty (30) days in advance of the presentation or publication date; and

(d) if, within thirty (30) days after receipt of such copies, the Sponsor requests in writing that the submission for the proposed presentation or publication be delayed on the basis that the proposed presentation or publication discloses “Confidential Information” (as defined in Article 4.1) which was disclosed by the Sponsor to the Investigator or the Institution, the Investigator and the Institution shall either remove said Confidential Information from the proposed presentation or publication or modify the proposed presentation or publication to the satisfaction of the Sponsor, after which time the Investigator and the Institution shall be free to proceed with the proposed presentation or publication;

4. CONFIDENTIALITY

4.1 Prior to or during the course of the Study, the Sponsor may provide or may have provided the Investigator and/or Institution with confidential information such as, for example, the Protocol (the “**Confidential Information**”). Such Confidential Information shall be marked in writing as “Confidential” or if disclosed orally or in other than documentary form shall be reduced to writing within thirty (30) days thereafter. Furthermore, Confidential Information shall exclude any information:

(a) already possessed by the Investigator or Institution prior to receipt from the Sponsor, other than through prior disclosure by the Sponsor, as evidenced by the Investigator’s and/or Institution’s business records;

(b) is in or becomes part of the public domain through no act or failure to act by the Institution or Investigator and without breach of the agreement;

(c) obtained by the Investigator or Institution from a third party with a valid right to disclose it, provided that said third party is not under a confidentiality obligation to the Sponsor;

(d) independently developed by employees, agents or consultants of the Investigator or Institution who had no knowledge of or access to the Sponsor’s information, as evidenced by the Institution’s or Investigator’s business records;

(e) required to be disclosed by law or a regulatory authority;

(f) reasonably required to be disclosed for the clinical care of a Study subject;

(g) published in accordance with the terms of this Agreement; or

(h) reasonably required to be disclosed to the Institution’s REB or the research ethics board of another site participating in the Study.

4.2 Subject to Articles 3.1 , the Investigator and Institution shall use reasonable efforts to not disclose the Confidential Information to anyone other than as provided for in this Agreement or in the Protocol without the prior written approval of the Sponsor. This obligation shall survive the completion or early termination of this Agreement and shall remain in effect for a period of five (5) years following the completion or early termination of the Study. Furthermore, Investigator and Institution shall not use, either directly or indirectly, any Confidential Information for any purpose other than as set forth herein without the prior written consent of the Sponsor.

4.3 In the event that the Investigator and/or Institution are required by judicial or administrative process to disclose any Confidential Information disclosed to him/her/it by Sponsor, the Investigator and/or Institution shall promptly notify the Sponsor and allow the Sponsor reasonable time to oppose such process before disclosing any Confidential Information.

5. PUBLICITY

5.1 Investigator and Institution may, without the consent of the Sponsor, disclose the existence of this Agreement, identify the parties to this Agreement, disclose the title or a general description of the Study, the duration of the Study and the nature and amount of funding and/or other support provided by the Sponsor pursuant to this Agreement in the Institution's customary publications or otherwise in satisfaction of the Institution's reporting requirements.

5.2 The Sponsor shall not use or permit others to use the name of the Investigator or the Institution or to refer to their participation in the Study for any sales or promotional purposes without their prior written consent. *[Sponsor may register the Study or cause the Study to be registered before the enrolment of the first Study subject in accordance with the requirements of the International Committee of Medical Journal Editors (ICMJE) initiative, which requires prior entry of clinical trials in a public registry as a condition for publication.]*

6. INTELLECTUAL PROPERTY RIGHTS

6.1 Data generated from the Study shall be the property of the Sponsor. Should any inventions, discoveries, new uses, processes, or compounds (the "**Inventions**") arise directly out of the Study, they shall also be the property of the Sponsor.

6.2 The Sponsor shall be entitled to file in its own name patent applications in respect of any Inventions. At the Sponsor's request, the Investigator and the Institution shall provide the Sponsor with such assistance as is reasonable to obtain and secure patent protection in respect of any Inventions, including the execution of legal documents related thereto, provided that all expenses related thereto, legal or otherwise, shall be paid by the Sponsor.

7. DISCLAIMER

7.1 The Investigator and the Institution shall carry out the Study in accordance with the Protocol. However, neither the Investigator nor the Institution promise success in achieving any particular result. The Investigator and the Institution make no representations, conditions, or warranties, either express or implied, with respect to the results of the Study.

8. INDEMNITY

8.1 The Sponsor will indemnify, defend, and hold harmless each of the Investigator and the Institution and their Boards of Governors/Directors, REB, trustees, officers, employees, agents, faculty,

students, trainees, medical and professional staff, Study personnel and contractors and their respective successors, heirs, and assigns (each, an “**Indemnitee**”) from and against any and all liabilities, losses, damages, costs and expenses (including legal fees) arising from actions, proceedings, investigations, judgments, demands, or claims (each a “**Claim**”) whatsoever arising out of, resulting from or relating to the Study, including but not limited to personal injury (including death) to Study subjects, property damage, or intellectual property infringement, caused by or attributable to (i) the use of the Study Drug or other substances provided by the Sponsor or its agents, (ii) any clinical intervention or procedure described in the Protocol; (iii) the negligence or wilful or wrongful acts or omissions of the Sponsor or its directors, officers, employees or agents; (iv) the use of materials, data or results of the Study; and (iv) failure by the Sponsor to comply with any applicable law, rule, regulation or governmental requirement, except to the extent that a Claim is caused by:

- a) the failure of the Indemnitee to comply with the material terms of the Protocol, or written and timely instructions of the Sponsor with respect to the administration of the Study Drug; or
- b) the failure of the Indemnitee to comply with the applicable laws and regulations of British Columbia and of Canada; or
- c) gross negligence or wilful or intentional malfeasance or misconduct of the Indemnitee.

8.2 The Investigator or the Institution shall promptly notify the Sponsor of any Claim for which indemnity may be sought. The Investigator and the Institution agree to cooperate fully with the Sponsor in the defense of any lawsuit, provided that each of the Investigator and the Institution be permitted to select its own legal counsel and provided that all expenses (including all legal fees and expenses) associated with such cooperation are paid by the Sponsor. No admission of liability shall be made by the Sponsor on behalf of an Indemnitee without the prior written approval of the Indemnitee.

8.3 The indemnity granted in Article 8.1 shall apply separately to each Indemnitee in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

9. INSURANCE

During and after the Study, the Sponsor shall procure and maintain, at its sole expense, policies of general liability insurance in amounts not less than \$10,000,000.00 per occurrence. Such insurance policies shall provide broad form contractual liability and product liability coverage for the Sponsor’s indemnification obligation hereunder. If the Sponsor cancels, reduces or otherwise materially modifies the insurance coverage, the Sponsor shall provide the Institution and Investigator with at least thirty (30) days written notice of the cancellation or modification, and the Institution and Investigator shall have the right thereafter to terminate their participation in the Study. The minimum amounts of insurance coverage required shall not be construed to create a limit of the Sponsor’s liability with respect to its indemnification obligations hereunder. The obligation to maintain the insurance shall survive the completion or early termination of this Agreement. The Sponsor shall provide the Investigator and the Institution with written evidence of such insurance, either in the form of a certificate or a letter of insurance upon the written request of the Investigator or the Institution.

10. NOTICES

10.1 All notices, requests, directions, reports, or other documents that any of the parties hereto are required or may desire to deliver to any other party hereto may be delivered only by personal delivery or by registered or certified mail, telex or telecopy, all postage and other charges prepaid, at the address for

such party set forth below or at such other address as any party may hereinafter designate in writing to the others. Any notice personally delivered or sent by telex or telecopy shall be deemed to have been given or received at the time of delivery, telexing or telecopying. Any notice mailed as aforesaid shall be deemed to have been received on the expiration of five days after it is posted, provided that if there shall be at the time of mailing or between the time of mailing and the actual receipt of the notice a mail strike, slow down or labour dispute which might affect the delivery of the notice by the mails, then the notice shall only be effected if actually received.

If to the Investigator: {NAME}
{ADDRESS}
{ADDRESS}
Vancouver, British Columbia, {POSTAL CODE}
Telephone: (604) {*}
Fax Number: (604) {*}

If to the Health Authority: Stephania Manusha, Regional Manager, Clinical Trials Administration
Vancouver Coastal Health Authority
Room 163 – Willow Chest Centre
2647 Willow Street
Vancouver, British Columbia, V5Z 3P1
Telephone: (604) 875-5649
Fax Number: (604) 875-4943

If to the University: Dr. J.P Heale, Associate Director
University - Industry Liaison Office
The University of British Columbia
#103-6190 Agronomy Road
Vancouver, British Columbia V6T 1Z3
Telephone: (604) 822-2199
Fax Number: (604) 822-8589

If to the Sponsor: (COMPANY NAME)
{ADDRESS}
{ADDRESS}
Telephone: (*)
Fax Number: (*)

11. ASSIGNMENT

11.1 No part of this Agreement may be assigned, delegated, or subcontracted by any party to any other person or third party without the prior written approval of the other parties.

12. GOVERNING LAW AND ARBITRATION

12.1 This Agreement shall be governed by and construed in accordance with the laws of the Province of British Columbia and of the Dominion of Canada in force therein without regard to its conflict of law rules. All parties agree that by executing this Agreement they have attorned to the exclusive jurisdiction of the courts of competent authority of British Columbia.

12.2 In the event of any dispute arising between the parties concerning this Agreement, its enforceability or the interpretation thereof, the same shall be settled by a single arbitrator appointed

pursuant to the provisions of the *Commercial Arbitration Act* of British Columbia, or any successor legislation then in force. The place of arbitration shall be Vancouver, British Columbia, Canada and the language to be used in the arbitration proceedings shall be English. Notwithstanding the foregoing, and in accordance with Article 11.1, any party may apply to a court of competent authority for interim protection such as, by way of example, an interim injunction.

13. TERM AND TERMINATION

13.1 This Agreement shall be effective from the Effective Date until the estimated end date in approximately (*) years, unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Articles 13.2 , 13.3 or 13.4 of this Agreement.

13.2 If any party shall be in default under or shall fail to comply with the terms of this Agreement then the non-defaulting parties shall have the right to terminate this Agreement by written notice to that effect if:

(a) such default is reasonably curable within thirty (30) days after receipt of notice of such default and such default or failure to comply is not cured within 30 days after receipt of written notice thereof, or

(b) such default is not reasonably curable within thirty (30) days after receipt of written notice thereof, and such default or failure to comply is not cured within such further reasonable period of time as may be necessary for the curing of such default or failure to comply.

13.3 In addition to termination for breach as specified in Article 13.2 , any party may terminate this Agreement upon sixty (60) days written notice to the other parties.

13.4 In addition to termination for breach as specified in Article 13.2 and termination without cause as specified in Article 13.3 , if any party determines that the Study Drug has excessive side effects, that party may terminate the Study and this Agreement immediately upon providing all of the other parties with written notice. In such event, the Sponsor shall reimburse the Investigator and the Institution for any and all expenses and non-cancelable obligations incurred prior to the date of receipt of such notice by the other parties up to a maximum of the total amounts set forth in Schedule "B".

13.5 In addition to termination pursuant to Articles 13.2 , 13.3 , and 13.4 , if the Sponsor determines that it no longer wishes to bring the subject of the Study to market, the Sponsor may terminate the Study and this Agreement immediately upon providing the Investigator and the Institution with written notice, provided that the Sponsor reimburse the Investigator and the Institution for any and all expenses and non-cancelable obligations incurred prior to the date of receipt of such notice up to a maximum of the total amounts set forth in Schedule "B".

12.6 If the Sponsor terminates this Agreement pursuant to Articles 13.2 , 13.3 , 13.4 , or 13.5 , or if the Investigator or the Institution terminate this Agreement pursuant to Article 13.2 or 13.4 or if the Investigator or the Institution are unable to complete the Study for reasons beyond their control, the Sponsor shall pay the Institution an amount equal to all non-cancelable costs that they have incurred plus all reasonable costs associated with shutting down the Study.

12.7 In the event of early termination, the Investigator and the Institution shall cease use of the Study Drug as soon as possible. All remaining supplies of the Study Drug shall be returned to the Sponsor together with the inventory records pertaining to the Study Drug.

13. STUDY SUBJECT INFORMATION

13.1 In order to protect the confidentiality of personal information of Study subjects, the parties agree as follows:

- (a) to use personal information only as permitted by the subject consent form or as required or permitted by law;
- (b) to refrain from publishing subject personal information in a form that could reasonably enable the Study subject's identity to be ascertained;
- (c) to refrain from obtaining additional personal information from a Study subject unless such subject has provided consent;
- (d) to be liable for the actions of their respective employees and agents for the collection, use or disclosure of personal information and for ensuring compliance with the relevant legislation by such persons.

13.2 The Sponsor acknowledges that the Institution is a public body subject to the provisions of the *Freedom of Information and Protection of Privacy Act* (British Columbia) and that the collection, use, disclosure and release of personal information under this Agreement is governed thereby.

14. GENERAL

14.1 This Agreement together with the schedules to this Agreement constitute the entire understanding between the parties hereto and supersede all previous agreements and undertakings with respect thereto. No modifications hereof shall be binding unless executed in writing by the parties hereto. The schedules will be binding upon the parties hereto except to the extent that they may conflict with the terms and conditions contained within this Agreement itself, in which case the terms and conditions of this Agreement shall govern.

14.2 The parties hereto are independent contractors. Nothing contained herein shall be deemed or construed to create between the parties hereto a partnership or joint venture or employment relationship. No party shall have the authority to act on behalf of any other party, or to commit any other party in any manner or cause whatsoever or to use any other party's name in any way not specifically authorized by this Agreement. No party shall be liable for any act, omission, representation, obligation or debt of any other party, even if informed of such act, omission, representation, obligation or debt.

14.3 Subject to the limitations hereinbefore expressed, this Agreement shall enure to the benefit of and be binding upon the parties, and their respective successors and permitted assigns.

14.4 No condoning, excusing or overlooking by any party of any default, breach or non-observance by any other party at any time or times in respect of any covenants, provisos, or conditions of this Agreement shall operate as a waiver of such party's rights under this Agreement in respect of any continuing or subsequent default, breach or non-observance, so as to defeat in any way the rights of such party in respect of any such continuing or subsequent default or breach and no waiver shall be inferred from or implied by anything done or omitted by such party, save only an express waiver in writing.

14.5 No exercise of a specific right or remedy by any party precludes it from or prejudices it in exercising another right or pursuing another remedy or maintaining an action to which it may otherwise

be entitled either at law or in equity.

14.6 Marginal headings as used in this Agreement are for the convenience of reference only and do not form a part of this Agreement and are not to be used in the interpretation hereof.

14.7 The terms and provisions, covenants and conditions contained in this Agreement which by the terms hereof require their performance by the parties hereto after the expiration or termination of this Agreement shall be and remain in force notwithstanding such expiration or other termination of this Agreement for any reason whatsoever.

14.8 In the event that any part, section, clause, paragraph or subparagraph of this Agreement shall be held to be indefinite, invalid, illegal or otherwise voidable or unenforceable, the entire agreement shall not fail on account thereof, and the balance of the Agreement shall continue in full force and effect.

14.9 Each party hereto acknowledges that it has been advised by the others to seek independent legal advice with respect to this Agreement and that it has not relied upon any of the other parties hereto for any advice, whether legal or otherwise, with respect to this Agreement.

14.10 Time shall be of the essence of this Agreement.

14.11 Whenever the singular or masculine or neuter is used throughout this Agreement the same shall be construed as meaning the plural or feminine or body corporate when the context or the parties hereto may require.

14.12 This Agreement may be signed by facsimile and simultaneously in two or more counterparts, each of which shall be deemed an original and all of which taken together shall constitute one and the same instrument.

15. FORCE MAJEURE:

Noncompliance by any party with the obligations of this Agreement due to force majeure, (including but not limited to laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers) or any other causes beyond the reasonable control of the applicable party, shall not constitute breach of this Agreement and such party shall be excused from performance hereunder to the extent and for the duration of such prevention.

IN WITNESS WHEREOF the parties hereto have hereunto executed this Agreement as of the Effective Date.

Signed for and on behalf of the **VANCOUVER COASTAL HEALTH AUTHORITY** by its duly authorized officer:

Name: Dr. Robert McMaster

Title: Interim Vice President, Research

Date: _____

Signed for and on behalf of **THE UNIVERSITY OF BRITISH COLUMBIA** by its duly authorized officer:

Name: Dr. J.P. Heale

Title: Associate Director, University Industry Liaison Office

Date: _____

Signed for and on behalf of **{SPONSOR}** by its duly authorized officer:

Name:

Title:

Date: _____

Signed for and on behalf of:

{INVESTIGATOR NAME}:

Date: _____

Schedule "A"

Study Protocol

Schedule “B”

Budget and Payment Schedule

Estimated Start Date: _____

Estimated End Date: _____

Budget:

Description	Fixed Cost	Per Subject Cost	# Subjects (est)	Extended Cost
Trial Set-Up				
Recruitment				
Patient Services				
Laboratory Services				
Other				
Subtotal				
Overhead (25%)				
Total				

Payment Schedule:

Upon Execution of this Agreement:.....\$ _____
 Progress Payment #1:.....\$ _____
 Progress Payment #2:.....\$ _____
 With Submission of Completed Case Report Form:.....\$ _____ per subject
 Final Payment:\$ _____

In the event that subjects are entered into but do not complete the Study, then in respect of such payments the Sponsor shall only be required to pay the Institution on a prorated basis.

REB fee of \$3000 will be payable to: The University of British Columbia and separate to the budget and payment schedule.

All payments called for in this Agreement shall be made by cheque payable to either Vancouver Coastal Health Authority or The University of British Columbia (G.S.T. N/A) c/o Stephania Manusha Regional Manager, Clinical Trials Administration (under Institution’s FAS# (*) at the following address:

Willow Chest Centre – Room 163
 2647 Willow Street
 Vancouver, BC
 V5Z 3P1