CLINICAL STUDY SUB-SITE AGREEMENT

This clinical study sub-site agreement (the "**Agreement**") is made effective as of <@> (the "**Effective Date**")

AMONG:

THE UNIVERSITY OF BRITISH COLUMBIA, a corporation continued under the *University Act* of British Columbia with offices at 103 - 6190 Agronomy Road, Vancouver, British Columbia, Canada V6T 1Z3 ("**UBC**") and **NAME OF AFFILIATED HOSPITAL**, [Address of Affiliated Hospital] ("**[Short Form of Name of Affiliated Hospital]**")

(UBC and [Short Form of Name of Affliated Hospital] will be referred to in the Agreement collectively as the "**Coordinating Institution**")

AND:

[Name of Principal Investigator], having an address at [Address of Principal Investigator] (the "**Principal Investigator**")

AND:

[Name of Sub-Site], having its administrative offices at [Address of Sub-Site] (the "**Site**")

AND:

[Name of Site Investigator], having an address at [Address of Site Investigator] (the "**Site Investigator**")

(the Coordinating Institution, the Principal Investigator, the Site, and the Site Investigator are referred to in the Agreement individually as a "**Party**" and collectively as the "**Parties**")

WHEREAS:

The term "UBC" includes both UBC-Vancouver and UBC-Okanagan campuses.

It is UBC's objective to exploit its technology for the public benefit in harmony with the UBC Global Access Principles, outlined at www.uilo.ubc.ca/global.asp, and to generate further research in a manner consistent with UBC's status as a non-profit, tax-exempt educational institution. Under UBC research policy and in agreement with its affiliated hospitals, UBC owns inventions, results, and/or data that arise from research performed by UBC and which are conceived and/or made by researchers who have an appointment with UBC.

The Principal Investigator designed and developed the protocol for a clinical study titled "**[Study Title]**" (the "**Study**").

[UBC/The Coordinating Institution] has received [a grant/funding] for the Study from [Name of Funding Source].

The Principal Investigator and the Coordinating Institution wish to engage the services of the Site Investigator and the Site for the Study, and the Site Investigator and the Site wish to be so engaged.

THE PARTIES AGREE AS FOLLOWS:

1.0 DEFINITIONS

1.1 In the Agreement:

(a) "**Confidential Information**" means the Protocol (as defined below) and all information, regardless of its form, that is disclosed by one Party (the "**Discloser**") to another Party (the "**Recipient**") and is clearly identified in writing as being confidential either at the time of disclosure or within 30 days thereafter, except that Confidential Information does not include information:

(i) possessed by the Recipient prior to receipt from the Discloser, other than through prior confidential disclosure by the Discloser, as evidenced by the Recipient's business records;

(ii) published or otherwise made available to the general public, other than through a breach of the Agreement;

(iii) obtained by the Recipient from a third party with a valid right to disclose it, provided that the third party is not under a confidentiality obligation to the Discloser in respect of the same; or

(iv) independently developed by employees, agents, or consultants of the Recipient who had no knowledge of or access to the Discloser's information, as evidenced by the Recipient's business records.

(b) "**Contract Period**" means the time period ranging from the Effective Date through <@> (the "**End Date**").

(c) "**Data**" means any and all data generated or collected during the Contract Period in the performance of the Study, including, but not limited to, medical information, diagnoses, and analyses of medical records.

(d) "**Data Collection Form/Case Report Form**" means the [document/collection of documents] attached to the Agreement as Schedule "A".

(e) "**Inventions**" means any and all knowledge, know-how, techniques, technologies, or other intellectual property that are conceived, invented, developed, improved, or acquired during the Contract Period in the performance of the Study.

(f) "**Protocol**" means the protocol for the Study attached to the Agreement as Schedule "B".

(g) "**Site Data**" means all Data solely generated or developed by the Site Investigator or the Site's Researchers.

(h) **"Site Researchers"** means any agents, employees, representatives, or sub-investigators of the Site.

(i) "**Study Budget**" means description of compensation attached to the Agreement as Schedule "C".

(j) "**Study Samples**" means any Study samples acquired by the Site during the Contract Period in the performance of the Study.

Comment [IH1]: If applicable.

2.0 SCOPE OF WORK AND FUNDING

2.1 The Site Investigator will conduct the Study at the Site in accordance with the Protocol and any approved amendments which form an integral part of the Agreement. The Principal Investigator and/or the Coordinating Institution may amend the Protocol from time to time during the Contract Period, and a copy of any such amendment will be promptly provided by the Principal Investigator to the Site Investigator. The implementation of any such amendment by the Site Investigator and the Site will be subject to any approval that may be required by the Site's Research Ethics Board ("**REB**").

2.2 The Coordinating Institution will provide funds to the Site for the performance of the Study by the Site Investigator in accordance with the Study Budget. The Principal Investigator and the Coordinating Institution, acting reasonably, reserve the right to withhold payment or request return of funds to the extent that the Study participants were not properly enrolled under the terms of the Protocol or the Study was not conducted in accordance with the Agreement or the Protocol. The Parties acknowledge and agree that the funding of the Site is contingent upon the receipt of grant funding from [Name of Funding Source] by the Coordinating Institution. The funding provided by the Coordinating Institution to the Site will be deemed inclusive of costs associated with the research at the Site, including any overhead or administrative charges of the Site.

3.0 PERIOD OF PERFORMANCE

3.1 The Agreement will continue in full force and effect for the duration of the Contract Period; or if the Study is completed prior to the End Date, until the date on which the Study is completed at the Site; or if the Parties agree to extend the Study at the Site beyond the End Date, until such date as is mutually agreed upon in writing; or if the Study is terminated in accordance with Section 10.0 of the Agreement, until the date on which the Study is terminated.

4.0 RESPONSIBILITIES OF THE SITE INVESTIGATOR

4.1 The Site Investigator will:

(a) exercise due care in conducting the Study in compliance with the International Conference on Harmonization E6: Good Clinical Practice: guidelines Consolidated Guideline ("**ICH-GCP**"), the Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans, the Canadian Institutes for Health Research: Best Practices for Protecting Privacy in Health Research, the Declaration of Helsinki, and all applicable Health Canada regulations and other applicable federal, provincial, and local laws, rules, regulations, procedures and guidelines;

(b) provide to the Coordinating Institution, prior to screening Study participants or

enrolling Study participants into the Study, a copy of the Study participant informed consent form that will be used in the Study and has been approved by the Site's REB; a copy of the *curriculum vitae* of the Site Investigator and any key Study personnel; and written evidence of the approval of the Protocol and any amendment to the Protocol by the Site's REB;

(c) assume responsibility for the conduct of the Study at the Site and conduct the Study at the Site in accordance with the Protocol (subject to any amendments approved by the Site's REB). Any changes in procedure set out in the Protocol will be made by the Site Investigator only if considered necessary by the Site Investigator to protect the safety, rights, or welfare of Study participants, provided that the Site Investigator promptly notifies the Principal Investigator of any such deviation. Such deviations from the terms of the Protocol will not constitute negligence, error, omission, malfeasance, or material breach of the Agreement on the part of the Site Investigator or the Site; and

(d) ensure that any sub-investigators and any support staff who are participating in the Study at the Site will comply with the terms of the Protocol and any amendments to the same extent as the Site Investigator. The Site Investigator will take appropriate steps to inform each such person of his/her obligations and to obtain his/her agreement to abide by the terms and conditions of the Agreement.

(e) complete accurately and promptly the Data Collection Form/Case Report Form and secure Study Samples in accordance with the Protocol and submit completed Data Collection Forms/Case Report Forms and Study Samples to the Principal Investigator on a timely basis and in accordance with the Protocol. Study Samples may only be used by the Principal Investigator and the Coordinating Institution for the limited purpose of performing the Study and in accordance with the Protocol, Study participants consent forms and all applicable laws. The Site retains ownership of the Study Samples. All unused Study Samples will be returned to the Site or destroyed by the Principal Investigator and the Coordinating Institution at the request of the Site Investigator and/or the Site, and if destroyed, the Principal Investigator and the Coordinating Institution will certify such destruction in writing.

Comment [IH2]: If applicable – in which case move "and" from end of (c) to end of (d)

5.0 RECORD KEEPING

5.1 The Site and Site Investigator shall maintain adequate and accurate records relating to the Study, including the Study participant informed consent and treatment records of the Study participants, for the minimum period following completion or termination of the Study that is required by Health Canada regulations or such other period required by local laws, regulations, or guidelines.

6.0 CONFIDENTIALITY

6.1 The Recipient will keep and use the Discloser's Confidential Information in confidence and will not, without the Discloser's prior written consent, disclose the Discloser's Confidential Information to any person or entity, except to the Recipient's directors, officers, employees, faculty, students, and professional advisors who require the Confidential Information in order to assist the Recipient in performing its obligations and/or exercising its rights under the Agreement.

6.2 If the Recipient is required by judicial or administrative process to disclose the Discloser's Confidential Information, the Recipient will promptly notify the Discloser of the requirement and allow the Discloser reasonable time to oppose the process before disclosing the Confidential Information.

6.3 The Parties agree that the provisions of this Section 6.0 will not prevent the Recipient from disclosing the Discloser's Confidential Information to: (i) the Recipient's REB; (ii) the REB of another site participating in the Study if it is necessary for the performance of the Study or for the safety of Study participants, provided that the Recipient notifies the Discloser in writing in advance of the Recipient's intention to do so; or (iii) Study participants, their doctors, or their legal representatives if required for the clinical or medical care or safety of the Study participants.

6.4 Notwithstanding any termination or expiration of the Agreement, the obligations set out in this Section 6.0 survive and continue to bind the Parties and their successors and assigns until 5 years after the date of such termination or expiration.

7.0 PRIVACY

7.1 The Parties agree that all personal information and personal health information (the "**Information**") provided by a Party to any other Party under the Agreement is subject to Canada's *Personal Information Protection and Electronic Documents Act* ("**PIPEDA**"). Each Party warrants that the Party and its employees and designee(s) will adhere to and comply with applicable laws and regulations regarding protection of Information, including but not limited to PIPEDA. In the event that a Party is subject to a substantially similar provincial legislation as acceptable under the terms of PIPEDA, the Party will comply with such provincial legislation in its use, retention, and destruction of all Information provided to it under the Agreement. Notwithstanding anything to the contrary in the Agreement, the Parties will continue to treat as confidential all Information of Study participants as set out in this Section 7.1 and as required by law.

8. DATA AND INVENTIONS

8.1 Subject to Section 9 (Publication), the Coordinating Institution and the Principal Investigator own all right, title, and interest in any and all Data, Site Data and Data Collection Forms/Case Report Forms.

8.2 The Coordinating Institution and the Principal Investigator hereby grant to the Site and the Site Investigator a non-exclusive, royalty-free, irrevocable, perpetual right to use any and all Site Data for the purpose of the Study and internal and academic research purposes.

8.3 The Site and the Site Investigator will promptly disclose to the Principal Investigator and the Coordinating Institution any Inventions made or conceived by the Site Investigator and/or the Researchers. Inventorship will be determined in accordance with United States patent law and ownership will follow inventorship. Where a joint Invention is made by naming at least one entity as inventor from each Party, the Site and the Site Investigator agree to enter into an agreement with the Coordinating Institution to administer such joint Inventions (the "**Joint Inventions Agreement**"). The Joint Inventions Agreement will specify, among other terms, the respective responsibilities of the Parties regarding patent costs and other reasonable costs, and a reasonable and equitable revenue sharing mechanism.

8.4 Each Party hereby grants to the other Parties a non-exclusive, royalty-free license to use Inventions for internal and academic research purposes.

9. PUBLICATION

9.1 The Parties agree that the first publication of the Study will be a joint, multi-centre publication involving all the investigators and sites that participated in the Study. Authorship of the multi-centre publication will be determined in accordance with academic standards for authorship. If such a multi-centre publication has not been submitted to an academic journal within 12 months after the conclusion, abandonment, or termination of the Study at all sites participating in the Study, or if the Principal Investigator confirms in writing that there will be no multi-centre publication, the Site Investigator may publish any Site Data. The Site Investigator will have the right to disclose information resulting from the Study or any background information provided by the Principal Investigator or the Coordinating Institution that is necessary to allow other scholars to verify research results.

9.2 The Site Investigator and the Researchers will not be restricted from presenting Site Data at symposia or national or regional professional meetings or from publishing Site Data in journals or other publications (collectively, the "**Proposed Disclosure**"), provided that any Proposed Disclosure is submitted to the Principal Investigator for review for Confidential Information and for comment at least 30 days before the date of presentation of the Proposed Disclosure or the date of submission of the Proposed Disclosure for publication. Any information identified by the Principal Investigator or the Coordinating Institution as being Confidential Information will be deleted from the Proposed Disclosure, provided that the Principal Investigator and the Coordinating Institution will not request the deletion of, and the Site Investigator and the Researchers will not be required to delete, any data, results, or information related to research methods used in the Study. At the request of the Principal Investigator or the Coordinating Institution, any Proposed Disclosure will be delayed for a further period not exceeding 60 days to enable the Coordinating Institution to protect its rights in such Confidential Information. If the Site Investigator and the Researchers do not wish to delay the Proposed Disclosure, the Site Investigator and the Researchers will delete the Confidential Information identified by the Principal Investigator or the Coordinating Institution from the Proposed Disclosure prior to its presentation or submission for publication.

Comment [IH3]: If applicable.

9.3 Other than with respect to Confidential Information, nothing in the Agreement will be construed as granting to the Principal Investigator or the Coordinating Institution any right to edit the Proposed Disclosure. The final analysis and interpretation of the Site Data remain with the Site Investigator and the Researchers.

10.0 TERMINATION

10.1 Any Party may terminate the Agreement upon 30 days' prior written notice to the other Parties. The 30 day notice will not be required if the Party wishing to terminate the Agreement, in its sole opinion, deems that the safety of the Study participants has been compromised provided that the Party wishing to terminate the Agreement due to safety concerns promptly notifies the other Parties of its decision to do so.

10.2 In addition, any Party may immediately terminate the Agreement by written notice of breach by any other Party if the other Party fails to remedy such breach within 15 days of receipt of such notice or such longer period as the Parties may agree to in writing, acting reasonably and giving consideration to the nature of the breach and time reasonably required to

cure the same. Breach will be defined as a failure to comply with any provisions of this Agreement and documents incorporated herein.

10.3 No termination of the Agreement, however effectuated, will release the Parties from their rights and obligations under Sections 5.0 (Record Keeping), 6.0 (Confidentiality), 7.0 (Privacy), 8.0 (Data and Inventions), 9.0 (Publication), 10.3, 10.4, 11.0 (Disclaimer of Warranty and Liability), 12.0 (Insurance), 13.0 (Use of Name), and 15.0 (General).

10.4 In the event of termination, the Coordinating Institution will reimburse the Site for all payments owing to the Site up to receipt of the written notice of termination, in accordance with the Study Budget, except that no such payment will be made in the event that the Agreement is terminated because of the Site's failure to adhere to the Protocol. The Site shall take all reasonable steps to minimize further costs after receiving notice of termination, regardless of the grounds for such termination.

11.0 DISCLAIMER OF WARRANTY AND LIABILITY

11.1 The Parties will perform the Study in accordance with the Protocol and the terms of the Agreement. However, no Party promises success in achieving any particular result. Except as expressly provided in the Agreement, no Party gives any warranty whatsoever, express or implied, as to any matter, including, without limitation, as to the results of the Study or regarding Confidential Information that a Party may disclose to another Party. No Party will be responsible for any lost profits, lost opportunities, or other indirect or consequential damages suffered by any other Party as a result of the conduct of the Study or the performance of the Agreement.

11.2 The Parties acknowledge and agree that each Party will be responsible and liable for any damage or loss to the extent that such damage or loss arises as a result of its own negligence or willful or wrongful acts or omissions in conducting the Study, such as a failure by that Party to: (a) adhere to the material terms of the Protocol; (b) comply with applicable governmental requirements or regulations of Canada or the province in which a Party operates; and (c) conduct the Study in accordance with the medical standards set out in the ICH-GCP. No Party ("the **First Party**") will be liable to any other Party (the "**Second Party**") or third party for any damage or loss that results from the use by the Second Party or third party of the Data or Inventions developed under the Agreement, Protocol, or Study, except to the extent that the damage or loss arises from the gross negligence or willful misconduct of the First Party.

12.0 INSURANCE

12.1 The Coordinating Institution and the Site will each maintain appropriate policies of liability insurance against any and all foreseeable risks of loss arising out of the Agreement or the Study, with limits of no less than $3,000,000 per occurrence, to cover the activities of their directors, officers, employees, faculty, students, and agents. The Coordinating Institution and the Site will provide evidence of such insurance to each other upon written request, and will provide each other 30 days prior written notice of cancellation or non-renewal of their respective coverage.

12.2 The Site Investigator represents and warrants that he/she is, and that any other licensed physician involved in the Study at the Site, including any co-investigator and sub-investigator, is a member in good standing of the Canadian Medical Protective Association and will maintain such standing during the conduct of the Study.

13.0 USE OF NAME

13.1 Notwithstanding anything to the contrary in the Agreement and without further notice, the Parties agree that each Party may disclose the existence of the Agreement, the Parties to the Agreement, the amount of funding received by the Site from the Coordinating Institution and the title of the Study in annual reports or in any publication or presentation relating to the results of the Study. However, no Party may use the name of any other Party or any other Party's trademarks or insignia in any publication, news release, promotion, advertisement, or other public announcement, whether written or oral, that endorses services, organizations, or products, or for any other purpose other than that expressly permitted by the Agreement, without the other Party's prior written consent.

14.0 NOTICES

14.1 All payments, reports, notices, or other documents that a Party is required or wishes to deliver to any other Party will be delivered:

(a) in writing, and

(b) either by personal delivery or by registered or certified mail (with all postage and other charges prepaid) at the address for the receiving Party as set out in Section 14.2 or as varied by any notice.

Any notice that is personally delivered is deemed to have been received at the time of delivery. Any notice that is mailed in accordance with this Section 14.0 is deemed to have been received at the end of the fifth business day after it is posted.

14.2 Addresses for delivery of notices:

To the Coordinating Institution
If to UBC:

Managing Director, UILO
UBC File No. [to be entered]
The University of British Columbia
University-Industry Liaison Office
#103 - 6190 Agronomy Road
Vancouver, British Columbia
Canada V6T 1Z3
Tel: (604) 822-8580
Fax: (604) 822-8589

If to [Short Form of Name of Affiliated Hospital]

[Name of Affiliated Hospital]
[Address of Affiliated Hospital]
Tel: [Telephone Number of Affiliated Hospital]
Fax: [Fax Number of Affiliated Hospital]

To the Principal Investigator
[Name of Principal Investigator]
[Address of Principal Investigator]
Tel: [Telephone Number of PI]
Fax: [Fax Number of PI]

To the Site:

To the Site Investigator

[Name of Site]
[Address of Site]
Tel: [Telephone Number of Site]
Fax: [Fax Number of Site]

[Name of Site Investigator]
[Address of Site Investigator]
Tel: [Telephone Number of SI]
Fax: [Fax Number of SI]

15.0 GENERAL

15.1 Nothing contained in the Agreement is to be deemed or construed to create between the Parties a partnership or joint venture. No Party has the authority to act on behalf of any other Party, or to commit any other Party in any manner at all or cause any other Party's name to be used in any way not specifically authorized by the Agreement.

15.2 The Agreement is governed by, and will be construed in accordance with, the laws of British Columbia and the laws of Canada in force in that province, without regard to its conflict of law rules. The Parties agree that by executing the Agreement, they have attorned to the exclusive jurisdiction of the Supreme Court of British Columbia.

15.3 No condoning, excusing, or overlooking by any Party of any default, breach, or non-observance by any other Party at any time or times regarding any terms of the Agreement operates as a waiver of that Party's rights under the Agreement. A waiver of any term or right under the Agreement will be in writing signed by the Party entitled to the benefit of that term or right, and is effective only to the extent set out in the written waiver.

15.4 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.

15.5 No right or license is granted under the Agreement by any Party to any other Party either expressly or by implication, except as specifically set out in the Agreement. Nothing contained in the Agreement will impose an obligation of exclusivity on one Party by any other Party. Each Party reserves the right to enter into and participate in other activities (either alone or with a third party), including, but not limited to, clinical trials and other research projects.

15.6 All terms in the Agreement which require performance by the Parties after the expiry or termination of the Agreement will remain in force despite the Agreement's expiry or termination for any reason.

15.7 Part or all of any section of the Agreement that is indefinite, invalid, illegal, or otherwise voidable or unenforceable may be severed from the Agreement, and the balance of the Agreement will continue in full force and effect.

15.8 Each Party will execute and deliver such further agreements and other documents and do such further acts and things as the other Parties reasonably request to evidence, carry out, or give full force and effect to the intent of the Agreement.

15.9 The Agreement and the Schedules set out the entire understanding between the Parties and no changes to the Agreement are binding unless in writing and signed by the Parties to the Agreement. The Parties will be bound by the Schedules, except to the extent that they may conflict with the terms and conditions contained in the Agreement, in which case the terms and conditions of the Agreement will govern.

15.10 Each Party acknowledges that it/he/she has been advised by the other Parties to seek independent legal advice with respect to the Agreement and that it/he/she has not relied upon any of the other Parties for any advice, whether legal or otherwise, with respect to the Agreement.

15.11 The Agreement may be executed in counterparts by the Parties, either through original copies or by facsimile or electronically, each of which will be deemed an original and all of which will constitute the same instrument.

15.12 In this Agreement, unless the contrary intention appears, “days” means calendar days.

[THE SIGNATURE PAGE FOLLOWS]

SIGNED BY THE PARTIES AS AN AGREEMENT and effective as of the Effective Date.

Signed for and on behalf of
THE UNIVERSITY OF BRITISH COLUMBIA
by its authorized signatory:

_____
Signature

Name:
Title:

_____
Date

Signed for and on behalf of
[NAME OF AFFILIATED HOSPITAL]
by its authorized signatory:

_____
Signature

Name:
Title:

_____
Date

PRINCIPAL INVESTIGATOR

_____
Signature

Name:
Title:

_____
Date

Signed for and on behalf of
[NAME OF SITE]
by its authorized signatory:

_____
Signature

Name:
Title:

_____
Date

SITE INVESTIGATOR

_____

Name:
Title:

_____
Date

SCHEDULE "A"

[DATA COLLECTION FORM/CASE REPORT FORM]

SCHEDULE "B"

PROTOCOL

SCHEDULE "C"

BUDGET AND PAYMENT SCHEDULE

The Study is investigator-driven and supported by <Name of Sponsor>. All payments will be made in Canadian dollars.

Payment Schedule:

1. A total of $<> will be paid for each Study participant that enrols in and completes the Study. Payment will be made as follows:

   $<> for <Item 1>
   $<> for <Item 2>
   $<> for <Item 3>

2. The Coordinating Institution will provide payment for each Study participant within 90 days of receipt by the Principal Investigator or [his/her] designate of all of the following:

   a) <Requirement 1>;
   b) <Requirement 2>;
   c) <Requirement 3>; and
   d) an invoice.

3. Invoices must be submitted to the Coordinating Institution within 90 days of each Study participant completing the Study. The Site may include multiple subjects on each invoice. Invoices should be directed to:

   <Contact Information>

4. No payment or partial payment will be made:

   a) for any Study participant entered in violation of the Protocol;
   b) for any [Data Collection Form/Case Report Form] deemed to be non-evaluable;
   c) for any enrolment after a notice of termination has been sent by the Coordinating Institution;
   d) for any enrolment after the designated recruitment period, unless approved in writing by the Principal Investigator; or
   e) if the Site is in breach of the Agreement.

5. If at the date of Study termination the total amount that the Coordinating Institution has paid exceeds the amount to which the Site is entitled hereunder, the Site will return the overpayment to the Coordinating Institution within 30 days after the termination date. If at the date of Study termination the total amount that the Coordinating Institution has paid is less that the amount to which the Site is entitled hereunder, the Coordinating Institution will pay the amount due the Site.