Board of Record Agreement (the “**Agreement**”)

# THIS AGREEMENT made as of and effective from the \_\_\_\_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_, (the “Effective Date”)

**BETWEEN:**

**ALBERTA INNOVATES, both on its own behalf and on behalf of the**

**Health Research Ethics Board of Alberta**

(“**HREBA**”)

  and –

**[FULL NAME OF INVESTIGATOR]**

(the “**Investigator**”)

  and

**[FULL LEGAL NAME OF CORPORATE / LEGAL ENTITY HOSTING SITE]**

(the “**Site**”, together with the Investigator the “**Applicant**”)

**WHEREAS** HREBA and its committees are a Research Ethics Board (“**REB**”) established pursuant to the *Health Information Act*, providing ethical reviews and ongoing ethical oversight of research involving humans;

**AND WHEREAS** HREBA functions as an independent, adjudicative REB which is administratively housed within Alberta Innovates;

**AND WHEREAS** the Investigator, wishes to pursue a research study involving humans (the “Study”) and by law requires the review and ongoing ethical oversight of the research by an established REB. The Investigator is the leader of the research team who is responsible for the ethical conduct of the research Study and for the actions of any member of its research team;

**AND WHEREAS** this Agreement will apply both to the Study presently being submitted by the Investigator, and to all future Studies that the Applicant submits to HREBA for review;

**AND WHEREAS** the Investigator will undertake the Study at one or more locations, with the primary Site being identified above;

**NOW THEREFORE,** in consideration of the covenants and agreements contained herein, including specifically HREBA agreeing to review the Study, and for other good and valuable consideration, the receipt and sufficient of which is hereby acknowledge,the parties agree to the following:

1. The Applicant hereby retains HREBA and HREBA agrees to act as the Research Ethics Board of Record (“**Board of Record**”) for the Applicant/Investigator in respect of all Studies which have been submitted to HREBA by the Investigator as of the Effective Date.
2. As the Board of Record, HREBA may approve, reject, propose modifications to, put on hold or terminate any of the Studies at its sole and unfettered discretion (“**HREBA Determinations**”).
3. In acting as the Board of Record, HREBA shall act in accordance with the responsibilities set out in the attached Schedule A. Specifically, in undertaking its review of the Studies HREBA shall operate in accordance with all applicable laws, regulations and guidelines, including but not limited to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS); the International Council on Harmonization (ICH), Good Clinical Practice (GCP) Consolidated Guideline E6; the Canadian Food and Drugs Act and its applicable regulations, in particular Part C, Division 5; the Alberta Freedom of Information and Privacy Act (FOIP); the Alberta Heath Information Act (HIA), HREBA’s internal Standard Operating Procedures (SOP’s), and its applicable regulations (“collectively the “**Applicable Laws and Regulations**”). HREBA committees are registered as Institutional Review Boards (“**IRB**”) with the U.S. Office for Human Research Protections (#00009687 and #00001209).
4. The Applicant shall comply with all HREBA determinations with respect to the Studies, whether conducted exclusively at the Site or at other locations, and shall conduct the Studies in accordance with all Applicable Laws and Regulations and in accordance with the Applicant’s responsibilities as set out in the attached Schedule A. The Investigator further represents and warrants that they have identified in the recitals the primary Site where most of the Study activities will take place, that they have received all necessary permissions to conduct the Study at the Site and that the entering into of this Agreement does not violate any obligation the Investigator has to the Site, contractual or otherwise.
5. HREBA can review a previously-approved Study if it becomes aware of ethical misconduct or disciplinary action related to the Investigator, a co-Investigator, the Site, or other research staff member(s) involved with the Study.  During this review process, any individual whose conduct is being reviewed will be given an opportunity to respond.  Following its review, HREBA may, in keeping with the gravity of the ethical misconduct or disciplinary action: (1) determine that no further action is necessary and close its file; (2) impose approval conditions for continuation of the Study; or (3) suspend or revoke its approval of the Study on an interim or permanent basis.
6. The parties acknowledge and agree that the Study, together with any supplemental documentation and information HREBA receives from the Applicant, together with the details of the Study (collectively the “**Submission**”) may contain trade secrets, or commercial, financial, scientific or technical information of the Applicant or an individual, company, institution or organization that has responsibility for the initiation, management or financial support of a Study. Accordingly, HREBA shall treat the entire Submission as confidential and may only disclose the Submission or portions thereof to its staff or external reviewers on a strictly confidential basis and where such staff are aware of the confidential and proprietary nature of the Submission and agree to keep it confidential. HREBA shall not disclose the Submission to any other third parties without the Investigator’s consent except as required by law or to protect the public safety, as contemplated below. It is the Applicant’s responsibility to also obtain approval from any individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of the applicable Study to disclose documents and information to a third party when requested by HREBA.

If HREBA, upon consulting with its legal counsel: (a) reasonably believes that the Submission or portions thereof must be disclosed in the interest of protecting the safety of Study participants, or; (b) HREBA is required by law, regulation or court order to disclose the Submissions or portions thereof (including pursuant to an access to information request under FOIP) then HREBA shall before making any such disclosure attempt to notify the Applicant so that HREBA and the Applicant may collectively determine how disclosure may be made without breach of any agreements with any individual, company, institution or organization of the applicable Study. The obligations contained in this paragraph shall survive completion or earlier termination of this Agreement.

For clarity, the duties of confidentiality set out in this section shall endure indefinitely, or until such time as the Applicant informs HREBA that the Submission is no longer confidential.

1. HREBA and the Applicant are and at all times shall remain independent of each other and are not and shall not represent themselves to be the principal, agent, joint venture, partner or employee of the other(s). No representations shall be made or actions taken by a party which could establish or imply any apparent relationship of agency, joint venture, partnership or employment with another, and no party shall be bound in any manner whatsoever by any agreements, warranties or representations of another party.
2. During the duration of this Agreement, and thereafter, HREBA must keep accurate and complete records in accordance with the Government of Alberta - Alberta Records Management Regulation and organizational policies.
3. HREBA may assign this Agreement upon written notice to the Applicant, the Investigator may not assign this Agreement without prior written permission from HREBA.
4. HREBA may, in its sole and unfettered discretion, elect to charge a reasonable review fee for Studies which receive funding support from industry (eg. Studies submitted by pharmaceutical / medical device companies) or other for-profit organizations. If HREBA determines that an administration fee is warranted, the Applicant will be sent an invoice over email setting out the fees to be paid, such invoice to be payable within thirty (30) days. The administration fee will be determined by HREBA in accordance with the fee schedule, which can be found at www.hreba.ca
5. This Agreement remains in effect from the Effective Date until such date as the Applicant notifies HREBA in writing that it no longer wishes to engage with HREBA as its chosen Board of Record (the “**Term**”), unless terminated earlier, in accordance with Sections 12 and 13, or unless termination is mutually agreed in writing by the parties, and providing that alternate REB oversight of the Studies is in place or the Studies are closed.
6. Any party not in default may terminate the Agreement by giving written notice to the other party if a party is in breach of any of its obligations under this Agreement and has failed to remedy the breach within thirty (30) days of having received notice, and providing that alternate REB oversight of the Studies is in place or the Studies are closed.
7. The parties may terminate the Agreement with sixty (60) days written notice to the other party and providing that alternate REB oversight of the Studies is in place, or the Studies are closed. Upon termination of this agreement, as contemplated by this Section or Sections 10 and 11, HREBA shall immediately cease any review or adjudication of the Study.
8. To the fullest extent permitted by law, HREBA shall not be liable in any way whatsoever to the Applicantor any of its directors, officers, employees, agents, personal legal representatives and/or heirs for any losses, damages or claims, including but not limited to indirect, incidental, consequential, or special damages or any loss of profits, loss of business opportunity, loss of revenue, or any other loss or injury suffered or arising in any way whatsoever arising out of this Agreement, or the Applicant undertaking the Study, whether arising before or after submitting a Study or entering into this Agreement with HREBA.

Further, the Applicant agrees to indemnify, defend, and hold harmless HREBA, its directors, officers, employees and agents against and from any and all third party claims, actions, and costs whatsoever (including legal costs on a solicitor and her own client full indemnity basis) that may arise directly or indirectly out of any act or omission of the Applicant, or any of its directors, officers, employees, contractors, agents or legal representatives or the negligence or tortious act or willful misconduct of theApplicant or anyone for whom it is responsible at law in relation to their obligations under this Agreement.

This section will survive any termination or expiry of this Agreement.

1. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws in force in the Province of Alberta and the parties shall exclusively attorn to the jurisdiction of Alberta.
2. If any provision of this Agreement is determined to be invalid or unenforceable in whole or in part, such invalidity or unenforceability shall attach to such provision and the remainder of the Agreement shall continue in full force and effect; and the parties shall in good faith negotiate a substitute for any provision declared unenforceable, which shall most nearly approximate the intent of the parties in entering into this Agreement.
3. This is the entire Agreement between the parties. This Agreement supersedes any prior contemporaneous written or oral agreements. This Agreement may only be amended or modified by subsequent written agreement executed by authorized representatives of HREBA and the Investigator.
4. This Agreement may be executed in counterparts and delivered electronically in portable document format. Each such counterpart, when so executed and delivered, shall be deemed an original and all such counterparts when taken together shall constitute a single instrument.

**[*The remainder of this page has been intentionally left blank. Signature page follows*]**

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

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| --- | --- | --- | --- | --- |
| ALBERTA INNOVATES, both on its own behalf and on behalf of the Health Research Ethics Board of Alberta | |  | **[FULL NAME OF INVESTIGATOR]** | |
| Per: |  |  | Per: |  |
|  | Name:  Title: |  |  | Title: |
| Per: |  |  |  | **[FULL LEGAL NAME OF SITE]** |
|  | Name:  Title: |  |  | Name:  Title:  I hereby represent and warrant that I have the legal authority to bind the Site to this Agreement. |

**Schedule “A”**

**RESPONSIBILITIES**

### The responsibilities of HREBA are to:

1. Review the ethics Submission (including but not limited to the application form, protocol, consent form(s) and other participant materials, the Applicant’s brochure, Study budget and curriculum vitae of Study team members) submitted by the Applicant.
2. Conduct the initial ethics review of the Studies, correspond with the Applicant regarding any issues or recommended changes to the REB Materials, and make a decision/determination about approval of the Studies.
3. Ensure ongoing REB oversight of the active Studies (active means there is an ethics approval in place), which include: reviews of the approved Studies either annually or more frequently at the discretion of HREBA; reviews of all relevant local and non-local serious adverse events (“**SAEs**”); reviews of new Study information; and review of and decisions made regarding the approval of any protocol amendments/modifications to the Studies submitted by the Applicant, as applicable.
4. Maintain Submissions as well as the HREBA review letter(s), Applicant response letter(s), HREBA determination letters, local SAEs and other reportable event reports acknowledgement letters within the IRISS electronic application system.
5. Maintain a current HREBA membership roster and post to HREBA’s publicly accessible website.
6. Maintain written policies and procedures, and make such documents, once they are finalized available on HREBA’s publicly accessible website.
7. Immediately notify the Applicant in writing if a Study is placed on hold, withdrawn or terminated by HREBA.
8. Immediately notify the Applicant in writing of any HREBA policy decisions or regulatory matters that might affect the Investigator’s reliance on HREBA reviews or ongoing oversight of the Studies.
9. Notify the Applicant in writing of any significant Study-related communication to HREBA that has not been received by the Investigator, including, but not limited to participant complaints, protocol deviations and privacy breaches.
10. Follow written procedures for reporting its findings and actions to the appropriate organizational officials and regulatory bodies.
11. Make relevant meeting minutes available to appropriate organizational officials.
12. Maintain its IRB registration(s) with the U.S. Office for Human Research Protections.

### The responsibilities of the Applicant are to:

1. Submit REB Materials to HREBA in accordance with HREBA policies, procedures and requirements.
2. Ensure that the Applicant and Study team members are appropriately qualified by education, training and experience to conduct the research.
3. Conduct each Study in accordance with the Study protocol, HREBA policies, procedures and required conditions of HREBA’s approval, and all Applicable Laws.
4. Submit to HREBA any amendments or modifications to a Study (including but not limited to protocol amendments, revised consent forms and participant materials) and all renewals in accordance with HREBA policies, procedures and requirements.
5. Promptly report to HREBA all local and non-local SAEs in respect to a Study (as defined by the Study protocol and by HREBA’s policies and procedures) and any new information (including but not limited to protocol deviations and other reportable event reports) that may adversely affect the safety of the participants or significantly affect the conduct of a Study. These reports are to be in accordance with HREBA policies, procedures and requirements.
6. Promptly report to HREBA all privacy breaches in respect to a Study, and any corrective action taken.
7. Comply with all HREBA ongoing oversight requirements, including but not limited to the submission of all protocol amendments/modifications to a Study, submission of annual reports of the approved Study (or more frequently at the discretion of HREBA), and provision of direct access to all Study documents in the direct or indirect control of the Investigator in the event of an on-site assessment by HREBA.
8. Notify HREBA as per HREBA’s reporting requirements if a Study has been placed on hold or terminated by the Applicant.
9. Notify HREBA as per HREBA’s reporting requirements of any significant Study-related communication that has not been received by HREBA, including, but not limited to participant complaints, protocol deviations and privacy breaches.
10. Ensure all submissions made to HREBA are accurate and complete. HREBA’s determinations are based on the information provided by the Investigator.
11. Retain each Submission and all REB correspondences as per the Applicant’s organizational policies and regulatory requirements.
12. Obtain whatever other additional decisions/approvals as may be required to conduct a Study, such as approval from a research institute, university, professional or regulatory body, or external sponsor, in addition to whatever ethical approvals are granted by HREBA in respect of the Study.
13. Retain all study documentation as per Applicable Laws and Regulations.
14. Not initiate the study until all ethics and other approvals are in place.
15. If applicable, the Investigator shall maintain a Federal Wide Assurance (FWA) and designate HREBA as its IRB.
16. Provide HREBA with a list of appropriate officials to report its findings and actions to when necessary.