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

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

**BETWEEN:**

**ALBERTA INNOVATES by its board known as the Health Research Ethics Board of Alberta,**

(“**HREBA**”)

 ‑ and ‑

**FULL NAME OF INVESTIGATOR**

(the “**Investigator**”)

**WHEREAS** HREBA and its committees are a Research Ethics Board (“**REB**”) providing ethical reviews and ongoing ethical oversight of research involving humans.

**AND WHEREAS** the Investigator wishes to pursue research involving humans and 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 and for the actions of any member of its research team.

**AND WHEREAS** this agreement will apply to all studies that the Investigator submits to HREBA (the “**Study**” for singular and “**Studies**” for plural) for review.

**NOW THEREFORE** the parties agree to the following:

1. The Investigator hereby retains HREBA and HREBA agrees to act as the Research Ethics Board of Record (“**Board of Record**”) for the Investigator in respect of all Studies which have been submitted to HREBA by the Investigator prior to the Effective Date and all Studies submitted to HREBA by the Investigator after 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. 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 Harmonisation (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) 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 Investigator shall comply with all HREBA determinations with respect to the Studies, and shall conduct the Studies in accordance with all Applicable Laws and Regulations and in accordance with the Investigator’s responsibilities as set out in the attached Schedule A.
5. The Parties acknowledge and agree that the documents and information HREBA receives from the Investigator, together with the details of the Study (collectively the “**Submission**”) may contain trade secrets, or commercial, financial, scientific or technical information of the Investigator 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 Investigator’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 (a) reasonably believes that information or documents obtained from the Investigator 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 information or documents obtained from the Investigator (including pursuant to an access to information request under Alberta’s Freedom of Information and Protection of Privacy Act (“**FOIP**”)), then HREBA shall before making any such disclosure attempt to notify the Investigator so that HREBA and the Investigator 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.

1. HREBA and the Investigator 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 Investigator, the Investigator may not assign this Agreement without prior written permission from HREBA.
4. For Studies which receive funding from industry (e.g., pharmaceutical/medical device companies) or other for-profit organizations, the Investigator will be charged by Alberta Innovates an administration fee. Further details can be found at [www.hreba.ca](http://www.hreba.ca).
5. This Agreement remains in effect from the Effective Date until at which time the Investigator chooses to no longer use HREBA as its Board of Record (the “**Term**”) unless terminated in accordance with Sections 11 and 12, 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.
8. Except as otherwise provided in this Agreement,
9. Each party assumes its/his/her own liability for any damages, losses or costs arising out of suits or claims on account of injuries (including death) to persons participating in the Studies or damage to property to the extent that such injuries or damage arise out of its/his/her activities in the course of the Studies or the performance of this Agreement, or out of the activities of those for whom in law it/he/she is responsible; and
10. No party or its/his/her trustees, directors, officers, employees, and agents (the “**first party**’’) shall be liable to the other party (the “**second party**’’) for any damages, losses or costs arising out of suits or claims brought by the second party or made against the second party except to the extent caused by negligence or willful misconduct on the part of the first party.

Notwithstanding anything else herein, neither party shall be liable to the other for any consequential, special, indirect or incidental losses or damages, including without limitation loss of revenue, loss of income or loss of anticipated profits, which result from or are in any way attributable to this Agreement regardless of fault, negligence, strict liability or other cause.

Each party shall indemnify, defend and hold harmless the other, its employees, directors, officers and agents, against and from any and all third party claims, demands, actions or costs (including legal costs on a solicitor-client basis) the extend arising from that party’s breach of this Agreement, or the negligence, other tortious act of wilful misconduct of that party, or those for whom it is legally responsible, in relation to the performance of its obligations under this Agreement or related to the Studies.

Each party shall maintain appropriate insurance sufficient to cover its/his/her liabilities that may arise in performance of the Studies or under this Agreement. Upon request, each party shall provide to the others a certificate of insurance or other proof of insurance, as appropriate*.*

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.

**IN WITNESS WHEREOF** the parties have hereunto executed this Agreement on the date first written above.

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| ALBERTA INNOVATES by its board known as the Health Research Ethics Board of Alberta | |  | **INVESTIGATOR** | |
| Per: |  |  | Per: |  |
|  | Name: Tammy Mah-Fraser  Title: Executive Director, Health Platforms |  |  | Name: Click here to enter text.  Title: Click here to enter text. |
| Per: |  |  |  |  |
|  | Name: Tim Murphy  Title: Vice President, Health |  |  |  |

**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, investigator brochure, Study budget and curriculum vitae of Study team members) submitted by the Investigator.
2. Conduct the initial ethics review of the Studies, correspond with the Investigator 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 Investigator, as applicable.
4. Maintain Submissions as well as the HREBA review letter(s), Investigator 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 Investigator in writing if a Study is placed on hold, withdrawn or terminated by HREBA.
8. Immediately notify the Investigator 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 Investigator 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 Investigator are to:

1. Submit REB Materials to HREBA in accordance with HREBA policies, procedures and requirements.
2. Ensure that the Investigator 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 Investigator or Sponsor.
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 investigators organizational policies and regulatory requirements.
12. HREBA may approve the ethical aspects of a Study, however, additional decisions/approvals are required to conduct a Study which rest with Investigator, Research Organization (defined as an entity, such as university or research institute, irrespective of its legal status or way of financing, whose primary goal is to conduct research) or Sponsor.
13. Retain all study documentation as per Applicable Laws and Regulations.
14. A Study should not be initiated until all applicable approvals have been granted including but not limited to ethics.
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. Use the form in Schedule “B”, attached herein.

**Schedule “B”**

**LIST OF ORGANIZATIONAL OFFICIALS**

### When necessary, HREBA may report its findings and actions to the following official(s):

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