

BOARD OF RECORD AGREEMENT

BETWEEN:

AURORA COLLEGE

- and -

[FULL NAME OF INVESTIGATOR]

("Investigator")

- and -

[FULL LEGAL NAME OF INVESTIGATOR'S INSTITUTE]

("Investigator's Institute")

(Investigator and Investigator's Institute collectively, "Applicant")

The Aurora College Research Ethics Committee ("ACREC") is established and empowered under the authority of Aurora College. Under the auspices of Aurora College, the ACREC operates as an independent, adjudicative multi-disciplinary ethics review committee to review the ethical acceptability of research involving humans.

The Applicant is a researcher pursuing a research study or studies (collectively, "Study") that legally requires the review and ongoing ethical oversight of the Study by an established research ethics committee acting as the Research Ethics Board of Record ("Board of Record") for the Applicant.

The Investigator is the leader of the research team and responsible for conducting the Study ethically and for the actions of members of the research team.

This Agreement will apply only to the Study presently being submitted by the Applicant, to ACREC for review.

The Investigator will undertake the Study at one or more locations within the Northwest Territories.

The Applicant wants ACREC to act as its Board of Record.

The parties agree as follows:

- 1. This agreement is effective when both parties have signed it.
- 2. The Study is summarized in Schedule A to this agreement.
- 3. The Applicant will pay \$5.00 to Aurora College.

- 4. The Applicant agrees that ACREC is an authorized agent and representative of Aurora College and that ACREC will act as the Board of Record for the Applicant in respect of the Study.
- 5. The Applicant will not initiate the study until it has received written approval from ACREC that it may commence the Study.

Determinations

6. ACREC may approve, reject, propose modifications to, put on hold or terminate the Study at its sole and unfettered discretion ("ACREC Determinations").

Compliance with Laws and other Requirements

- 7. Aurora College will ensure that ACREC operates 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"); and the Association of Canadian Universities for Northern Studies and other funding agencies, ACREC's internal standard operating procedures.
- 8. The Applicant shall comply with all ACREC determinations with respect to the Study, shall obtain all necessary approvals and permissions, and shall conduct the Study in accordance with all applicable laws and regulations.

Other Obligations of ACREC

- 9. Review the Submission, including the application form, protocol, consent form(s) and other participant materials, the Applicant's brochure, Study budget and curriculum vitae of Study team members.
- 10. Conduct the initial ethics review of the Study, correspond with the Applicant regarding any issues or recommended changes to research ethics materials, and make a decision/determination about approval of the Study.
- 11. Ensure ongoing oversight of the Study when there is an ethics approval in place, which includes: reviews of the Study either annually or more frequently at the discretion of ACREC; 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.
- 12. Store Submissions as well as the ACREC review letter(s), Applicant response letter(s), ACREC determination letters, local SAEs and other reportable event reports, and acknowledgement letters within its record management system.
- 13. Maintain a current ACREC membership roster.
- 14. Maintain written policies and procedures, and make such documents, once they are finalized available on ACREC's publicly accessible website.
- 15. Notify the Applicant forthwith in writing if a Study is placed on hold, withdrawn or terminated by ACREC.

- 16. Notify the Applicant forthwith in writing of any ACREC policy decisions or regulatory matters that might affect the Investigator's reliance on ACREC reviews or ongoing oversight of the Study.
- 17. Notify the Applicant in writing of any significant Study-related communication to ACREC that has not been received by the Applicant, including, but not limited to participant complaints, protocol deviations and privacy breaches.
- 18. Follow written procedures for reporting its findings and actions to the appropriate organizational officials and regulatory bodies.

Other Obligations of Applicant

- 19. Maintain compliance of the Study with all applicable laws and with all ACREC policies, procedures and requirements.
- 20. Submit research ethics materials to ACREC in accordance with ACREC policies, procedures and requirements.
- 21. Ensure that the Investigator and Study team members have the required and appropriate education, credentials, training, experience to conduct the research, have all insurance coverage required by law and by ACREC, and have completed police and other background checks for their assigned role in the research.
- 22. Ensure that the Applicant and Study team members adhere to ACREC's and Aurora College's institutional and/or investigator conflicts of interest policies and procedures, with any applicable COI management plan related to the study.
- 23. Conduct the Study in accordance with the Study protocol submitted to ACREC, ACREC's conditions approval, and all Applicable Laws.
- 24. Maintain the ability to monitor the conduct of research after approval by ACREC and ensure that any relevant findings are reported to ACREC upon its request.
- 25. Submit to ACREC any renewals of the Study and any amendments or modifications to the Study, including but not limited to protocol amendments, revised consent forms and participant materials.
- 26. Promptly report to ACREC all local and non-local SAEs in respect to a Study 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 ACREC policies, procedures and requirements.
- 27. Promptly report to ACREC all privacy breaches in respect to a Study, and any corrective action taken.
- 28. Comply with all ACREC ongoing oversight requirements, including but not limited to the submission of all protocol amendments/modifications to a Study, submission reports of the approved Study annually or more frequently at the discretion of ACREC, 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 ACREC.

- 29. Notify ACREC in accordance with ACREC's reporting requirements if a Study has been placed on hold or terminated by the Applicant.
- 30. Notify ACREC in accordance with ACREC's reporting requirements of any significant Study-related communication that has not been received by ACREC, including, but not limited to participant complaints, protocol deviations and privacy breaches.
- 31. Ensure all submissions made to ACREC are accurate and complete. ACREC has the sole discretion to determine if submissions are complete. The Applicant acknowledges that ACREC's decisions and determinations are based on the information provided by the Investigator.
- 32. Retain each Submission and all correspondence in accordance with both the Applicant's and ACREC's organizational policies and regulatory requirements.
- 33. Obtain all required decisions and approvals required to conduct the Study, such as approval from a research institute, university, professional or regulatory body, or external sponsor.
- 34. Retain all study documentation in accordance with applicable laws and ACREC policies, procedures and guidelines.
- 35. Provide to ACREC, and maintain, a list of all officials and agencies to which it will report its findings and actions.

Confidentiality, etc.

- 36. The parties acknowledge and agree that the Study, together with any supplemental documentation and information ACREC receives from the Applicant (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.
- 37. Aurora College and ACREC shall treat the Submission as confidential and may only disclose the Submission or portions thereof to its staff or external reviewers on a strictly confidential basis.
- 38. Aurora College and ACREC shall not disclose the Submission to third parties other than the external reviewers without the Applicant's consent except, in its sole discretion, as required by law or to protect public safety or the safety of Study participants.
- 39. If Aurora College or ACREC requires the Applicant to disclose any part of the Submission, the Applicant shall obtain any approvals necessary for that disclosure.
- 40. If Aurora College or ACREC reasonably believes that the disclosure of the Submission or portions thereof is required by law or in the interest of protecting public safety or the safety of Study participants, ACREC shall notify the Applicant of the disclosure and will consult with the Applicant prior to the disclosure when doing so is reasonable and possible in the sole discretion of ACREC.

Independence

41. Aurora College, ACREC 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.

Record Keeping

42. The parties shall keep accurate and complete records in accordance with applicable law and policies.

Breach

- 43. If ACREC determines that the Applicant is in breach of its obligations it may give notice to the Applicant of the breach.
- 44. Upon receipt of the notice of breach the Applicant shall rectify the breach within 20 business days or a mutually agreed time period.

Termination

- 45. The Applicant may terminate this agreement if it has (a) given ACREC 60 days written notification that the Applicant no longer wants ACREC to be its Board of Record, (b) secured oversight of its Study by another research ethics board of record, and (c) is in compliance with the TCPS.
- 46. Aurora College, or ACREC on its behalf, may terminate this agreement if (a) ACREC determines that the Applicant has not rectified its breach of this agreement within the time period established pursuant to this agreement, or (b) if Aurora College or ACRED gives the Applicant 60 days written notice of termination.
- 47. If Aurora College gives the Applicant notice of termination, the Applicant shall secure oversight of its Study by another research ethics board of record, or close its Study to the satisfaction of ACREC, and this obligation survives the termination of this agreement.
- 48. Immediately upon either termination of this agreement by ACREC or notice thereof, ACREC no longer has any obligation to review or adjudicate the Study.

Indemnification

49. ACREC is not be liable in any way whatsoever to the Applicant or any of the Applicant's 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 ACREC. This clause survives termination of this agreement.

50. The Applicant agrees to indemnify, defend, and hold harmless ACREC, 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 the Applicant or anyone for whom it is responsible at law in relation to their obligations under this Agreement. This clause survives termination of this agreement.

General Matters

- 51. Aurora College or ACREC may assign this Agreement upon written notice to the Applicant.
- 52. The Applicant may not assign this Agreement without prior written permission from ACREC or Aurora College.
- 53. ACREC may, in its sole and unfettered discretion, elect to charge a reasonable review fee for Studies which are sponsored by or receive funding support from for-profit corporations and organizations. If ACREC determines that an administration fee is warranted, the Applicant will be sent an invoice over email setting out the fees to be paid and the name of the payee to be used for payment, and the Applicant shall pay the invoice within 30 days. The administration fee will be determined by ACREC, which can be found at Aurora Research Institute (nwtresearch.com).
- 54. This agreement shall be governed by, and construed and interpreted in accordance with, the laws in force in the Northwest Territories and the parties shall exclusively attorn to the jurisdiction of Northwest Territories.
- 55. 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.
- 56. This agreement constitutes the entire understanding between the parties with respect to the subject matter of this agreement and supersedes all other prior agreements, whether written or oral, between the parties.
- 57. No amendment of this agreement will be effective unless it is in writing and signed by the parties. No waiver under this agreement will be effective unless it is in writing and signed by the party granting the waiver. A waiver granted on one occasion will not operate as a waiver on other occasions.
- 58. This agreement may be signed electronically.
- 59. If this agreement is signed in several counterparts, each will be deemed an original but all parts together will constitute one instrument.

Each party is signing this agreement on the date stated below that party's signature.

AURORA COLLEGE

[FULL NAME OF INVESTIGATOR]

Per:		Per:
	Name:	Title:
	Title: Vice President, Research	Date:
	Date:	
Per:		[FULL LEGAL NAME OF INSTITUTE]
	Name:	Name:
	Title: Chair, Research Ethics Committee	Title:
	Date:	Date:
		I hereby represent and warrant that I have the legal authority to bind the corporation/legal entity to this Agreement.