

HEALTH RESEARCH ETHICS BOARD OF ALBERTA BOARD OF RECORD AGREEMENT

INFO SESSION - JULY 2019

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WHY IS THE AGREEMENT BEING IMPLEMENTED?

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2), A.6.1
- Provides clarity

<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#toc06-1a>

TCPS2

TRI-COUNCIL POLICY STATEMENT

Ethical Conduct for Research Involving Humans

2010

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council of Canada

Please cite this document as follows:

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada,
and Social Sciences and Humanities Research Council of Canada. *Ethical Conduct for Research Involving Humans*. December 2010.

Note: For the most recent information on amendments, please consult the official online version of the
TCPS at www.pre.ethics.gc.ca.

Permission is granted to photocopy this material.

WHO IS THE AGREEMENT BETWEEN?

Alberta Innovates (AI) by its board the Health Research Ethics Board of Alberta (“HREBA”)	+	the “Investigator”
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OR

Alberta Innovates (AI) by its board the Health Research Ethics Board of Alberta (“HREBA”)	+	the “Organization” that employs the Investigator
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<https://hreba.ca/board-of-record-agreement/>

WHO ARE THE PARTIES?

“**HREBA**” = is a Research Ethics Board (“**REB**”) that provides ethical reviews and ongoing ethical oversight of research involving humans.

“**INVESTIGATOR**” = wishes to pursue research involving humans and requires the review, approval and ongoing ethical oversight of the research by an established REB. The Investigator is responsible for the ethical conduct of the research and the actions of any member of the research team.

“**ORGANIZATION**” = has employed the Investigator to perform research under its auspices and is responsible for the actions and activities of the Investigator.

THE AGREEMENT – GENERAL INFORMATION

- Investigator/Organization retain HREBA
- HREBA agrees to act as the “Board of Record”
- One agreement per Investigator
- All studies submitted by the Investigator for review
- Remains in effect for “the Term” of the agreement
- Governed by the laws in force in the province of Alberta
- Supersedes any prior written or oral agreements

RESPONSIBILITIES OF HREBA

- Operate in accordance with all “Applicable Laws and Regulations” and with Schedule “A” of the agreement
- Treat submissions made by the Investigator as confidential
 - May only disclose to staff & reviewers on a confidential basis
 - Can’t disclose to third parties without the investigators consent except as required by law or to protect public safety
- Remain independent of the Investigator/Organization
- Maintain accurate and complete records
- Maintain appropriate insurance to cover liabilities that may arise

RESPONSIBILITIES OF HREBA (SCHEDULE “A”)

- Review, correspond, recommend and make determinations regarding all ethics Submissions
- Ensure ongoing oversight of active Studies
 - Amendments, Reportable Events, Renewals, Closures
- Maintain Submissions and all HREBA correspondences within the IRISS system
- Maintain a current HREBA membership roster
- Maintain written policies and procedures
- Make relevant meeting minutes available to officials

RESPONSIBILITIES OF HREBA (SCHEDULE “A”, CONTINUED)

- Notify the Investigator/Organization
 - study is placed on hold, reliance on HREBA has been compromised, study related communications such as complaints or privacy breaches
- Follow procedures for reporting findings to regulatory agencies
- Maintain IRB registrations with the US Office for Human Research Protections

<https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc>

RESPONSIBILITIES OF THE INVESTIGATOR/ ORGANIZATION

- Conduct studies in accordance with all “Applicable Laws and Regulations”
- Comply with “HREBA Determinations”
- Remain independent of HREBA
- Maintain accurate and complete records
- REB administration fee for studies receiving funding from industry
- Maintain appropriate insurance to cover liabilities that may arise

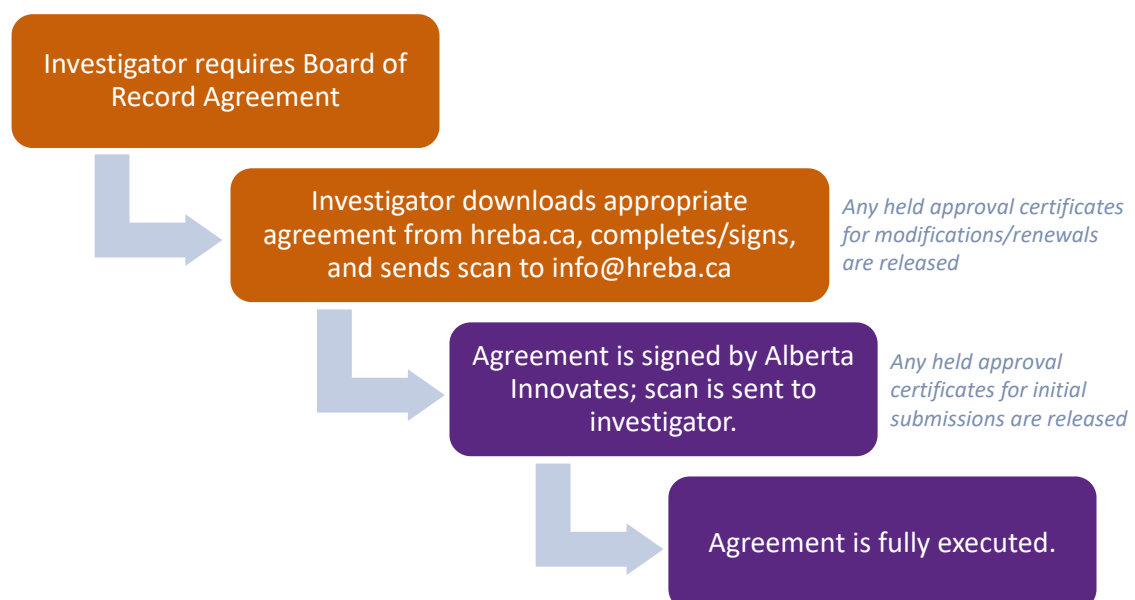
RESPONSIBILITIES OF THE INVESTIGATOR/ ORGANIZATION (SCHEDULE A)

- Submit REB Materials in accordance with HREBA policies and procedures
- Ensure Investigator and Study Team Members are qualified
- Conduct the research in accordance with the study protocol, HREBA policies and procedures, HREBA’s conditions for approval, and all applicable laws
- Submit to HREBA all amendments, reportable events, renewals and closure in accordance with HREBA policies, procedures and requirements
- Notify HREBA if a study has been terminated or put on hold, or if there is any significant study communication that HREBA might not be aware of

RESPONSIBILITIES OF THE INVESTIGATOR/ ORGANIZATION (SCHEDULE A, CONTINUED)

- Ensure that all submissions are complete and accurate; HREBA's determinations are based on the information provided
- Retain all study documentation as per organizational and regulatory requirements
- Obtain additional approvals (i.e., Health Canada, Operational Approvals, etc.) as required prior to initiating the research
- If applicable, maintain a Federal Wide Assurance (FWA)
- Provide HREBA with a list of appropriate officials to report its findings

PROCESS – AGREEMENT EXECUTION



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- Deadline for signed agreements **AUGUST 1, 2019**
- Questions can be directed to info@hreba.ca

ADDITIONAL INFORMATION

- New Document - [HREBA Terms of Reference](#)
- 2019 [Clinical Health Research Conference](#)
 - Best Western Plus Village Park Inn
 - Calgary, Alberta
 - September 20, 2019 (8:00 am to 4:30 pm)
 - Registration Opening Soon!