

# Health Research Ethics Harmonization (HREH)

## Project Vision:

To achieve an integrated model for health research ethics review in Alberta that supports health research, encourages multi-site research and attracts additional health research activity and investment to the province. The achievement of this vision will also support our national ability to attract research to Canada.

## Background and Who's Involved?

The Council of Chairs of health Research Ethics Boards (REBs) designated by the Health Information Act (HIA) of Alberta and the six institutions who sponsor these REBs have committed to HREH through *A Strategy for Moving Forward Alberta Health Research Ethics Boards (March 2010)* and the *Executive Sponsors' Strategic Intent (March 2011)* document. A key goal of the strategy was advanced in February 2011 with the signing by the Executive Sponsors of the six institutions of the health Research Ethics Reciprocity (RER) Agreement, making Alberta the first province or territory in Canada to achieve such an agreement. The six institutions include: Alberta Health Services, Alberta Innovates – Health Solutions, College of Physicians & Surgeons of Alberta, University of Alberta, University of Calgary, and University of Lethbridge.

## What will HREH achieve?

The HREH Initiative aims to achieve a streamlined, effective, collaborative and integrated model for health research ethics review supported by appropriate technology. The integrated model will:

- Ensure protection of research participants;
- Facilitate multi-site research;
- Support provincial level metrics for strategic management of health research ethics in Alberta; and
- Contribute to Alberta's and Canada's potential as an attractive and competitive research environment.

## The model will include:

- A single application form and standard process for handling multi-REB approvals; and
- Platform technology for capture of appropriate information across the province to support not only the RER Agreement but to contribute

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system-level metrics for ongoing monitoring and improvement of health research ethics in Alberta.

## What does the HREH mean for stakeholders?

The model will introduce reciprocity and harmonization into the health research ethics system, and meet system-level needs for information.

**Reciprocity** means that if a health research project requires ethics approval by more than one Research Ethics Board (REB) in Alberta, the researcher applies to the first REB which completes its review. Then, according to the established Research Ethics Reciprocity (RER) Agreement, subsequent REB reviews and approvals are completed in an expedited manner and enabled by effective channels of communication between REBs and the researcher. Currently, the REBs are pilot testing common processes for protocols requiring multi-REB approvals and are working toward common forms to support the agreed process that is ultimately operationized. Such forms and processes for reciprocity will be fully realized when information platforms connect the REBs electronically.

**Harmonization** means that the administrative processes, from the point of view of the researcher, will be transparent and consistent. The Research Ethics Offices, while maintaining their independence, will work in a collaborative manner to facilitate the provincial health research ethics system.

**System-level information needs** are those that apply to the entire ethics review system across the province in relation to strategic planning, policy and

programming to support health research. Ability to provide system level information will enable metrics for ongoing efficiency and effectiveness.

**Researchers** will be able to operate within a more transparent, streamlined and efficient research ethics review system. A researcher will use common templates for ethics review submissions across the health REB system. Ethics submissions, communications, process tracking, and reporting will be completed electronically.

**Research funders**, such as pharmaceutical companies, will experience a more streamlined multi-REB approval process, and as a consequence reduced start-up times for clinical studies.

**The Public** will benefit from enhanced access to the latest treatments and quality of care through a more efficient ethics review process that encourages research in Alberta.

## Alberta Clinical Research Consortium (ACRC) Initiative

HREH is strongly linked with the Alberta Clinical Research Consortium (ACRC) in assisting the fulfillment of the Alberta Health Research and Innovation Strategy (AHRIS), jointly developed by the Alberta Ministries of Advanced Education and Technology and Health and Wellness. Specifically, both HREH and ACRC are contributing to fulfillment of the Innovation Platforms strategy section of AHRIS, which focuses on enabling actions to address system and infrastructure challenges for health research and innovation in the province.

## For More Information:

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