

# Process for the Review of Multi-Site Health Research Ethics Applications in Alberta

## *ALBERTA'S HEALTH RESEARCH ETHICS HARMONIZATION INITIATIVE*

In response to the creation of the *Alberta Health Research Ethics Reciprocity Agreement* in February, 2011, Alberta's six Health Information Act-designated research ethics boards (REBs) have now developed, agreed upon and implemented processes to streamline the approval of ethics applications requiring more than one REB approval.

### **Background**

The Alberta Health Research Ethics Harmonization (HREH) initiative is led by the Executive Sponsors – a group of senior representatives from each of the five institutions in Alberta that host Health Information Act (HIA)-designated research ethics boards (REBs). Resources, facilitation and secretariat services for the initiative are provided by Alberta Innovates Health Solutions.

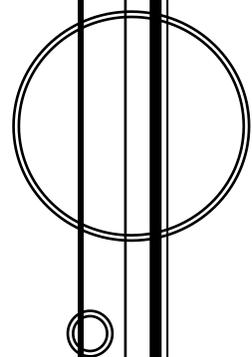
The HREH aims to achieve a streamlined, effective, collaborative and integrated model for human health research ethics review supported by appropriate technology. "Harmonization" in this initiative means that administrative processes associated with human health research ethics review, from the point of the view of the researcher, will be transparent and consistent, and that the Research Ethics Offices, while maintaining their independence, will work in a collaborative manner to facilitate the provincial health research ethics system.

### **The Research Ethics Reciprocity Agreement**

The *Alberta Health Research Ethics Reciprocity Agreement* (RER) was signed by the Executive Sponsors in February 2011. The agreement provides the framework for cooperation and mutual recognition of reviews among the signatories' REBs, particularly as it pertains to multi-site protocols, and ethics reviews under the jurisdiction of two or more REBs.

"Reciprocity" means that when an ethics approval is required by more than one health REB in Alberta, the researcher applies to the first REB (i.e. the researcher's home REB), which conducts a "full" review as has been done in the past. Following approval by the first REB, subsequent REB reviews ("reciprocal reviews") are completed in a delegated manner and enabled by effective channels of communication between REBs and the researcher.

This applies to all ethics applications, including those determined to be "high risk," which previously would have undergone a full review by the second and subsequent REBs. Alberta is the first province or territory in Canada to achieve such an agreement.



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### *Status*

In October 2011, chairs, representative members and administrators from the six REBs came together for the first time to develop and agree upon a set of common processes for reciprocal reviews. To pilot the processes, REB administrators from the six HIA-designated REBs tracked information about reciprocal reviews conducted by their REBs between November 2011 and April 2012. The results were evaluated, and input gained from REB administrators, researchers and study coordinators.

Based on the pilot's findings and recommendations, finalized processes both health research and clinical trials are now in place for ethics for multi-site applications.

### *Procedure for Research Ethics Boards Multi-Site Reviews*

The common processes to be used for applications involving multi-site reviews by each of the six HIA-designated REBs, as confirmed and refined through the pilot process, are as follows:

- The first REB will receive and review the application as per the usual process.
- Once approved, the researcher will forward the approved application and supporting documentation, including the approval letter/certificate, to the subsequent REBs. The researcher must let the subsequent REB administrator(s) know the protocol has been approved by one of the six HIA-designated REBs as that will, under the reciprocal process, permit this protocol and application to be reviewed as a delegated review.
- The subsequent REB administrator(s) will review, as per normal process, for any missing documents or required information. When the application package is complete, the administrator will forward to the chair or delegate for a delegated review.
- If there are minor concerns, they will be dealt with directly with communication between the subsequent REB and the researcher.
- If the concerns are more substantial they will be addressed through chair-to-chair communication.

The improved processes are expected to reduce the time required for ethics approvals, while decreasing administrative workload and timelines for researchers and REBs.

The processes will be reviewed in approximately a year, when all six REBs will be using a common electronic platform for ethics application, review and reporting.