

STRATEGIC INTENT OF THE HEALTH RESEARCH ETHICS BOARDS EXECUTIVE SPONSORS

Overview

The Executive Sponsors¹ of Alberta's Health Research Ethics Boards (REBs) have met as a group a number of times with the intent of framing and supporting harmonization of these REBs. It is expected that this harmonization will encourage research across institutions, and that additional health research activity and investment in Alberta will result.

A major element in this harmonization is the creation of an environment to share information. Currently, a research team working in separate institutions in this province must have their research ethics application approved by the REBs associated with each institution. A recently signed reciprocity agreement will ensure that approval in one institution will facilitate approval in the others. Critical to implementation of this process is the creation of an environment in which appropriate² information can be shared.

The framework of information sharing is being put in place. Today we have two comprehensive platform initiatives to modernize the Alberta REB information environment. One is in use at the University of Alberta and the other is being implemented at the University of Calgary. Based on business needs and implementation opportunities, other REBs are interested in sharing the capacities of these platforms or accessing their own platform. Collectively, the technology can provide a level of integration and information sharing between institutions and REBs.

Strategic Intent

On June 14, 2010, the Executive Sponsors confirmed the commitment of our institutions to work together to achieve the goals of *A Strategy for Moving Forward Alberta's Health Research Ethics Boards, Final Report, March 2010*.

On January 13, 2011 the Executive Sponsors confirmed the value of system-wide information for Alberta's health REBs to support a competitive advantage, and we confirmed the commitment of our institutions to a level of integration between REB platforms to enable appropriate information sharing.

¹ Institutions and organizations who sponsor HIA-designated health research ethics boards in Alberta

² For the use of REBs and the health ethics review system, subject to legislation, policy, guidelines and agreements

It is our intent to ensure all stakeholders understand the scope and direction of information sharing necessary and appropriate to achieve a vision of health REB harmonization, an integrated model in Alberta that will support health research, encourage multi-site research, and attract additional activity and investment.

The scope and direction of our strategic intent is as follows:

- *For human health research in Alberta, any given study will have a virtual single point of entry to the ethics review process.*
- *An information environment and supportive technology that allows for the capture of appropriate system-level information to inform health research ethics review and provincial research system needs.*
- *Appropriate information sharing for human health research, including multi-site studies, to support reciprocity and enable harmonized processes.*
- *The design, development and implementation of compatible platforms that allow for seamless, appropriate information flow, including the use of common forms and templates as required.*
- *Information sharing processes and supports that increase efficiency and rationalize the research ethics review process.*

Principles

We, the Executive Sponsors, recognize that implementation of an information sharing environment can be accomplished in a variety of ways. It is not our intent to specify how this should be done. Rather, we expect that the Implementation Committee will find the best way to do this.

We state in this section the principles that must be honoured in this implementation process; to wit:

- Information sharing will recognize the autonomous nature of the REBs' decision-making that is mandated by the TCPS and supported by institutional leadership, and will not impede REB independence.
- Information will reside with the institution or entity that has initial custody of it.
- Information sharing will comply with all relevant policy, regulation and legislation, including the Health Information Act, the Freedom of Information and Protection of Privacy, the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS) and other agreements.
- The information environment will support the management and administration of REB processes and policies, and will not impede institutional initiatives.
- As much information will be shared as is required to implement reciprocity (as outlined in the Reciprocity Ethics Reciprocity Agreement) and to facilitate the strategic intent.
- Each REB will take due care in safeguarding its information storage and transmission.

- The participating entities will share costs on a basis that reflects investment to date, required effort and benefits received, with specific arrangements to be developed and agreed to as costs arise.
- The Executive Sponsors will work to provide resources as required.
- Recognizing their current duties and primary responsibilities, administrative staff will support and expedite the work of the strategic intent, with additional staff identified as required for implementation.
- The Implementation Phase will be completed in fiscal year 2011-2012. Any undue delays should be brought back to the Executive Sponsor for each entity, or the Executive Sponsor Table for discussion and resolution.

Governance

It is not our intent to specify how the strategic intent should be achieved. Rather, we nominate an Implementation Steering Committee, to be formed immediately, to work collectively on achieving the strategic intent in accordance with the guiding principles.

The Implementation Steering Committee will be responsible for implementation of the next stage of harmonization, including the creation of capacity for appropriate information sharing across health REBs through a level of integration and alignment of information management and technologies.

To ensure that this project proceeds in an effective and efficient manner, our institutions are committed to participation in the following guiding and decision-making groups that form the governance framework for health REB Harmonization:

- The Executive Sponsors provide strategic direction for the provincial harmonization effort and commitment of the REB sponsoring institutions
- The Council of Chairs provides leadership to the autonomous functions of the REBs, as mandated by the TCPS, including aspects of harmonization that relate to ethics review and approval decisions. It also advises on the needs and commitments of the REBs and identifies system issues to strengthen research ethics.
- The Implementation Steering Committee undertakes the planning, management and evaluation for all aspects of harmonization requiring inter-institutional cooperation, coordination and alignment. It will strike implementation teams (working groups) as required to achieve objectives.