

# ARECCI Background and History

## Background

- ARECCI was created in 2003 to address issues in the province related to ethics review of knowledge-generating health projects (quality improvement, evaluation, and research).
- Several problematic issues:
  - unclear what projects needed review
  - same project treated differently by Research Ethics Boards (REBs) in different jurisdictions
  - assumption that Quality Improvement (QI) and program evaluation projects did not need ethical review
  - assumption that simply following professional codes of conduct were enough to protect people
  - at-risk and vulnerable populations in QI and evaluation projects not given the same protections through ethical scrutiny as research subjects
- Consensus that:
  - all projects that generate knowledge (QI, evaluation, and research) can create risks for participants that need to be identified, assessed, and addressed in the context of the type of project
  - health organizations that conduct QI and evaluation projects should assume responsibility for their ethical oversight
  - all ethics review processes in Alberta (REB review for research/health organization oversight of QI and evaluation) would benefit from increased clarity, consistency, transparency, and efficiency.
- Over the past seven years, the ARECCI collaboration has worked to build capacity and implement a higher standard of practice related to ethics review across the province and beyond. Some of the highlights of ARECCI collaboration include:
  - development of five recommendations (principles) to support the integration of ethics considerations across all knowledge-generating projects that involve people or their health information.
  - pilot testing and release of two decision-support tools that assist in determining, minimizing, and mitigating risks to all project participants: *ARECCI Guidelines for Quality Improvement and Evaluation Projects* and the online *ARECCI Ethics Screening Tool*
  - development and testing of two levels of educational modules: one that assists project leaders/managers of QI and evaluation projects to integrate the ARECCI concepts and tools into practice and one that assists reviewers of higher risk QI and evaluation projects.

## History

### Phase I: Establishing the Basics (January 2003 – November 2004)

- Under the leadership and funding support of the Alberta Heritage Foundation for Medical Research (AHFMR), establishment of a steering committee that included representatives from REBs, regional health authorities, and Alberta Health and Wellness.
- Consensus and establishment of ARECCI's goals and key recommendations for ethics screening and review and development of several screening tools to assist with the application of the recommendations.
  - **ARECCI Goals:**
    - To develop a common understanding and broad consensus on issues of ethics review across a range of knowledge generation projects (research, QI, and evaluation).
    - To increase the clarity, consistency, transparency, and efficiency of ethics review processes in Alberta.
    - To recommend an approach to answering the questions:
      - What kind of investigation project is it?
      - What process of ethics review should be used for each kind?
      - What level of review is appropriate: full or expedited?
    - To develop guidelines and tools for Alberta's health researchers, managers, ethics boards, and other stakeholders to implement the recommendations.
    - To inform regional, provincial, and federal policy related to ethics review processes.
  - **Five ARECCI Recommendations:**
    1. Screen all knowledge generating projects to ensure ethics risk is considered and people are protected.
    2. Sort by Project Primary Purpose (a sorting tool is available) to determine if the project is research or non-research to assist appropriate review.
    3. Sort by Level of Risk to the participant to determine the level of review that may be needed (two ethics risk filter tools are available: one for those whose primary purpose is research and one for those most likely to be non-research).
    4. Build capacity across the province - collaboratively with suggested processes and tools as well as education to support implementation of the recommendations.
    5. Progressive implementation once there is capacity to effectively use the recommendations and decision support tools.
- Development of draft ethics screening tools and risk filters. These draft tools included a checklist intended to classify a project by its primary purpose (e.g., research or quality improvement and evaluation), as well as a series of risk filters designed to determine a project's level of risk (e.g., minimal risk or more than minimal risk).

## **Phase II: Piloting the Concepts and Tools (January 2005 – November 2005)**

- Creation of the foundational document *Protecting People While Increasing Knowledge Recommendations (2005)*, which outlined the philosophical and conceptual underpinnings of the five ARECCI recommendations on integrating ethics in knowledge-generating projects and enhancing consistency at the systems level.
- Pilot testing and refinement of the ARECCI ethics screening tools. 104 projects were tested and evaluated to assess the feasibility of the ARECCI recommendations and screening tools in practice. Three tools to support implementation were revised, finalized, and

produced as one-page stand-alone documents. They included: 1) *Project Primary Purpose: Checklist for Determining the Appropriate Route for Ethics Review*, 2) *Quality and Evaluation Risk Filter*, and 3) *Research Risk Filter*.

### **Phase III: Resource Development (February 2006 – December 2008)**

- Automation and integration of the three paper-based screening tools tested in Phase II into one ethics screening tool.
- Pilot testing of the new web-based *ARECCI Ethics Screening Tool*.
- Development and refinement of *ARECCI Guidelines for Quality Improvement and Evaluation Projects* for ethics review of higher risk non-research projects. This ethics decision-support tool assists project leaders and organizations to integrate ethics considerations in QI and evaluation projects to ensure participants are respected and protected.
- Hosted *Protecting People While Increasing Knowledge: Ethics in Health Research, Evaluation and Quality Improvement* conference May 4-6, 2008 in Calgary. This inaugural, groundbreaking, interactive national conference fostered national dialogue and identified actions to address grey areas surrounding ethics in research, QI and evaluation.

### **Phase IV: Capacity Building for Implementation (January 2009 to the present)**

- Development and refinement of two levels of project ethics education:
  - **Project Ethics Course Level 1** – Course manual and workbook developed and pilot tested. This course provides health service managers and project leaders with basic knowledge and skills in ethics considerations of QI and PE projects.
  - **Project Ethics Course Level II** – Currently being developed and tested. This course will assist development of reviewers of higher risk QI and PE projects and provides advanced skills to enable organizations to integrate consistent ethics oversight mechanisms for these types of projects.
- Development of a “Train the Trainer” program model for the Level 1 course (in progress).
- Ongoing evaluation and refinement of the online *ARECCI Ethics Screening Tool*: [www.ahfmr.ab.ca/arecci/screening](http://www.ahfmr.ab.ca/arecci/screening)
- Automation of the *ARECCI Ethics Guidelines for Quality Improvement and Evaluation* decision-support tool: [www.ahfmr.ab.ca/arecci/guidelines](http://www.ahfmr.ab.ca/arecci/guidelines)
- Broad dissemination (provincial and national) of both the online and print versions of the two ARECCI ethics decision-support tools (*ARECCI Ethics Guidelines for Quality Improvement and Evaluation* and *ARECCI Ethics Screening Tool*).
- Publication of a manuscript targeting QI audiences that addresses ethics considerations for non-research projects. Other manuscripts targeting evaluation and QI audiences are being developed.

ARECCI remains an ongoing and collaborative process. Feedback is welcomed and can be forwarded to:

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