



Introduction to the Concepts and Tools

of the

**Alberta Research Ethics Community
Consensus Initiative (ARECCI)**

Health Projects are Changing

- Climate of accountability → commitment to quality improvement and evaluation
- Increasing volume and complexity
- Increasing scope and sophistication
- Changing methods and approaches

What's the problem?

- QI and evaluation projects and research projects are all knowledge-generating and important to the management of quality health services
- All pose risks and burdens to patients or clients
- Sometimes it's hard to tell the difference between research and QI & evaluation
 - Design: methods, recruitment, data collection strategies, data analysis

What's the problem? ...continued

- Only research projects have legislation or formal processes to protect individuals and their personal information
 - Tri Council Policy Statement (TCPS)
 - Health Information Act of Alberta (2001)
- Interpretation – ethics in QI, evaluations are less important and these types of projects do not require ethical scrutiny or formal review

Challenges and Issues

- Lack of clear ethical standards for QI and evaluation projects
- Assumption that QI and evaluation projects are without risk
- Conflict of interest
- Vulnerable populations
- Easy access to participants and their health records, and potential lack of QI and evaluation skills

Challenges and Issues ...continued

- Professional frameworks are not enough
- Lack of clarity of what projects require review
- Inconsistent treatment of projects
- Lack of clarity re: Who is responsible for ethics approval
- If project leader requests evaluation or QI review – no where to go
- Avoidance of the REB review process (time, cost, unclear, cumbersome etc) by labeling project as QI or evaluation

Alberta Research Ethics Community Consensus Initiative (ARECCI) Response

AHFMR brought stakeholders together to establish ARECCI

1. A collaboration by representatives of health services and research ethics boards across Alberta as well as other stakeholders from research, QI and evaluation
2. Developed a new approach that aims to strike balance between:
 - consistency in ethical scrutiny to protect people, and
 - flexibility to encourage projects that pursue innovation

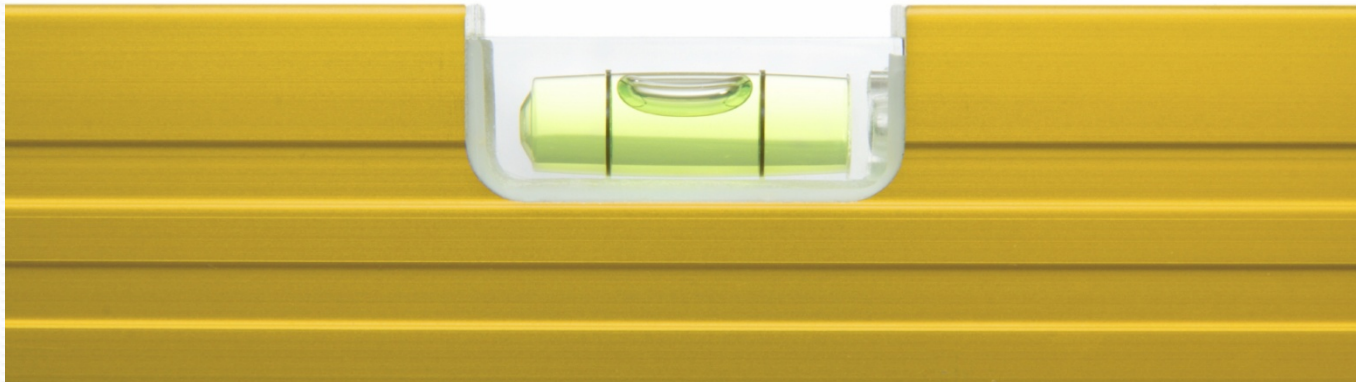
ARECCI Strikes a Balance

Protection of People

**Pursuit of knowledge
(innovation and
improvement)**

**Consistent ethical
scrutiny/review
structure**

**Flexibility and
appropriate
level of review**



Project Ethics

- Involves the integration of ethics considerations from the planning through to the reporting stages of a project to ensure that the rights of the people involved are respected

DIFFERS FROM

- Professional codes of ethics - which focus on individual conduct
- Bioethics - which is the application of overarching moral values, principles, and thinking to problems that arise in health research or service.

Main Beliefs in Project Ethics

- Ethical principles apply across the range of knowledge-generating health projects (research, QI and evaluation)
- All knowledge-generating projects would benefit from screening for ethical implications to manage risk for participants
- Ethics screening and review processes ought to encourage (not impede) knowledge-generating projects while ensuring risk and harm to people are minimized

Main Beliefs in Project Ethics... continued

- **Health organizations that conduct QI and evaluation projects should also assume responsibility for their ethical oversight**
- All ethics review processes in Alberta (*REB review for research and health organization oversight for QI and evaluation*) would benefit from increased clarity, consistency, transparency, and efficiency

What's Envisioned?

**All Projects Involving People or
their Health Information
(Initial screening)**

Research:
REB screening and
review processes

Quality / Evaluation:
Screening and review
processes in local
contexts

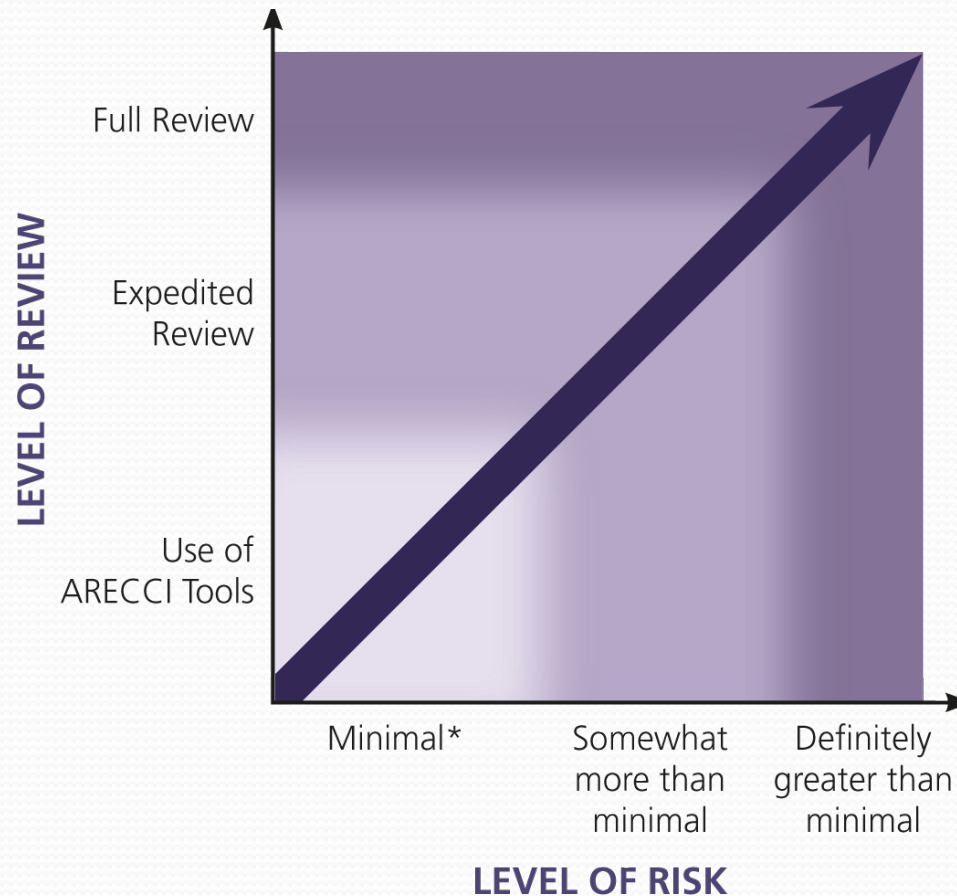
ARECCI Recommendations/Principles (Online screening tool available)

1. **SCREEN** all knowledge-generating projects for ethical risk to participants
2. **SORT** by project primary purpose to determine the appropriate review mechanism
 - Research or Non-research pathways
3. **SORT** by level of risk to determine level of review needed
 - Risk filter for research projects
 - Risk filter for QI and Evaluation projects

ARECCI Project Ethics Resources: Decision-Support Tools & Courses

- *Ethics Guidelines for QI and Evaluation Projects* – designed for project leads/teams to assist integration of ethics from initial planning through to reporting
- *Online Ethics Screening Tool* – a 3 step web tool to sort whether a project is research or QI/evaluation and then determine level of risk to participants to recommend appropriate review (www2.ahfmr.ab.ca/arecci/tool)
- *Project Ethics Course Level 1* – for project leaders aimed at enhancing knowledge and skill in ethics and QI / evaluation projects.
- *Project Ethics Course Level 2* – for those with responsibility for ethics oversight of QI and evaluation (in development)

QI/Evaluation: Level of Risk Determines Level of Review



*There is always potential for ethical risk in projects that involve people or their personal information.

Ethics Screening Score for QI and Evaluation

Score	Level of Risk	Recommended Ethics Review
15 or greater	Definitely greater than minimal	Full review* consistent with local policies
8 – 14	Somewhat more than minimal	Expedited** review consistent with local policies
0† – 7	Minimal	Use the ARECCI tools to identify and manage risk consistent with local policies

* The “full review” of QI and Evaluation type projects means independent ethics scrutiny by a group or individual(s) who are removed from the project, but who understand its context. The specific setting determines how full review will be operationalized.

** The term “expedited” comes from REB literature. Here it means scrutiny by someone other than the project team within your setting.

† There is always potential for ethical risk in projects that involve people or their personal information.

Key Points on Managing Risk in QI and Evaluation

- There is always potential for ethical risk in projects that involve people or their personal information
- Incorporate ethics considerations at the project planning stage to protect project participants (benefits should outweigh risks)
- Important to show due diligence by ethics screening prior to involving people or their information
- Projects need not be risk free but strategies to minimize and mitigate any identified risk ought to be planned ahead of time
- Use the ARECCI tools as decision-support guides to help identify risk and to manage risk in projects

For more information:

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