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Ethics in Quality Improvement and Evaluation
BC Patient Safety and Quality Council Webinar
By Linda Barrett-Smith, November 16 2011

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ARECCI Project Ethics Approach

The Issues:

- Gray areas in distinguishing research from non-research for purposes of ethics review (e.g. evaluation and quality improvement (QI))

- How to ensure ethical risks for participants are identified and managed in non-research projects

The Goal:

- Develop a consistent process for ethics screening and review across a range of knowledge-generating activities (research, evaluation and QI) which involve people or their information

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ARECCI Project Ethics Approach: History and Timelines

2003
Alberta Heritage Foundation for Medical Research (AHFMR) led the establishment of Alberta Research Ethics Community Consensus (ARECCI) Initiative to deal with the issues identified

2004
ARECCI developed five recommendations and five draft ethics screening tools (paper-based)

2005/2006
Context validity testing /pilot testing of recommendations and tools

2006/2007
Automation of three paper screening tools into one online ethics screening tool; development of second tool – guidelines for project planning and review

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ARECCI Project Ethics Approach: History and Timelines…continued

2007–2008
Ongoing context validity testing /pilot testing of automated screening tool; publication of *ARECCI Guidelines for Quality Improvement and Evaluation Projects*

2009-2010
Automation of Guidelines Tool; ARECCI Level 1 courses begin; AHFMR becomes Alberta Innovates – Health Solutions; development of Level 1 Train the Trainer Program and Second Opinion Reviewer Program; first Level 1 course taught outside Alberta

2011
ARECCI renamed - *A Project Ethics Community Consensus Initiative* to reflect adoption of the framework and tools more broadly

Visit **www.ahfmr.ab.ca/arecci** *for the most up-to-date information on courses, webinars and forums.*

Project Ethics

- The application of ethics considerations across a range of knowledge-generating investigations (evaluation, QI, and research projects) so that people or their information are protected and respected

- Involves the integration of ethics considerations from the planning through to the reporting stages of a project

Main Beliefs in Project Ethics

- Ethical principles apply across a range of projects

- Organizations that conduct quality and evaluation projects should also assume responsibility for their ethical oversight

- *Ethics Screening* ought to be done for all projects that involve people or their data to identify ethical risks and determine review requirements

- *Ethics Review* for quality and evaluation projects (higher risk) is needed but the process must be flexible and integrated in the organization to encourage (not impede) worthwhile projects

- All ethics review processes would benefit from increased clarity, consistency, transparency, and efficiency: *REB/IRB/REC review for research & Organizational oversight for evaluation and QI*

Striking a Balance

Distinguishing Ethics

|		
bioethics	→	Is the application of moral principles, values, and thinking to problems that arise in the delivery of health services or research related to health
professional codes of ethics	→	Focuses on the individual practitioner and his or her personal conduct
project ethics	→	Focuses on the conduct of projects

Project Ethics Principles

- Screen all projects to determine ethical risks and review requirements
- Sort according to project 'primary purpose'
- Determine category of risk for project participants
- Review according to category of risk for the project
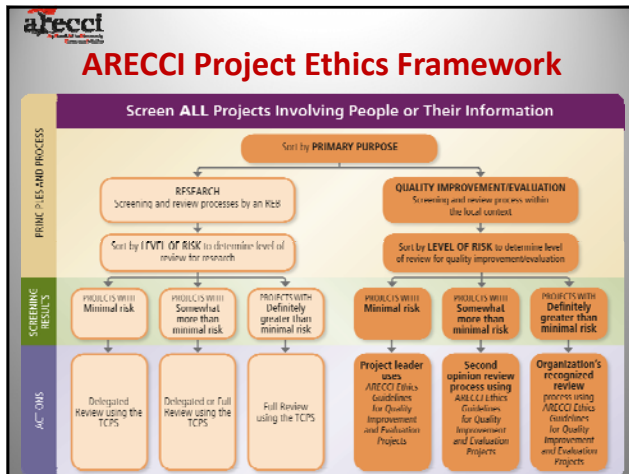
ARECCI Project Ethics Framework

Project Ethics Foundation

- The ARECCI project ethics concepts and tools are grounded in key ethical principles:
  - Respect for Human Dignity
  - Respect for Free and Informed Consent
  - Respect for Vulnerable Persons
  - Respect for Privacy and Confidentiality
  - Respect for Justice and Inclusiveness
  - Balance of Harms and Benefits
    - -- Minimizing Harm /Maximizing Benefit
- These principles and the implications that flow from them have been incorporated into the ARECCI framework and tools
- Use of the ARECCI tools can help ensure that you have done due diligence to apply these principles in your projects

Defining Ethical Risk

Risk is defined as the "possibility of suffering harm or loss"

Ethical risk is defined from the perspective of the participant in the project in terms of the possibility of suffering harm or loss based on what is wrong for a person, family, or community

Ethical risk includes, without limitation, real or potential threat:

- ❖ to privacy and confidentiality of individuals or communities,
- ❖ of physical, mental, psychological, emotional, financial or legal impact on individuals or communities, or
- ❖ of additional burden to the system if gains of project do not justify risks imposed and resources spent.

ARECCI ©Six Ethics Considerations

- How will the knowledge gained from this project be useful?
- How will the described method or approach generate the desired knowledge?
- How will you ensure that the participant (or data) selection process is fair and appropriate?
- What have you done to identify and minimize risks as well as maximize benefits? Are the remaining risks justified?
- How are the rights of individuals, communities, and populations respected in this project?
- Is informed consent needed in this project?

ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects

Research & Non-Research Projects

Commonalities	Differences
Ethical principles	**PRIMARY PURPOSE**
Person-centered perspective	How change is viewed
Knowledge-generating	The role of context
Systematic	Relationship to the organization's business
Design features	Legislation

ARECCI Ethics Screening Tool

- **Step 1** – Rules out obvious research projects
- **Step 2** – Determines Project Primary Purpose
- **Step 3** – Screens for ethical risk to participants
- **Step 4** – Determines category of risk and recommended review action

Level of Risk Helps Determine Review Process
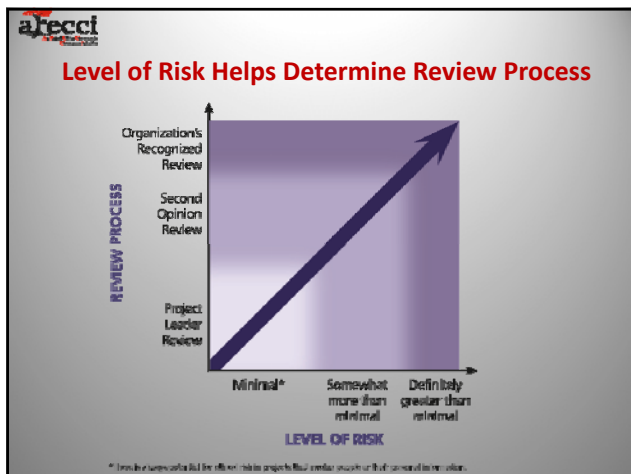
QI/Evaluation Ethics Review ≠ REB Review

Summary of Tools

The online ARECCI tools are meant to support decision-making:

1. <u>Guidelines Tool</u>: facilitates thinking during project planning to help uncover and address risks to participants in the plan.

2. <u>Screening Tool</u>: sorts the primary purpose of a project and identifies ethical risks to help project leaders/teams ensure risk management. This tool has proven to be valuable in identifying those projects which have a higher level of ethical risk.

Caution: The scores on the screening tool are not intended to provide a scientific determination but are an indicator of the level of ethical risk in a project.

Summary of Key Concepts

- Evaluation projects are integral to improving quality & safety in health and human services organizations

- Ethical issues exist in quality and evaluation projects and should be considered at all stages of a project by those responsible within an organizational context

- Ethics screening of a project is quick using the *Ethics Screening Tool* **(www.ahfmr.ab.ca/arecci/screening)**

- Higher levels of risk require greater levels of ethical scrutiny –use the *ARECCI Ethics Guidelines for QI and Evaluation Projects* to review these projects **(www.ahfmr.ab.ca/arecci/guidelines)**

- ARECCI education (Level 1 Course, Train-the-Trainer Program, Second Opinion Reviewer Program) assist organizations to build their own capacity for project ethics

What can you do? Implications for Projects

- Be aware and consider ethics in any project you do – privacy and confidentiality are very important but only one aspect of a range of ethics considerations

- Project Ethics concepts and tools can help assure identification of ethical risk and point to ways to manage these risks

- Projects do NOT need to be risk free, but strategies to minimize and mitigate any identified risk ought to be planned ahead

- Documented use of the tools and seeking a 2nd opinion for riskier ones can help demonstrate that you have taken reasonable measures to protect people

- Use of the ARECCI tools and processes can assure the public that you have acted to conduct your project ethically

Thank you for attending this session!

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