

# ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects

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# ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects

## Introduction

A Project Ethics Community Consensus Initiative (ARECCI) Network<sup>1</sup> identified a lack of guidelines and other resources to assist project leaders in considering the ethical implications of quality improvement (QI) and evaluation projects.

In response to this need, the ARECCI Network developed two online ethics decision-support tools to assist leaders and organizations in the integration of appropriate ethics considerations in their projects: the *ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects* and the *ARECCI Ethics Screening Tool*.

Together, these tools are a resource that provides a quick and easy system of prompts to assist you in evaluating your projects to ensure that ethics considerations are included and that you have done due diligence to protect people and/or their information while enabling worthwhile initiatives.

This booklet provides the complete print version of the *ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects*, and gives an overview of the *ARECCI Ethics Screening Tool*. Information on scholarly citation and terms of use are found at the back of the booklet.

## ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects

Grounded in ethical principles, the *ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects* consists of **Six Ethics Considerations**<sup>2</sup> with detailed “Points to Consider” that help identify and address ethical issues in QI and evaluation projects. The guidelines are also automated and available at: [www.aihealthsolutions.ca/arecci/guidelines](http://www.aihealthsolutions.ca/arecci/guidelines).

The term “considerations” is used purposefully by the ARECCI Network to label key elements of the guidelines, rather than such terms as “principles” or “requirements” commonly used when referring to research ethics reviews. The intent of these guidelines is to stimulate thinking and discussion

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<sup>1</sup> Information about the ARECCI Network and its work can be found online at: [www.aihealthsolutions.ca/arecci](http://www.aihealthsolutions.ca/arecci)

<sup>2</sup> These considerations are based on the July 2006 Hastings Center Report: *The Ethics Of Using QI Methods To Improve Health Care Quality and Safety* by Baily, Bottrell, Lynn, and Jennings and a subsequent publication in the *Annals of Internal Medicine* by Lynn et al. (May 2007) *Ethical Requirements for the Protection of Human Participants in Quality Improvement Activities*. Baily et al. outline the following ethical requirements for QI activities: social or scientific value, scientific validity, fair participant selection, favorable risk-benefit ratio, respect for participants, informed consent, and independent review.

amongst individuals and organizations to enhance the integration of relevant ethical elements into QI and evaluation projects. The guidelines are also meant to cultivate internal adoption of the six considerations in the local context and practice, rather than lead to external REB/IRB ethics review process. If your organization lacks an internal review process, these guidelines can be flexibly integrated as a first step in documenting that project ethics have been considered in the design and execution of QI and evaluation projects.

The guidelines also help support an organization's established oversight process for QI and evaluation projects, particularly where such projects are screened to be more than minimal risk for their participants by helping provide an objective ethical assessment of the project in question (e.g., using the *ARECCI Ethics Screening Tool*). The reviewers in such processes should be independent of the project with no vested interest. Their role is to strengthen how project ethics are managed in projects to ensure benefits are maximized and risks to participants are reduced and mitigated.

## Considerations to Strengthen Your Project

### ©SIX ETHICS CONSIDERATIONS

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

### INSTRUCTIONS

The **Six Ethics Considerations** for QI and evaluation projects developed by the ARECCI Network are provided below in question format. After each question, detailed "Points to Consider" help you apply each consideration to a specific project. A series of prompts then guide you in fully addressing the question posed. The authors have tried to provide enough detail to be helpful, yet stay broad enough for a variety of contexts.

Comments to assist in the improvement of these guidelines are welcomed. Contact information is provided on page 11 for this purpose.

**1. How will the knowledge gained from this project be useful?**

**POINTS TO CONSIDER**

- What is the specific context of the problem or issue?
- Why do you want to obtain the information (e.g., for the purpose of evaluation, decision making purposes, information)?
- What relevant literature or better/best practices have you consulted?
- Who will benefit from this project (e.g., patients/clients, providers, families)?
- How will you let others know about your results?

Describe what you hope to find out in doing this project.

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Describe who will benefit from this project.

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Describe how the results will be communicated.

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## 2. How will the described method or approach generate the desired knowledge?

### POINTS TO CONSIDER

- Why is the approach or method or strategy you have chosen the right one for your particular project?
- How will you collect data?
- How will you analyze the data once it is collected?
- Is the information individually identifying? *(Please refer to consideration #5 for data retention, storage, and security information.)*
- How can you be relatively certain that these methodologies will assist you to obtain reliable information? *(Define reliable in this context.)*
- How will you know when you have obtained enough information to meet your project goal?
- Is there a need for consultation in areas where you don't have the expertise? For example, if your project uses quantitative or qualitative approaches, have you consulted a data analyst or statistician about your sample size (if applicable), or have you consulted someone about your data collection and analysis plan?
- Are you collecting too much identifiable information (i.e., data that is "nice to know" versus what "you need to know")?

Describe your approach or method or strategy.

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Outline your plan for analyzing the data.

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Explain how your method or approach will attain your goal.

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**3. How will you ensure that the participant (or data) selection process is fair and appropriate? Please provide rationale for your choices below.**

**POINTS TO CONSIDER**

- Is anybody or any group being excluded? If yes, why?
- Are you overburdening anybody or any group (e.g., marginalized groups, cultural groups, people with a particular disease or disorder, staff, management, community members)?
- If you are using a convenience sample (i.e., simply whoever is available), what are the risks?
- If participants are being compensated, is it fair and equitable?
- Are participants going to be provided any sort of honorarium to cover any personal costs they incur as a result of involvement in this project?
- Is any specific training needed by those who are going to approach people to participate in your project?
- Are you accessing participant data through records or charts?

Describe how you will select your participants.

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Describe how you will decide how many participants to include in your project.

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Identify who you have decided to deliberately exclude and the reason why.

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Describe how you will approach people to participate in your project.

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**4. What have you done to maximize benefits and identify and minimize risks?  
Are the remaining risks justified?**

**POINTS TO CONSIDER**

- What are the risks of not doing this project?
- Have you considered the risks outlined on the *ARECCI Ethics Screening Tool* in relation to this project? ([www.aihealthsolutions.ca/arecci/screening](http://www.aihealthsolutions.ca/arecci/screening))
- What strategies have you used to ensure that all reasonable and potential risk has been identified?
- If there is risk related to a power relationship in the project (e.g., between provider and patient/client, between staff and supervisor), how are you minimizing or mitigating this risk?
- Have you considered that the level of risk in the project increases if data is individually identifying? (*Please refer to consideration #5 below for data retention, storage, and security information.*)

Describe the potential risks for participants.

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Describe the potential benefits to participants.

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Describe the potential risks for your organization.

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Describe the potential benefits for your organization.

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Describe what you have done to maximize benefits as well as minimize risk (i.e., decrease the number of them) and mitigate risk (i.e., decrease the severity of the remaining ones) for both the participants and your organization.

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If there are remaining risks, describe how they are justified by the potential benefits of the project for the participants and your organization.

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**5. How are the rights of individuals, communities, and populations respected in this project?**

**POINTS TO CONSIDER**

- How are you protecting the privacy of individuals considering their cultural values and norms?
- Is personally identifying information being collected? If yes, how are you maintaining the confidentiality of that identifying information?
- If personally identifying information is being collected, are you collecting the least amount needed to complete the project?
- If personally identifying information is being collected, who will have access to the data and in what form?
- How will personally identifying data be recorded and stored, and for how long before it is destroyed? How will it be destroyed?
- Is data being transferred across regional, provincial, national, or international boundaries?

*...continued*

**5. How are the rights of individuals, communities, and populations respected in this project?...continued**

- Have you taken into account your organization’s policy regarding records retention?
- Have you considered security measures for any electronic and/or hard copy record(s) (e.g., password protection and locked filing cabinet storage; data encryption tools to secure data on laptops or other personal computers)?
- How will you maintain the welfare of participants during the course of the project?
- How will you inform participants if risks or benefits develop as the project progresses?
- What are your plans or mechanisms to inform participants of the results?
- How will you ensure that individuals will not be identifiable if the results are shared publicly, or in anything that might be published?
- For what other purposes might the data be used?

NOTE: If your project involves individually identifying health information, please ensure that you are meeting the applicable legal obligations in your jurisdiction. For example, in the province of Alberta you are required to complete a Privacy Impact Assessment (PIA) in some circumstances. Rather than duplicating the privacy information in that case, please attach the PIA and in this consideration, note the page on the PIA where the privacy information can be found.

Describe how you intend to protect the privacy and confidentiality of participants in your project.

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Describe how you will retain, store, and secure the data.

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**6. Is informed consent needed in this project?**

**POINTS TO CONSIDER**

- Are you or other team members in a position of power or authority over the people who need to be part of the project? If yes, how will you ensure that they do not feel coerced into participating?
- Do you or other team members have a conflict of interest with any aspect of this project? (e.g., potential for financial gain)
- Is the approach to informed consent appropriate for the project and its participants?
- Are you using any undue influence or pressure (whether obvious or implied) when asking participants to part of the project?
- How will you let people know that they can withdraw from the project at any time?
- Will people likely consent to their information being used, or information about them being used, to carry out your project?
- Consider the implications for consent should there be potential for some comments to identify an individual in the case where you are using a small sample. This possibility should be explained to the participant.
- If you could get informed consent, but you are choosing not to obtain consent, why did you make that choice? Will anyone be angry, frustrated, or hurt if they find out about your project afterwards and realize they weren't informed of their participation or asked for their consent?

Consent can be verbal or written.

Consider the possibility that participants may have literacy issues and use appropriate approaches for effective communication in such instances.

Any information provided should be in plain language with all technical terms explained.

When written, the information should be presented from the participants' perspective and at a language level used for the general public (Grade 6 or 7).

Describe how you will determine whether or not informed consent is needed in this project.

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If consent is needed, describe how you will obtain it. Attach any forms and/or scripts that will be used.

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## The ARECCI Ethics Screening Tool

After using the guidelines, it is recommended that you apply the online ARECCI Ethics Screening Tool to help determine the category of risk for project participants and appropriate ethics review requirements. The tool has been automated to enhance easy access and timely use by individuals or groups responsible for projects. It is available at: [www.aihealthsolutions.ca/arecci/screening](http://www.aihealthsolutions.ca/arecci/screening).

The ARECCI Network developed this tool to help determine appropriate ethics review requirements of projects that involve people and/or their information. It can be used for QI, evaluation and research projects.

The screening tool assists you in deciding:

- the primary purpose of a project (i.e., research or something other than research)
- the category of risk to project participants
- the type and level of ethics review needed (if any)

If the *ARECCI Ethics Screening Tool* indicates a project score of more than minimal risk, please consider seeking an objective opinion from a knowledgeable source about the risks involved in your project before proceeding to involve any participants.

## Scholarly Citation and Terms of Use

### SCHOLARLY CITATION

Scholarly citations of the *ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects* should be formatted as follows: *ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects* developed by the Alberta Research Ethics Community Consensus Initiative (ARECCI) Network (2008).

Scholarly citations regarding the *ARECCI Ethics Screening Tool* should be formatted as follows: *ARECCI Ethics Screening Tool* developed by the Alberta Research Ethics Community Consensus Initiative (ARECCI) Network (2005, revised 2008).

### TERMS OF USE

Both ethics decision-support tools are the subject of ongoing development, and members of the ARECCI Network assume no liability arising from their use. The Guidelines and Screening Tool may not be modified or adapted without the express written consent of the ARECCI Network. The Guidelines and Screening Tool may be reproduced and disseminated for non-commercial purposes, but only in their entirety, without abridgement, and must contain this notice.

## Feedback Welcomed on the ARECCI Decision-Support Tools for Projects

The ARECCI Network continues to refine and improve the usefulness of these guidelines and the screening tool for projects. Your feedback is very much welcomed and can be forwarded to:

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