

ARECCI Ethics Decision-Support Tools for Projects

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ISBN: 978-1-894927-53-6 (print)
ISBN: 978-1-894927-54-3 (online)

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Introduction

Two ethics decision-support guides have been developed by the Alberta Research Ethics Community Consensus Initiative (ARECCI) Network¹ to assist leaders and organizations in their projects. They are the *ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects* and the *ARECCI Ethics Screening Tool*.

These decision-support guides are a resource to assist integration of appropriate ethics considerations in projects to protect participants, whether the project is evaluation, quality improvement (QI), quality assurance (QA), or research.

Section I of this document provides an overview of the two guides/tools, describes how they work together, and outlines information on scholarly citation and terms of use. Section II provides the complete ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects (July 2008) with an optional form. The ARECCI Ethics Screening Tool is available online at: www.ahfmr.ab.ca/arecci/tool.

Section I – Overview of the ARECCI Tools/Guides

1. ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects

These ARECCI Ethics Guidelines aim to assist project leaders and organizations to ensure effective consideration of ethics in QI, QA and evaluation type projects. They are best used as the project is developed, but can be used at any stage – it is never too late to consider ethical implications in a project.

The guidelines include an **optional form** which is meant to be used:

- a) By a *QI/QA or Evaluation Project Lead* to work through the six ethics considerations developed by the ARECCI Network, and
- b) By a *reviewer* in the case of **higher risk** QI, QA, or evaluation projects. The reviewer should be independent of the project to provide an objective assessment. The role of the reviewer is to strengthen how ethics are handled in a higher risk project and to ensure risks are managed to protect the participants and/or their health information.

¹ More information about the ARECCI Network and its work can be found at: www.ahfmr.ab.ca/arecci

Once a project is developed using the above guidelines, it is helpful to use the online ARECCI Ethics Screening Tool to assist with determining the level of risk for project participants and appropriate ethics review requirements.

2. ARECCI Ethics Screening Tool

The ARECCI Network developed this web-based screening tool to help determine appropriate ethics review requirements of projects that involve people and/or their health information. It can be used for quality improvement, quality assurance, evaluation, and research projects.

The tool assists leaders and organizations in deciding:

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

The tool has been automated to enhance easy access and timely use by individuals or groups responsible for projects. It is available at: www.ahfmr.ab.ca/arecci/tool

Adding the *ARECCI Ethics Guidelines for Quality Improvement and Evaluation* and the *ARECCI Ethics Screening Tool* to your project management toolkit will provide a quick and easy system of prompts to help with:

- a) Identification of ethical considerations to be incorporated in a project, and
- b) Assessment of a project to determine appropriate review requirements.

Together, these two decision-support guides can assist you in evaluating your projects to ensure that ethics considerations are included and that you have done due diligence to protect people or their health information.

3. 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 decision support guides 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 the Screening Tool may be reproduced and disseminated for non-commercial purposes, but only in their entirety, without abridgement, and must contain this notice.

Section II – ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects

OVERVIEW

This section outlines *Six Ethics Considerations* developed by the ARECCI Network to assist individual project leaders and organizations in the integration of ethics in *QI, QA, or Evaluation projects* so that people are respected and worthwhile initiatives are enabled.

The term “considerations” is used purposefully by the ARECCI Network to label key elements of the guidelines for QI, QA and Evaluation projects, rather than such terms as “principles” or “requirements” commonly used elsewhere when discussing ethics from a research perspective. The intent of these guidelines is to provoke thinking and enhance the integration of relevant ethical elements in such projects by both individuals and organizations. Thus, the guidelines are meant to cultivate internal adoption of the six considerations in the local context/practice, rather than lead to external imposition of requirements such as occurs through an REB/IRB ethics review process.

Further, the considerations are meant to be sensible at an operational level to enhance consistency of practice for those individuals and organizations who choose to apply them. The considerations can form part of a process set up in an organization or professional practice to document that ethical implications are being addressed in QI, QA and Evaluation projects.

The six considerations can also be used by an independent reviewer when a project has been determined to have more than minimal risk for participants using the online ARECCI Ethics Screening Tool.

Where a project has been determined to be higher risk for participants, ARECCI recommends that a knowledgeable, independent reviewer assess it with the aim of strengthening the project to minimize the risks for participants.

To assist the application of the Six Ethics Considerations, an optional form is provided:

- a) **to support QI, QA and evaluation project leads** to ensure that the six ethics considerations have been integrated into their projects, and
- b) **for use by a reviewer who is independent of an identified higher risk project** to assist in strengthening how ethics are being handled in that project.

SIX ETHICS CONSIDERATIONS²

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 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?

FEEDBACK: Comments to assist the improvement of the guidelines are welcomed. Contact information is provided on page eight for this purpose.

CONSIDERATIONS TO STRENGTHEN YOUR PROJECT

The six ethical considerations for QI and evaluation projects developed by the ARECCI Network are provided below in question format. For each consideration, bulleted prompts are provided to guide the reader in addressing the question posed. In addition, “Points to Consider” are included to assist the application of each consideration to a specific project. The authors have tried to provide enough detail to be helpful, yet stay broad enough for a variety of contexts.

The attached optional form outlines each consideration, together with its bulleted prompts to support the application of these guidelines. “Project” in this context refers to a QI, QA, or evaluation proposal. The “you” in the items below refers to the individual(s) and/or group(s) involved on the project team.

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

- Describe what you hope to find out.
- Describe who will benefit from this project.
- Describe how the results will be communicated.

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?

² 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.

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

- **Describe your approach or method or strategy (e.g., focus group, survey, observation, implementation of best practice).**
- **Explain how it will attain the goal(s) of the project.**

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 and analyze data?
- 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")?

3. How will you ensure that the participant (or data) selection process is fair and appropriate?

- **Describe how you will select your participants.**
- **Describe how you will decide how many participants you will need.**
- **Identify people who may have been appropriate as a participant or subject, but whom you have decided to deliberately exclude. Please explain your decision.**
- **Describe how you will approach people to participate in your project.**

(PROVIDE RATIONALE FOR ALL YOUR CHOICES.)

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?

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

- **Describe the potential risks for participants (e.g., embarrassment, fear that services will be withdrawn).**
- **Describe the potential benefits to participants.**
- **Describe the potential risks for your organization.**
- **Describe the potential benefits for your organization.**
- **Describe what you have done to minimize these risks (i.e., decrease the number of them) and mitigate these risks (i.e., decrease the severity of the remaining ones) for both the participants and your organization.**
- **If there are remaining risks, describe how they are justified by the potential benefits.**

POINTS TO CONSIDER

- What are the risks of not doing this project?
- Have you considered the risks outlined on the ARECCI Risk Filter for Quality and Evaluation Projects in relation to this project? (www.ahfmr.ab.ca/arecci/tool)
- 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.)*

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

- **Describe how you intend to protect the privacy and confidentiality of participants in your project.**
- **Describe how you will retain, store, and secure the data.**

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?
- 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 note the page on the PIA where the privacy information can be found in #5 on the attached *Form for Ethics Considerations in Quality Improvement and Evaluation Projects*.

6. Is informed consent needed in this project?

- **Describe how you will determine whether or not informed consent is needed in this project.**
- **If consent is needed, describe how you will obtain it.**
- **Attach any forms and/or scripts that you will use.**

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?
- 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?
- 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?

NEXT STEPS

Now that you have answered all of the above questions, please use the *ARECCI Ethics Screening Tool* to assess the level of risk involved in your project to determine review requirements.

It is available online: www.ahfmr.ab.ca/arecci/tool

If you are unsure about any of the above, please consult a knowledgeable source about your project.

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

Feedback Welcomed on the Ethics Guidelines for QI and Evaluation Projects

The ARECCI Network wishes to refine and improve the usefulness of these guidelines for QI and evaluation projects involving people or their health information.

Your feedback is very much welcomed and can be forwarded to:

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 Edmonton AB T5J 4A7
 Canada
 Email: linda.barrett-smith@ahfmr.ab.ca
 Tel: 780.423.5727

Form for Ethics Considerations in QI and Evaluation Projects

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

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

Describe who will benefit from this project.

Describe how the results will be communicated.

2. How will the described methods generate the desired knowledge?

Describe your approach or method or strategy.

Explain how it will attain your goal.

Form for Ethics Considerations in QI and Evaluation Projects...continued

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

Describe how you will select your participants.

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

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

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

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

Describe the potential risks for participants.

Describe the potential benefits to participants.

Form for Ethics Considerations in QI and Evaluation Projects...continued

Describe the potential risks for your organization.

Describe the potential benefits for your organization.

Describe what you have done to 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 as identified above.

If there are remaining risks, describe how they are justified by the potential benefits.

Form for Ethics Considerations in QI and Evaluation Projects...continued

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

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

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

6. Is informed consent needed in this project?

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

If consent is needed, describe how you will obtain it.

ATTACH ANY FORMS AND/OR SCRIPTS THAT WILL BE USED.



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