

Ethical Project Reviews

A Framework For Building Your Organization's Recognized Review (ORR)

Managed by





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GLOSSARY OF TERMS

ARECCI	A pRoject Ethics Community Consensus Initiative
Community of Practice	A group of people who share a common concern, a set of problems, or an interest in a topic and who come together to fulfill both individual and group goals.
ARECCI 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/maintaining benefit)
Ethical Review	An established process of ethical principles to review projects.
Ethical Risk	The possibility of suffering harm or loss for an individual or community, and includes real or potential threat: • to privacy and confidentiality • of physical, mental, psychological, emotional, financial or legal impact • of additional burden
Evaluation	A systematic assessment of the design, implementation or results of an initiative of learning or decision-making (Canadian Evaluation Society).
Human Services	A broad category of services dedicated to enhancing economic and social well-being by helping citizens lead more stable and self-sufficient lives by meeting human needs through an interdisciplinary knowledge base.
Knowledge- generating	Includes both research and non-research that strives to enhance understanding and learning.
Organization	In the context of this project, the term community represents a geographical area, institution/company or groups that share common interests.

GLOSSARY OF TERMS

Organization Recognized Review (ORR)	The highest level of systematic ethical review for non-research projects that scores greater than minimal risk on the ARECCI Ethics Screening Tool.
Project	Any temporary endeavour with a definite beginning and end that involves a sequence of tasks to achieve a specific outcome.
Project Ethics	The application of ethics consideration across a range of knowledge- generating investigations, including quality improvement, evaluation, research and innovation projects, so that people or their information are protected and respected.
Quality Improvement	A framework used to improve processes and systems systematically and continuously toward a specific goal or outcome (Institute of Healthcare Improvement).
Research	An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.
Research Ethics Board	A body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices (TCPS 2 2018).
Risk	The possibility of the occurrence of harm including magnitude or seriousness to participants or third parties.
Second Opinion Review (SOR)	An ARECCI-trained reviewer with knowledge and skills to conduct ethical reviews for projects that are more than minimal risk.

INTRODUCTION



We must improve our awareness and understanding of the ethical risks associated with quality improvement and evaluation projects. Research projects and Research Ethic Boards (REBs) have a well-established system and process to identify and mitigate for ethical risk, but there is a gap for non-research projects such as quality improvement and evaluation. Any knowledge-generating project involving people or their information should be reviewed for ethical risk.

Quality improvement, evaluation or needs assessments are not subject to REB but still require ethical review.

ARECCI: A pRoject Ethics Community Consensus Initiative started in 2003 to address the gap in ethical oversight with quality improvement and evaluation projects in health and human services.

In twenty years, progress is made but there remains significant opportunities to advance and embed ethical review as a standard process and system for non-research projects. For example, a family has experienced the passing of their loved one in hospice, and the family is asked to complete a satisfaction survey about the care received. In another example, a project team asks a vulnerable population sensitive questions at a difficult time. These are examples of ethical risks due to the nature and context of what is asked. Organizations that conduct these types of projects should assume responsibility for their ethical oversight. It is suggested that organizations routinely conduct ethical reviews by creating their Organization Recognized Review (ORR).

There are standardized processes (ARECCI Ethics Screening Tool, the ARECCI Ethics Guidelines Tool, the Second Opinion Reviewer (SOR) Training and ARECCI Project Ethics Course) identifying and mitigating risk in quality improvement and evaluation projects. An ORR in the broad context of ethical reviews is the final process step.

The number and complexity of projects not requiring REB approval are growing but with considerable ethical risk, and the ability to have smooth, timely reviews is not happening. There is a shortage of skilled, trained and dedicated reviewers to conduct ethical reviews of projects that are not subject to REB. An ORR would address non-research projects with a high level of risk.

To support the ARECCI community and knowledge-generating projects, organizations are encouraged to build their internal capacity to support an ORR process. An ORR would ensure that projects are reviewed, people are respected and protected in high-risk projects, and it also provides organizations with a mechanism to assess and decide if they proceed with high-risk projects.

An ORR is beneficial to any organization with quality improvement and evaluation projects as it would support project teams, project sponsors and any participants associated with or impacted by these projects.

Alberta Innovates assembled a working group of individuals from diverse organizations or groups involved with ARECCI. Stemming from Alberta Innovates' modernizing activities of ARECCI, the ORR working group was convened in November 2022 to develop a framework to support and build the capacity of the community for ethical review of quality improvement and evaluation projects.

The working group achieved its goal to co-develop the ORR framework through virtual, facilitated discussion. This dynamic document (framework and guide with the tools, templates and resources) will support an organization in implementing an ORR.



FRAMEWORK BACKGROUND

The working group first met in December 2022 upon invitation from Alberta Innovates as the sponsor. Alberta Innovates lays the foundation for the goal and purpose, highlighting that organizations are structured and resourced differently. The working group should strive for feasible, common principles and approaches contributing to learning.

While the term 'organization' is applied to the work and goal, the working group leveraged the Canadian Institutes of Health Research (CIHR) definition of 'community' where an organization may represent a geographical area, institution/company or groups that share common interests.

To develop a framework, Alberta Innovates provided these guiding principles:

A = applicable and adaptable, strive for the lowest common denominator where the framework can be adopted or adapted in different communities or applied in different settings.

B= build, leveraging the modernization work with ARECCI training, tools, and guidelines. As there is parallel activity occurring, the working group can help ensure consistency, transparency, and community.

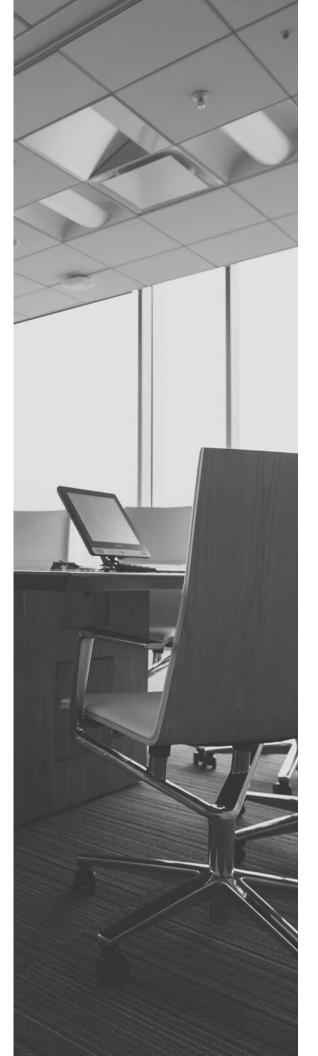
C = compliance, incorporating best practice and applicable guidelines to support rigour, quality, and best evidence. Consideration of regional and organizational differences.

D = dissemination, promoting sharing of project outcomes and learnings. Informing and educating others.

F = fun, the most important is to have fun.

The working group members established their principles of working together:

- Confidentiality
- Respect
- Co-creation
- Collaboration
- Humility



WHAT IS AN ORGANIZATION RECOGNIZED REVIEW (ORR)?

The first step for the working group was to gain clarity on what is an ORR by building shared understanding. The working group consisted of different organizations and entities with varying perspectives and experiences, but they successfully arrived at a consensus on the definition of ORR.

An ORR is defined as:

The highest level of systematic ethical review for non-research projects scoring greater than minimal risk on the <u>ARECCI Ethics Screening Tool</u>.

WHY AN ORR FRAMEWORK?

The working group envisioned a future where:

- An ORR is embedded in larger organizations and available ad hoc in communities.
- An ORR is an operational, integrated review process that is used and valued.
- An ORR is a recognized and valued process available to support project teams conducting highrisk knowledge-generating projects that do not fall under the scope of research projects and Research Ethics Boards.
- An ORR is a recognized, sustainable project review process that will benefit project teams, sponsors and Second Opinion Reviewers through a collaborative, supportive approach.



There needs to be more awareness within organizations of the risks associated with projects that involve people or their information. The broader community and more people (executive leaders, project sponsors, quality improvement teams, evaluation teams and community) need to understand the risks and mitigation strategies from conducting systematic ethical reviews.

Alberta Innovates is committed to offering training in project ethics (identifying and managing ethical risk) and fostering connections between organizations to promote learning, but they look to organizations to take the lead in driving policy and commitment for an ORR.

The framework was co-developed to help build capacity in the system and support the practice of ethical reviews in non-research projects that are quality improvement and evaluation in health and human services. The framework graphic presents several vital components such as the value proposition, purpose and leadership, people and leaders, policies, process and procedures, practice, performance, and partnerships and support. The details of all the components are available in the guide to the framework, including tools, templates and resource links to support an organization in creating its own ORR.

FRAMEWORK

Organization Recognized Review Framework

Ethical Review of Non-Research Projects

PROPOSITION

A systematic process for ethical review of non-research projects that will help mitigate risks to an organization and protect people.

PURPOSE & LEADERSHIP

Champion and lead the organization to build internal capacity for ethical review and support risk management.

POLICIES

Reinforce accountability, expectations and role clarity for ethical projects.

PROCESS & PROCEDURES

Establish standardized steps and guidelines for consistent ethical reviews.



PEOPLE & LEADERS

Engage, train and mentor people and leaders in the value and importance of ethical reviews.

PRACTICE

Conduct ethical reviews and apply learnings to mitigate risks.

PERFORMANCE

Monitor, track and evaluate competency, effectiveness, risk mitigation and value.

PARTNERSHIPS & SUPPORT

Link with organizations and community entities to share learning and build capacity across systems for ethical reviews.



ORR GUIDE

WHAT IS IT ABOUT

This guide provides the framework details for an 'organization' to consider implementing its organization recognized review (ORR) for quality improvement and evaluation projects in health and human services. In the context of this guide, an organization may represent a geographic area or community, institution, company or group with a shared common interest.

An ORR is the highest level of systematic ethical review for non-research projects scoring greater than minimal risk on the ARECCI Ethics Screening Tool. An ORR is the final process of identifying and reducing ethical risk in a larger system.

WHO IS THIS FOR

This guide supports any organization's leader(s) and their teams to develop internal organizational capacity to manage risk and conduct ethical project reviews. It provides all the necessary elements (information, tools/templates) and resources that can be adopted and adapted to meet your organizational needs.

WHY IS IT IMPORTANT

This guide supports organizations in reducing ethical risks in their projects. An ORR should be considered if these scenarios are observed in your organization.

- Many quality improvement and evaluation projects are occurring without ethical review in a year.
- Projects are planned or designed without consideration for ethical principles.
- Projects regularly involve vulnerable populations as participants.
- Projects that collect and use sensitive information or personally identifiable information for purposes not originally intended.
- Projects with data collection methods that may cause burden or harm to participants.
- Passionate leaders and people with ARECCI Project Ethics and Second Opinion Review exist.

Ethical reviews examine all factors, but the combination of risks may result in a project that scores as high risk. As the complexity of projects increases, the level of risk may also increase, and the accumulation of risks requires an ORR.

ORR GUIDE

WHERE TO SEEK SUPPORT

<u>ARECCI</u> is committed to offering support. Reach out for assistance.





PROPOSITION

Why is it important to consider a systematic review process for project ethics within your organization? There are many benefits to considering an ORR in your organization, and these include:

- Significant risk to an organization is identified and mitigated.
- Consideration of ethical risk in advance of unintended impacts and consequences.
- Appropriately designed projects are cost-effective.
- There is reduced ethical risk for participants.
- Increased efficiency of reviews (reduce delays).
- Expertise and built-in internal capacity.
- The reviews are conducted independently of the project team.
- A set of standardized tools and resources.
- Community support and networking (Community of Practice, continuous learning and professional development, connections to other organizations).

Why should an organization create an ORR? Projects are becoming more complex, and the number of stakeholders is large. There are multi-year projects that are higher risk and need multiple types of expertise and content knowledge. Second Opinion Reviewers (SORers) conduct reviews and they are limited in number, often external to an organization and rarely are they solely dedicated to conduct reviews. Projects that need a review are waiting longer creating risk as projects may proceed without this ethical review. Routine



PROPOSITION

ethical review of quality and evaluation projects that are high risk is needed, and the process must be flexible and integrated into the organization to improve and mitigate risk in worthwhile projects. No organization is accountable for managing all ethical reviews across all systems (e.g., Health, Justice, Indigenous, and Human Services), and organizations with an internal need would benefit from creating an ORR. Furthermore, an ORR will not impede ethical projects but will build the knowledge, understanding and value of conducting ethical project reviews.

While an ORR is about the highest level of risk as per the <u>ARECCI Ethics Screening Tool</u>, only some projects will require the full ORR process. By building an ORR, staff trained in the ARECCI Project Ethics Course strengthen the internal capacity, positioning the organization with the awareness and knowledge to address ethical considerations in the early stages of project planning and design that is cost-effective and efficient. Educating people in the ARECCI Second Opinion Reviewer Training provides the appropriate organizational safeguard to mitigate risk further.

A value proposition infographic is available and supports communication and change management with leaders and decision-makers. The supplemental conversation tool will also aid to guide discussions.

Organization Recognized Review (ORR) Protecting People and Organizations from Ethical Risks

Are you conducting projects that involve people's information and data? If so, can your organization afford the risks associated with these projects (Quality Improvement and Evaluation in Health & Human Services)?

Examples of ethical risk:

- Questions in a data collection tool may cause psychological stress
- The absence of ethical principles in project design may cause undue burden or hardship on participants
 A project with a survey that collects sensitive or
- A project with a survey that collects sensitive or highly personal information
- A poorly designed project results in imbalanced relationships and power dynamics with vulnerable populations
- A project that uses people's information or data that was originally collected for different purposes

Value and benefits to the organization and project teams



Reduced Organizational Risk

An ORR will help mitigate the highest level of ethical risks for non-research quality improvement and evaluation in health & human services projects. An organization's can conduct their own project reviews for ethical risk.



Ethically Designed Projects

Building the internal knowledge and capacity in ARECCI's Project Ethics and Second Opinion Review places the organization in a better poslion to identify and reduce ethical risks during project planning and design which may mitigate costs (legal, reputational) due to unintended harm and risks.



Better Designed Projects

Projects that are better-designed result in quality submissions for review leading to fewer delays and efficiences for an organization's non-research projects. Appropriately designed projects are more cost-effective (e.g. removing data collection methods that will not provide expected results).



Reduced Risk To People

Significant risk to project participants is mitigated with an ORR as a review would be independent of the project team. The management, collection and use of people's information and their data is a RISK.



Support From ARECCI

An ORR will have the support of the ARECCI community at large. An organization is not alone as there is a set of standardized tools and resources with plenty of knowledge, expertise and good will. There will be opportunities to learn and share.



Why This Matters

Protecting people and their information should matter to everyone. Non-research projects are becoming more complex and the increased complexity leads to higher risk for people and organizations.



ORGANIZATION RECOGNIZED REVIEW (ORR) CONVERSATION TOOL

ORGANIZATION

CONVERSATION STARTER

Does your organization conduct any of these?

- Quality Improvement
- Evaluation
- Needs Assessment
- Mealth & human service projects

What kind of projects happen within the organization?

What is your awareness of the risks with these types of projects?
What do you have in place to review

them for ethical risk?

LEADERS

- Awareness of ARECCI
- Staff trained in ARECCI Project Ethics
- Staff trained as Second Opinion Reviewers
- Leaders trained in ARECCI
- O Leaders as champions
- Organizational buy-in
- Organizational commitment
- Capacity and resources

What would help you consider an

CONVERSATION STARTER

ORR for the organization?

What do you know of the benefits

and value of an ORR?

What are the barriers to considering

an ORR?

What support does the organization

need for an ORR?

RESORICES ANDUP PROT

- O Consult with ARECCI
- ARECCI Project Ethics Course
- ARECCI Second Opinion Reviewer Program



PURPOSE & LEADERSHIP

Organizational leadership and commitment are critical for the development of an ORR. A primary step for any organization, large or small, is understanding the purpose of an ORR, and the value of conducting ethical reviews of non-research projects, particularly for any organization with knowledgegenerating projects.

A key responsibility of leaders is to protect and minimize risk to people and their organization. If leaders are unaware, there is an opportunity to inform and create awareness. Ethical reviews can mitigate risks for any organization, and developing leaders to understand the variety and complexity of risks that may exist in quality improvement, evaluation, need assessments, or any health and human services projects is an important step.

Leaders with a solid understanding of the value proposition of an ORR are strong advocates to support and lead your organization in the building of an ORR. These leaders are not intended to be the ethics police but have a role within an organization to build engagement and understanding of the value of ethical reviews. There is value in a centralized place for projects to get reviewed internally. The volume of projects that fit the criteria for an ORR may be small; however, the risks to the organization may be significant as projects are much more complex.

Leaders should improve the awareness and understanding of the risks to organizations from non-research knowledge-generating projects across all systems. A pre-requisite for an ORR is organizational buy-in, followed by an intentional decision to act to mitigate risks.

The value proposition and a conversation tool assist with awareness building and engagement. Building an ORR and organizational capacity to review your projects goes beyond a simple decision. It demonstrates an organization's philosophy, ability and commitment to enhance ethical review mechanisms and increase system capacity for consistent, standard processes.

POLICIES

A **Project Ethics Policy** is necessary to build organizational awareness, reinforce expectations and support role clarity. In the context of ethical reviews, an organization-wide policy is a vital component of the ORR framework to protect people and the organization from risk through all stages of a non-research project.

A policy is essential to ensure an understanding of roles, responsibilities and accountabilities within your organization. For individuals conducting ethical reviews on your organization's behalf, the procedure can address personal liability concerns. A policy can also define expectations such as project teams will not review their projects.

A policy template example is available as part of this guide. The policy template requires the insertion of your organizational context, and it is an excellent starting point for an ethical review policy. The policy template defines all the applicable terms, roles and duties, compliance, and procedure providing including resource links.

Part of building an ORR includes adding new policies and updating your existing policies:

- Risk management and ethical reviews.
- Project management and ethical reviews roles (sponsor & authority, etc.).
- Privacy, storage, record retention and ethical reviews.
- Staff education and training for ethical reviews.
- Personnel and competency to conduct reviews.
- Standards and performance metrics for the review process.

The Project Ethics Policy template may provide the applicable content and language to amend your existing policies.



PEOPLE & LEADERS

Key to an ORR process is the people from the leaders at all levels of the organization who are aware and understand the implications of ethical risks and protecting people, to those who are the change champions advocating for risk management with ethical reviews, to informed individuals that seek reviews and to those trained to conduct reviews.

Large and small organizations that routinely conduct quality improvement projects or evaluate programs and services must be aware of the risks these projects could involve for people and the organization. Executive and project sponsors often endorse these projects without a critical lens for the ethical risks. Project leaders and managers plan these projects without the necessary understanding of the complexity and risks associated with managing, collecting and using people's information and data.



Building the internal capacity and awareness of the ethical risks from these projects can be undertaken with education and training available through ARECCI.

The training material is undergoing modernization with work to transition to a learning management platform and modules to support self-directed learning, interactivity and multi-media content. The online learning management system caters to different levels of learners and their learning needs.

The available core training is the <u>ARECCI Project Ethics Course</u> a three-part online course that is completed in 4 weeks.

Part One: Foundational Concepts
Part Two: Identifying and Managing
Ethical Risk
Part Three: Apply the ARECCI Process

to Your Project

Beyond the foundational ethics training, your organization can build champions in ethical reviews by promoting advanced ethics training for individuals to become reviewers. The Project Ethics Course will develop the pool of Second Opinion Reviewers (SORers).

The ARECCI Second Opinion Reviewer Training takes Second Opinion Reviewers through an 8-10 months program with certification aimed at building their knowledge and skill in performing project ethic reviews for quality improvement, evaluation needs assessment, and other kinds of projects that are not subject to Research Ethics Board (REB) review.

SORers work with project leaders, both internal and external to their organization, to strengthen the ethical oversight in these types of projects. They can help to sort whether your project is research and should go to an REB for review or whether the SOR process is the more appropriate review pathway. Specifically, a SOR has the skills to conduct project ethics reviews of higher-risk quality improvement and evaluation projects.

SORers provide knowledgeable project ethics skills to help build organizational capacity to manage ethical risk. They help project leads design and implement ethically sound, knowledge-generating projects.

SOR-trained staff are beneficial to an organization with a large volume of quality improvement or evaluation projects. The time for reviews is dependent upon the quality of the submission. A better-designed project and its methodology requires less effort to review. ARECCI is working to ensure a baseline level of project planning to improve project design knowledge.

A complete system for ethical review includes an ORR which is only necessary for very high-risk projects.



For your organization, engagement, communication and education/training are the building blocks, but having the right people trained to lead and conduct reviews is also critical. Some of the skills and competencies required are:

a) Effective Oral and Written Communication

- Keeping project teams informed along the review process (i.e., what happens at each stage and the expectations)
- Providing feedback in a constructive manner

b) Conflict Management

 Willingness to have difficult conversations to resolve conflict.

c) Time Management

- Ensuring projects are reviewed promptly
- Devoting adequate time to review projects

d) Knowledge Translation

- Connecting people to resources
- Sharing non-identifying information with the project teams and with other SORs as appropriate

e) Leadership

- Coaching and mentoring project teams and other reviewers
- Linking project teams with similar projects to each other
- Advocating and promoting the ethical review process and ARECCI

Organizational champions are essential in promoting ethical principles and risk management of quality improvement and evaluation projects. Training more people within your organization to be aware and understand the implications is a risk management strategy.

Additionally, staying connected to the practice requires people and leaders to remain current with ongoing learning, professional development and networking as projects and landscapes evolve.



PROCESS & PROCEDURES

The processes to conduct ethical project reviews are well established within ARECCI and will provide your organization with its start. The guide describes all the significant process steps, but the process assignment (where and who) is for your organization to decide. A process map is also available for your use.

SUBMISSION OF REVIEW

For organizations, large or small, where do requests for reviews go? Does the organization need a single central area or multiple areas depending upon the size of the organization? A Request Form for a Project Review is available to support your organization's process. The form only applies to quality improvement and evaluation projects, not research, as there are clearly defined processes and systems for knowledge-generating research endeavours.

SCREENING

Preliminary screening should occur once a request for review is received, ensuring completeness, including the attachment of all appropriate project documents. This step will reduce unnecessary reviews from project teams that have not thoroughly planned their projects. Suppose all documents are in order and the risk score is greater than minimal risk as per the ARECCI Ethics Screening Tool. In that case, the next step of the process is a Second Opinion Review. For those projects that obtain minimal risk scores, there is no action beyond screening, as the project may proceed as planned.

SECOND OPINION REVIEW

A Second Opinion Reviewer Training (SOR) involves a reviewer who has completed all the necessary training through ARECCI and has gained experience conducting reviews. The reviewer will examine all the project documents for any ethical risk and provide recommendations to the project team to mitigate risk. A Second Opinion Reviewer (SORer) engages and consults with the Project Team (Sponsor and Lead).

A SOR would include a review letter to document the interaction between a Reviewer and the Project team. During the review and consultation with the project lead, the SOR reassesses the project to be high-risk (combination of all risks), and the review proceeds to an Organization Recognition Review (ORR) process.

CONDUCTING AN ORGANIZATION RECOGNIZED REVIEW

The criteria that distinguish an ORR from a SOR:

- 1. The project obtains a score greater than 47 and is high risk as per the ARECCI Ethics Screening Tool.
- 2. The project begins with a SOR, but the SOR determines that an ORR is more appropriate upon review. For example, discussions with the project team reveal additional factors or information that increase the risk level. The combination of all the risks determines the level of risk.
- 3. The project has many phases or components that overlap between research and non-research.

An ORR is necessary when a high-risk project requires more than one reviewer to assess for ethical risks. Your organization will assume responsibility for deciding if the ORR process includes two reviewers, a panel or a committee structure. The Standard of Work (SOW) describes the process steps for an ORR with two reviewers. The SOW can be adapted if your organization plans for a panel or committee.

Like a SOR, an **ORR Review Letter** documents all interactions.

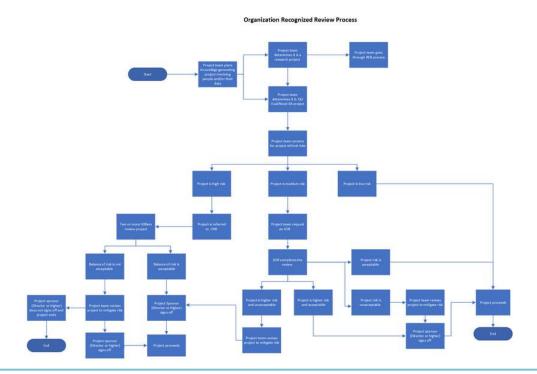
RECOMMENDATIONS AND SIGN-OFF

A vital process of an ethical project review is the understanding and acknowledgement of the recommended changes to the project to mitigate risk and a decision by a recognized authority within your organization to either proceed or not proceed with the project. A Director-level or higher should be your recognized authority or sponsor. A **Project Ethics Sponsor Approval** form to document the approval process is required.

The onus lies with your organization's Project Sponsor or authorized delegate to manage any concerns or appeals of a decision. A reviewer is not responsible for this step of the process and should not be held accountable on behalf of the organization. A reviewer's role is to provide their expertise to assess for ethical risks and provide recommendations to the Project Team (Lead and Sponsor). An ORR would allow the organization the ability to mandate change.

REVIEW CLOSURE

A final step in the ethical review process is the closure stage, with the last communication back to the Project Lead and Sponsor with retention of all documents per your internal records management policies. An email message to close the communication loop is sufficient, with an example provided.





PRACTICE

Building an ORR and having people become fully competent and capable of conducting ethical reviews will take experience and time. From a practice point of view, your organization needs to define the expectation for proficiency and competency. How many reviews need completion to be considered competent within your organization?

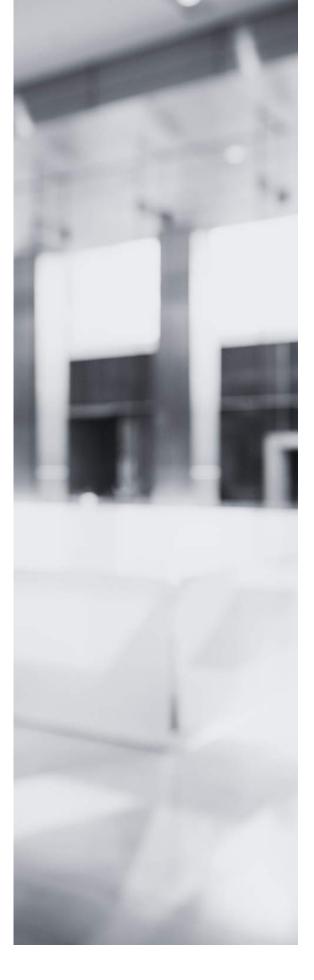
To support people in their ethical review process, your organization may want to consider the following ideas:

- A. Buddy or Phone-a-friend
- B. Mentorship Program
- C. Reviews and Shadowing
- D. Community of Practice

Consider a buddy or phone-a-friend to provide one-to-one support, just-in-time learning or virtual learning to support people who want to check their thinking. A list of the people trained within your organization could be something to share. Try building organizational and individual practice by leveraging opportunities to mentor other organizations.

Another way to support people's practice and competency is to provide shadowing opportunities during the review process. If there is project team consent, these shadowing experiences allow people to observe and listen during the engagement and consultation process.

A mentorship program is not a requirement for an ORR, but it is beneficial for large organizations that conduct many non-research projects. Suppose your goal is to train a large volume of staff; mentorship is a formal process that your organization could establish. The Second Opinion Reviewer Training Program does provide mentorship as part of its course; however, the mentee/mentor relationship is not ongoing.



Finally, a community of practice (CoP) internal to your organization may be beneficial depending upon the number of your staff who receive training. A community of practice does not need to be onerous as the intention of a CoP is to be member-led, voluntarily, and a vehicle to share experiences and build the practice in a particular area. A CoP is a beneficial way to disseminate knowledge as well.

Alberta Innovates supports a community of practice scheduled quarterly. The CoP has not been active but will be with ARECCI's modernization efforts. This CoP is an informal mechanism for sharing and learning with an open call to participate with no formal agenda or minutes. The CoP is an open discussion space led by the reviewers to learn and share. The CoP is a drop-in format with reviewers attending as they see fit. A CoP is an excellent opportunity to learn about different topics, share challenges or ask questions.

One final consideration to support and enhance practice is the availability of a secure file-sharing platform for your ORR. Email is not a secure method for transmitting, receiving or storing project documents for ethical review. A repository is a benefit to support learning.

PARTNERSHIPS & SUPPORT



ARECCI, managed through Alberta Innovates, receives requests for ethical project reviews and works with many different organizations or groups in Alberta to review the projects. There is a centralized intake process to accept review requests, conduct a preliminary review for appropriateness and completeness, and a matching process with the project to trained volunteer Second Opinion Reviewers. The volume of submissions requiring a SOR, or an ORR is manageable currently. ARECCI hopes organizations prepare more Second Opinion Reviewers or set up their internal processes for review, paying attention to efficiency and quality.

ARECCI continues to support projects without an organization; however, the ARECCI community would benefit from ORRs as reviewers are busy and reviews are delayed, with challenges matching reviewers. Some projects have tight timelines and specific periods of the year are challenging to find reviewers. An ORR would add capacity, making reviews much more efficient and timelier.

A goal voiced over time by the ARECCI community is to connect organizations, teams, and communities for learning. The review process is one way to increase those connections and to recognize and find expertise. A CoP for organizations as a forum to connect for support and learning would be beneficial. There is an opportunity to build knowledge networks, share project initiatives and identify areas for collaboration and partnership. Cross-organizational interactions would be helpful for smaller organizations. These interactions could occur organically or facilitated through Alberta Innovates, which continues to promote and encourage collaboration by hosting an annual event.

Established partnerships would also benefit organizations as it provides an alternative process for ethical reviews when a project is not reviewed internally due to a conflict of interest or other specific circumstances. Partnerships also help facilitate the mentorship of reviewers and provide learning opportunities in different contexts and content-specific scenarios. Applicable partnerships relevant to ethical reviews and risk management include Information and Privacy and the Research Ethics Boards. Your organization decides whether to formalize collaborative relationships or develop a memorandum of understanding to support your ethical review process and risk management.

One area of support from ARECCI is the availability of a system to receive, assess, track, manage, and report with a knowledge repository. The repository contains non-identifying projects and case scenarios to promote learning. Having a single online knowledge repository with different nodes of expertise could expedite the coordination of information across the ARECCI community.



PERFORMANCE

The timeline for implementation of an ORR is estimated to take at least a minimum of 9 months to over a year or more. Following implementation, how does your organization measure success? What is important for your organization to evaluate, and what do you need to track and monitor? The value proposition is a good start for performance metrics and risk management. Other types of information to consider are:

- The number of people trained.
- The number of submissions per specific period.
- The number of submissions that were low risk.
- The number of submissions that were greater than minimal risk requiring a SOR.
- The number of projects that required an ORR.
- The number of projects where ethical risk was identified.
- The number of projects that reduced ethical risk.
- Time and effort to conduct reviews.
- The return on investment.

An ORR will require ongoing organizational commitment and considerations of sustainability. Retaining reviewers has been a challenge in the ARECCI community, and the pool of Second Opinion Reviewers needs to be sustained and grown. The ability to gain experience and expertise in different content and context areas is essential with the rising complexity of projects.

This challenge may be similar in your organization, and strategies to mitigate it are:

- Socialize the value proposition tool
- Engage leaders and others in conversation about project ethics risks
- Maintain applicable policies
- Train leaders and people in ARECCI courses
- Participate and collaborate in communities of practice
- Organize and sustain mentorship

GETTING STARTED

Project ethics and risk management are the responsibilities of an organization. While building an ORR may seem daunting, the framework and the guide with the tools, templates and resource links to get you started are here. Start small! Create a pilot to build your experiences and process.

Your organization could start with your quality improvement or evaluation teams, as these groups support other organizational projects. Train a few people in ARECCI Project Ethics and build from there. Assess where your organization's risks are and develop a policy that provides structure and leadership. Start the conversation to build awareness and socialize the value proposition of ethical reviews and an ORR.

ACKNOWLEDGEMENT

This ORR framework and guide is only possible with the contributions of the ORR working group members who dedicated many hours to meet and share learnings and expertise in pursuit of building capacity for ethical project reviews in quality improvement and evaluation projects in health and human services.

We thank them all for their passion and responsiveness in advancing the purpose, practice and processes to reduce risk to people or their information.

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APPENDIX

Organization Recognize Review (ORR) Framework Graphic

ORR Value Proposition

ORR Conversation Tool

ORR Project Ethics Policy Template

ORR Process Flow Map

ORR Standard of Work

Request Form for Project Ethics Review

Project Sponsor Approval Form

Project Ethics Review Letter

Project Ethics Closing Email Template

Organization Recognized Review Framework

Ethical Review of Non-Research Projects

PROPOSITION

A systematic process for ethical review of non-research projects that will help mitigate risks to an organization and protect people.

PURPOSE & LEADERSHIP

Champion and lead the organization to build internal capacity for ethical review and support risk management.

POLICIES

Reinforce accountability, expectations and role clarity for ethical projects.

PROCESS & PROCEDURES

Establish standardized steps and guidelines for consistent ethical reviews.



PEOPLE & LEADERS

Engage, train and mentor people and leaders in the value and importance of ethical reviews.

PRACTICE

Conduct ethical reviews and apply learnings to mitigate risks.

PERFORMANCE

Monitor, track and evaluate competency, effectiveness, risk mitigation and value.

PARTNERSHIPS & SUPPORT

Link with organizations and community entities to share learning and build capacity across systems for ethical reviews.



Organization Recognized Review (ORR) Protectimg People and Organizations from Ethical Risks



Are you conducting projects that involve people's information and data? If so, can your organization afford the risks associated with these projects (Quality Improvement and Evaluation in Health & Human Services)?

Examples of ethical risk:

- Questions in a data collection tool may cause psychological stress
- The absence of ethical principles in project design may cause undue burden or hardship on participants
- A project with a survey that collects sensitive or highly personal information
- A poorly designed project results in imbalanced relationships and power dynamics with vulnerable populations
- A project that uses people's information or data that was originally collected for different purposes

Value and benefits to the organization and project teams



Reduced Organizational Risk

An ORR will help mitigate the highest level of ethical risks for non-research quality improvement and evaluation in health & human services projects. An organization's can conduct their own project reviews for ethical risk.



Reduced Risk To People

Significant risk to project participants is mitigated with an ORR as a review would be independent of the project team. The management, collection and use of people's information and their data is a RISK.



Ethically Designed Projects

Building the internal knowledge and capacity in ARECCI's Project Ethics and Second Opinion Review places the organization in a better position to identify and reduce ethical risks during project planning and design which may mitigate costs (legal, reputational) due to unintended harm and risks.



Support From ARECCI

An ORR will have the support of the ARECCI community at large. An organization is not alone as there is a set of standardized tools and resources with plenty of knowledge, expertise and good will. There will be opportunities to learn and share.



Better Designed Projects

Projects that are better-designed result in quality submissions for review leading to fewer delays and efficiencies for an organization's non-research projects. Appropriately designed projects are more cost-effective (e.g. removing data collection methods that will not provide expected results).



Why This Matters

Protecting people and their information should matter to everyone.

Non-research projects are becoming more complex and the increased complexity leads to higher risk for people and organizations.

ORGANIZATION RECOGNIZED REVIEW (ORR) CONVERSATION TOOL

ORGANIZATION

CONVERSATION STARTER

Does your organization conduct any o
these?

- O Quality Improvement
- C Evaluation
- Needs Assessment
- O Health & human service projects

What kind of projects happen within the organization?

What is your awareness of the risks with these types of projects?

What do you have in place to review them for ethical risk?

LEADERS

Awareness of ARECCI

- O Staff trained in ARECCI Project Ethics
- Staff trained as Second Opinion
 Reviewers
- Leaders trained in ARECCI
- Leaders as champions
- Organizational buy-in
- Organizational commitment
- Capacity and resources

CONVERSATION STARTER

What would help you consider an

ORR for the organization?

What do you know of the benefits

and value of an ORR?

What are the barriers to considering

an ORR?

What support does the organization

need for an ORR?

RESOURCES AND SUPPORT

- Consult with ARECCI
- ARECCI Project Ethics Course
- ARECCI Second Opinion Reviewer Program



Organization Logo Here	Policy	Policy No.	XX
	Project Ethics	Effective Date	<mark>Date</mark>

1.0 Purpose

This policy and procedure outline the responsibilities of project Sponsors, Leads and team members to systematically consider and apply ethical considerations to any projects, quality improvement initiatives or evaluation (program or project) involving people and their data or their confidential information. The intention is to protect both people and the organization from risk throughout all phases of a project.

2.0 Scope

This policy applies to all staff involved and/or conducting projects, quality improvement initiatives and evaluation.

3.0 Policy

This policy is to ensure:

3.1. Ethical Review

During the lifecycle of a quality improvement or evaluation project, to protect and respect people's data and their confidential information, the ARECCI Decision Support Tools will be applied. These tools consider ethical risks from the perspective of the project participants and provide a numeric value representing the level of risk that the project may put upon the participants, including the organization. This enables those responsible to plan appropriate mitigation strategies before involving participants. Using these tools provides a standardized framework to ensure a consistent approach to Project Ethics in our organization

3.2. Roles and Responsibilities

Project Leads or team member(s) ensure projects are reviewed for their level of ethical risk according to the Project Ethics Procedures (see Section 6.0). Professional judgement is required in interpreting the results. Those responsible will plan appropriate mitigation strategies before involving participants. The Project Sponsor will assume any ethical risk associated with the project on behalf of the organization. The decision to proceed with a project is the sole responsibility of the Project Team and Sponsor.

3.3. Compliance

The Project Team is expected to comply with all policies, procedures and guidelines for the use and release of confidential information. This includes information for education, teaching, research, quality improvement, or other secondary purposes outlined in policy.

Policy Sponsor:		x of X
Policy Steward:		
Date Approved:	Date(s) Reviewed-r/Revised-R:	

4.0 Definitions

TERM	DEFINITION	
ARECCI	An acronym created by Alberta Innovates-Health Solutions that stands for "A pRoject Ethics Community Consensus Initiative". It is sometimes used interchangeably with the term "Project Ethics".	
ARECCI Decision Support Tools	Two web-based decision-support tools developed by Alberta Innovates-Health Solutions to assist leaders and organizations with identifying the purpose of their project (Research, Quality Improvement or Evaluation) and the ethical risk associated with non-research projects. They are the ARECCI Guidelines for Quality Improvement and Evaluation Projects and the ARECCI Ethics Screening Tool.	
ARECCI Ethics Guidelines Tool	Online ethics decision-support tool which helps integrate six areas of ethical considerations into projects from the planning phase to reporting out at the completion of the project.	
ARECCI Ethics Screening Tool	Online ethics decision-support tool which helps sort projects into their most likely category (research or non-research), determines the category of ethical risk and appropriate level of ethical review.	
Confidential Information	 Whether oral, written, electronic or film, includes the following: a) personal information about any individual that includes: name, address, or telephone number, race, national or ethnic origin, colour, or religious beliefs or associations, age, gender, sexual orientation, marital status, or family status, Personal Health Number (PHN), identification number, symbol or another assigned identifier, fingerprints, blood type or inheritable characteristics, health care history, including a physical or mental condition, diagnosis, or disability, information about their educational, financial, criminal or employment history, personal views or opinions, except if they are about someone else, and anyone else's opinions about themselves. 	

Policy Sponsor:		x of X
Policy Steward:		
Date Approved:	Date(s) Reviewed-r/Revised-R:	

TERM	DEFINITION		
	b) business information collected or created by the organization that exists regardless of form and includes, but is not limited to:		
	 information provided to the organization by an external vendor or service provider which, if disclosed, would harm the business interests of the third party, information prepared as part of pending or ongoing litigation, law 		
	enforcement investigation, quality assurance review, Workers Compensation Board or Ombudsman investigation, information related to credentialing, discipline, privilege, quality		
	 assurance reviews, and external review of the quality of care, in-camera deliberations of the organization where such topics as budget strategies, personnel, labour relations, land acquisitions, or litigation may be discussed, 		
	 unpublished statistical information and internal correspondence related to organizational initiatives, and information supplied in confidence to a mediator or arbitrator to resolve 		
	or investigate a labour relations dispute. c) all information that, if disclosed without authorization, could be prejudicial to		
	the interests of the organization and associated individuals or agencies; and organizational business information that would harm the organization's financial interests and/or information that relates to the management of the		
	organization that has not yet been implemented or made public, such as information that identifies the security architecture and infrastructure of the organization's information systems.		
Organization's Recognized Review (ORR)	The highest level of systematic ethical review for non-research projects scoring greater than minimal risk on the ARECCI screening tool.		
Program Evaluation	Systematic collection and analysis of information about a program's activities, characteristics, and outcomes to make judgments about the program, improve program effectiveness, and/or inform decisions about future programming.		
Project	An initiative or collaborative endeavour with a defined purpose/aim which has a start and finish, which is organized and implemented. Examples of projects in health and human services may monitor, assess, and improve the quality and safety of current and future systems. Where this policy may apply is seen in (and not limited to) quality improvement, evaluation, needs assessments, innovation and knowledge translation.		
Project Ethics	Integration of ethical considerations from the planning to the reporting stages (from the beginning to the end) of a project.		
Quality Improvement	A framework to systematically improve processes and systems. The goal of quality improvement in any organization is to examine ways to improve the organization's services, products or outcomes.		

Policy Sponsor:		x of X
Policy Steward:		
Date Approved:	Date(s) Reviewed-r/Revised-R:	

5.0 Project Ethic Procedures

To ensure a consistent approach to Project Ethics, the online ARECCI Decision Support Tools will be used. The completion of these tools is best led by someone who completed the ARECCI Project Ethics Level 1 Course. If there is not an ARECCI-trained person working on the project, contact ______ for support.

- 5.1 To assist in identifying ethical risks within the project, teams should utilize the six ethical considerations found in the <u>ARECCI Ethics Guidelines Tool</u> or any other IH document that embeds the ethical considerations.
- 5.2 Use the <u>ARECCI Ethics Screening Tool</u> to determine the primary purpose (research, QI or evaluation) of the project (See Appendix B: ARECCI Process Flow Chart).
- 5.3 If the primary purpose of the project is for research, refer to the appropriate Research Ethics Board for ethical review.
- 5.4 If the primary purpose of the project is non-research (i.e. QI or Evaluation), continue with completing the ARECCI Screening Tool in order to identify the level of risk and the appropriate type of ethics review required. The higher the level of risk to project participants, the greater the scrutiny required by the organization. This type of review ensures that the ethical considerations identified are sufficiently addressed and that the level of risk is acceptable to the organization. The category of risk is based on the numerical value determined after completing the Screening Tool. The categories of risk are as follows:
 - Minimal Risk (0-7): the Project Lead ensures the ethical considerations identified are sufficiently addressed or the level of risk isacceptable.
 - Somewhat more than minimal risk (8-46): the project requires a Second Opinion Review (SOR). A trained Second Opinion Reviewer who is not involved in the project conducts the SOR. The Reviewer uses the six ethical considerations of the ARECCI Guidelines Tool to facilitate a discussion with the Project Lead about the risks identified in the ARECCI Screening Tool, focusing on strategies to mitigate or eliminate risks to participants in the project. The Reviewer provides a written summary of the discussion to the Project Lead.
 - Definitely greater than minimal risk (47 or greater): the project requires an
 Organization's Recognized Review (ORR). The ORR is conducted by a duly
 constituted group independent of the Project Team who are trained to do project
 ethics reviews and whose decisions are recognized by the organization. Signoff by
 the Sponsor, VP of the appropriate portfolio, or their designate is required prior to
 the project moving forward.

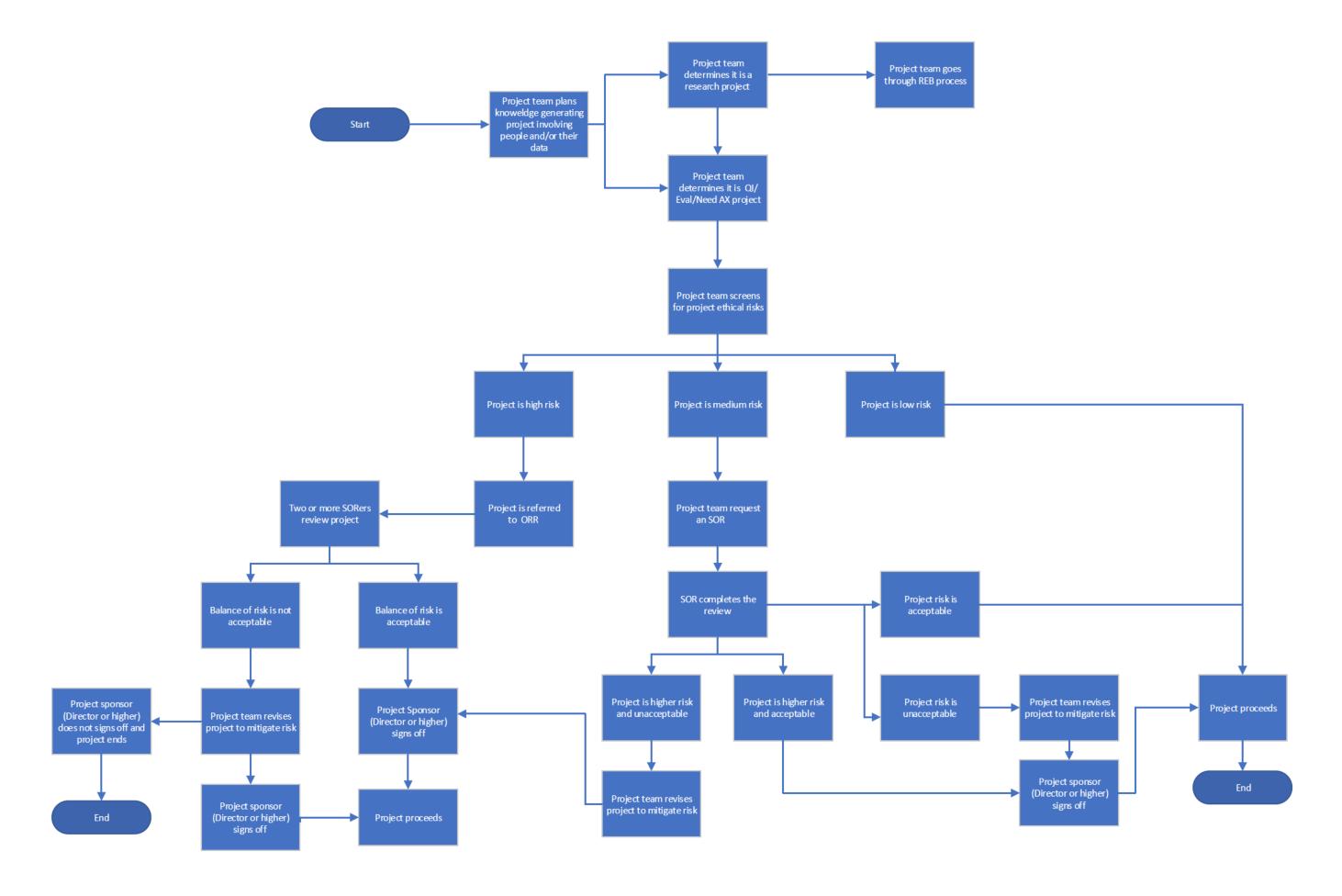
Policy Sponsor:		x of X
Policy Steward:		
Date Approved:	Date(s) Reviewed-r/Revised-R:	

5.5 When a SOR or ORR is required, the Project Lead prepares and submits documentation for the review including ARECCI Decision Support Tools (Guidelines and Screening Tools), Project Charter, data collection tools, and any other supporting documentation. If the Project Team has completed a Project Charter or other Interior Health tool that has the six ethical considerations embedded within it, completing the ARECCI Guideline tool is not required.



Policy Sponsor:		x of X
Policy Steward:		
Date Approved:	Date(s) Reviewed-r/Revised-R:	

Organization Recognized Review Process





Standard Process Description:

Conducting an Organization's Recognized Review

Purpose: Conduc	ting an Organizat	ion Recognized Review (ORR) Standard of Work	
Related Policies of	or Evidence:		
Roles/Work Units	s Who Must Adop	ot This Process: Second Opinion Reviewers	
Step	Responsible person	Task Description	Tools
Accept Lead Reviewer Role	Lead Reviewer	Accept role as Lead Reviewer for the ORR by responding to an email request from Project Ethics Inbox Administrator.	
Review all documentation and screen project to confirm that ORR is the appropriate type of ethical review	Lead Reviewer	Review all documentation to determine if anything further is required from the Project Lead. Contact Project Lead if additional documentation is required. Read through all materials, make notes and screen the project to confirm that it is receiving the appropriate level of review (ORR). Confirm the project is an ORR as soon as possible to submit a request for a Second Reviewer.	Request Form for Project Ethics Review ARECCI Guidelines Tool ARECCI Screening Tool
If ORR is NOT the appropriate type of ethical review	Lead Reviewer	If after the screening, the Lead Reviewer determines the appropriate type of review should be a SOR, email Project Lead and Project Sponsor to advise and cc Proceed with SOR as normal. If the appropriate type of review should be REB, email Project Lead and Project Sponsor to advise	
Accept Second Reviewer Role for ORR	Second Reviewer	Accept the Second Reviewer role for ORR by responding to an email request.	
Book meeting to prepare for ORR	Lead Reviewer	Contact Second Reviewer and schedule a meeting to prepare for ORR together.	
Book ORR meeting	Lead Reviewer	Book date and time for ORR meeting with Project Lead, Project Sponsor and Second Reviewer. *NOTE* Project Sponsor is REQUIRED to attend.	



Standard Process Description:

Conducting an Organization's Recognized Review

Review project	Lead and	Each reviewer independently reviews all project	ARECCI Screening Tool
documentation	Second	documentation, makes notes, and prepares	ARECCI Guidelines Tool
	Reviewer	questions for discussion.	
Reviewers	Lead and	Both reviewers meet and prepare for ORR: go	ARECCI Screening Tool
meet and	Second	through submitted documentation to clarify	ARECCI Guidelines Tool
prepare for ORR	Reviewer	understanding of the project, discuss differences	ORR Letter Template
		in scoring of ARECCI Screening Tool, identify	
		ethical considerations, strategies to eliminate or	
		mitigate risk to project participants, and	
		questions for the Project Lead/Sponsor. Lead	
		Reviewer prepares draft ORR letter with	
		strengths, questions and recommendations.	
Conduct ORR	Lead and	Conduct ORR with Project Lead and Project	
	Second	Sponsor. Lead Reviewer asks the majority of	
	Reviewer	questions that have been prepared in advance	
		and guides the conversation. Second Reviewer	
		asks any additional questions and clarifies	
		information, as needed.	
		Review all submitted documentation, clarify	
		understanding of the project, and	
		discuss differences in scoring of the ARECCI	
		Screening Tool, recommend strategies to	
		eliminate or mitigate risk to participants, and	
		make recommendations to improve the project.	
		Explain that with an ORR, all recommendations to	
		minimize ethical risk to participants must be	
		agreed to by Project Lead and Sponsor. Project	
		Sponsor must sign a Project Sponsor Approval	
		Document either recommending that the project	
		proceeds or not. If they decide to proceed, the	
		Project Sponsor assumes responsibility for the	
		remaining risk to participants on behalf of the	
		organization.	
Complete ORR	Lead Reviewer	Revise draft ORR Letter summarizing the ORR	ORR Letter Template
Letter		discussion, including project strengths,	
		weaknesses, ethical risks to participants,	
		strategies to eliminate or mitigate risk,	
		recommendations to improve the project and	
		links to resources, as appropriate.	
		Send the revised ORR letter to Second Reviewer	
		for any additional edits.	
		Prepare the Final Draft of ORR incorporating any	
		revisions from the Second Reviewer.	

Insert Logo



Standard Process Description:

Conducting an Organization's Recognized Review

Complete	Lead Reviewer	Fill out Project Ethics Sponsor Approval Document	Project Ethics Sponsor
Project Ethics		with information specific to ORR.	Approval Document
Sponsor			
Approval			
Document			
Send ORR	Lead Reviewer	Send ORR Closing Email to the Project Lead and	ORR Closing Email
closing email		Project Sponsor; cc the Second Reviewer and	Template
with attached		Attach a PDF copy of the ORR Letter and the	
ORR Letter and		completed Project Ethics Sponsor Approval	
Project Sponsor		document.	
Approval			
Document			



REQUEST FORM FOR PROJECT ETHICS REVIEW

Request Type	Second Opinion Review
	Organization Recognized Review
Date of Submission	
(dd/mm/yyyy)	
Project Lead	
(Name & title)	
Project Lead	
(Email & phone #)	
Project Sponsor	
(Name and title)	
Project Sponsor	
(Email & phone #)	
Project Title	
Purpose of Project	
(Brief Description –	
non-confidential	
information)	
Project Type	Needs Assessment
	Evaluation Evaluation
	Quality Improvement
	Other (please specify):
Project Timeline	Start date: Completion date:
(dd/mm/yyyy)	Start date: Completion date:
ARECCI Screening	
Score	
Areas of Ethical	
Concern in Project	
(Explain the elevated	
ARECCI Score)	



Organization Logo

Attachments Checklist	Complete ARECCI Ethics Screening Tool
	Completed ARECCI Ethics Guidelines Tool
	Data Collection Tools (if applicable)
	Project Documents (Project charter, proposal, plan, etc.)
	Any additional material to support review process



Project Ethics Organization's Recognized Review (ORR)

Project Sponsor Approval Document

Project Title	
ARECCI Screening Tool Score	
Project Sponsor Name and Title	
Project Lead Name and Title	
Reviewers Names and Titles	
Date of ORR	
Project Sponsor Decision:	
I am aware of the ethical risks identifie	d in this non-research project and approve this project going
forward based on the implementation of ide	entified mitigation strategies.
	this non-research project, the project is not approved to
move forward	
Sponsor Signature:	
Date:	
	
A copy of this signed document must be ke	ept with the project documents and the ORR letter.
Please forward a signed copy of this docun	nent to

Version date: March_2023



Project Ethics Review Letter

Date	Project Title	
Project Lead	Type of Project	
Project Sponsor	Organization Recognized Reviewers	

Dear:

Thank you for the opportunity to review your project. This letter is in follow-up to our discussions and confirms a summary of the feedback and suggestions we recommend strengthening your project.

The purpose of the Organization's Recognized Review (ORR) is to:

- provide Project Leads and teams with objective advice and guidance related to project ethics,
- offer recommendations that improve a project's ethical soundness, and
- ensure that the level of risk and mitigation strategies have been approved by the senior leader or Project Sponsor.

Any decisions about how, or whether, the project proceeds remain with the Project Sponsor. Please see a more detailed description of the ORR process at the end of this letter.

The ORR is based on ARECCI's six ethics considerations and provides feedback on the key strengths of your project and recommendations to address ethical concerns.

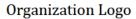
Project Lead ARECCI Ethics Screening Tool score	
Reviewers' ARECCI Ethics Screening Tool score	

Your project scored Definitely Greater Than Minimal Risk and required the highest level of review, Organization's Recognized Review (ORR).

|--|



1. How will the knowledge	gained from this project be useful?
Key strengths:	
Recommendations:	
2. How will the described m	nethod or approach generate the desired knowledge?
Key strengths:	
Recommendations:	
3. How will you ensure that appropriate?	t the participant (or data) selection process is fair and
Key strengths:	
Recommendations:	
4. How will you maximize b project?	enefits and minimize or mitigate the ethical risks in the
Key strengths:	
Recommendations:	
5. How will the rights of ind project?	lividuals, communities, and populations be respected in this
Key strengths:	
Recommendations:	





6. Will informed consent be	e needed in this proj	ect?
Key strengths:		
Recommendations:		
Thank-you for the opportun clarifications. We wish you success as you Sincerely,		roject. Please feel free to contact us for any this project.
ARECCI Second Opinion Re	viewer Signature	
Name & affiliation (if appro	opriate)	
ARECCI Second Opinion Re	viewer Signature	
Name & affiliation (if appro	opriate)	

Signoff by the Project Sponsor, using the *Project Ethics Organization Recognized Review* (ORR) Sponsor Approval Form, is required.



Project Ethics Organization Recognized Review (ORR) Closing Email to Project Lead and Project Sponsor

То
Cc
Subject: ORR Letter and Project Ethics Sponsor Approval Document: Please sign and return
Dear
Please find attached a copy of the Organization's Recognized Review (ORR) letter for This letter summarizes our conversation from our meeting on , including recommendations to improve the design of your project, to minimize and mitigate ethical risk to project participants.
All recommendations must be adopted by the Project Team in the design of your project. Also attached, is the <i>Project Ethics Sponsor Approval Document</i> . This document needs to be signed by the Project Sponsor and a copy retained by the Project Lead, along with the ORR letter and other project documents.
Lastly, please send one copy of the signed Sponsor Approval Document to for our records.
If you have any questions, please feel free to contact either me or
Good luck with your project!
Regards,





CONTACT US

Email: ARECCI@albertainnovates.ca

Website: https://albertainnovates.ca/strategic-initiatives/a-project-ethics-community-consensus-initiative-arecci/

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