



Fall 2024 Meeting Report

Culture, Strategy, and Change.

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Managed by



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Dictionary / Acronyms

	DEFINITION
AI	Artificial Intelligence
CAPA	Corrective and Preventative Action
CHREB	Conjoint Health Research Ethics Board
CoP	Community of Practice
HHS	Health and Human Services
HIA	Health Information Act
HREBA	Health Research Ethics Board of Alberta
HREB	Health Research Ethics Board
IRISS	Institutional Research Information Services Solution (University of Calgary)
OIPC	Office of the Information and Privacy Commissioner
ORR	Organization Recognized Review
PE	Project Ethics
PIA	Privacy Impact Assessment
PP	Project Plan
QI/E	Quality Improvement / Evaluation
QIPS	Quality Improvement and Patient Safety
REB	Research Ethics Board
SOR	Second Opinion Review
TCPS	Tri Council Policy Statement: Ethical Conduct for Research Involving Humans

1. Opening Remarks

Alberta Innovates is Alberta's research and innovation engine. A pRoject Ethics Community Consensus Initiative (ARECCI) was formed as an Alberta Innovates strategic initiative to assist project sponsors with ethics reviews, tools, resources, and oversight for projects that do not require research ethics board approval. In the 20 years since ARECCI was formed, the tools, training, and ethics consultation processes have continually evolved to meet the needs of the stakeholder communities that are served.

The key themes of 'Culture, Strategy, and Change' for the ARECCI 2024 Fall Meeting were introduced by Tammy Mah-Fraser, Executive Director of Health Platforms at Alberta Innovates as she welcomed the participants and delivered opening remarks.

To have a strong, balanced, and progressive culture, we need to know our stakeholders and work with them. With ARECCI, that includes both our staff and the ARECCI community of subject matter experts. Building a strong inclusive culture that can be sustained and scaled up requires a willingness to change and investment in organizational growth. What Alberta Innovates and ARECCI understand clearly is the incredible value that the ARECCI community of subject matter experts contribute to the program's growth and reputation in the broader ecosystem. When we have a unified culture aligned with purpose, we can be confident that our growth will be accelerated.

A number of recent updates at Alberta Innovates were highlighted.

1. ARECCI has heard from stakeholders that there remains no unified process, pathway, nor widespread agreement about how to consistently conduct ethics reviews in quality improvement and evaluation and in a way that protects the public.
2. With a recent program and personnel change in Health Research Ethics Board of Alberta (HREBA), there are now three complementary ethics programs at Alberta Innovates: HREBA which provides oversight to research studies, Ethics of Innovation Consortium which supports innovators in identifying the principles and values for development and implementation of innovation; and ARECCI.
3. Tammy also spoke briefly about the proposed opening of the Health Information Act (HIA)¹ to undergo amendments and Alberta Innovates involvement in gathering recommended changes. In 2024, Mark Holland, Minister of Health, introduced Bill C-72, the *Connected Care for Canadians Act* which reflects the ways in which Canadians will be empowered to securely access their own health data. The Pan-Canadian Interoperability Roadmap which is being implemented will ensure privacy and security of information sharing across platforms. Changes to the HIA may impact access and management of data for research and quality improvement.

¹ <https://www.canada.ca/en/health-canada/news/2024/06/the-government-of-canada-introduces-the-connected-care-for-canadians-act-improving-patients-safety-and-access-to-their-health-information.html>

2. Executive Summary

In 2023, the ARECCI two-day Fall Meeting celebrated ARECCI's 20-year anniversary by bringing together members of ARECCI's past and present stakeholder community. These individuals who are respected subject matter experts have been integral to ARECCI's growth and reputational strength over the past 20 years. At that meeting, the group agreed to remain engaged and involved in informing the design and further development of ARECCI's strategic ecosystem where strategy, informed by consensus, will continue to build a strong program culture. Consensus is defined as:

*"a cooperative process in which all group members develop and agree to support a decision in the best interest of the whole. In consensus, the input of every participant is carefully considered and there is a good faith effort to address all legitimate concerns."*²

Across the ARECCI community we understand that the range of contextual and organizational cultural influences may not result in a 'one size fits all' approach to ethics education and support. However, through collaboration and harnessing the expertise of the community, it is more likely that creative and innovative solutions will unfold.

To support the ambitious priorities that were identified in 2023, the 2024 Fall meeting agenda addressed progress associated with strategy development, progress on four current projects, two projects in redevelopment, and two new initiatives. Two professional development opportunities included a case study highlighting *"Indigenous Cultural Safety Considerations in the ARECCI Process"* and a discussion about the rapidly evolving influence of Artificial Intelligence (AI).

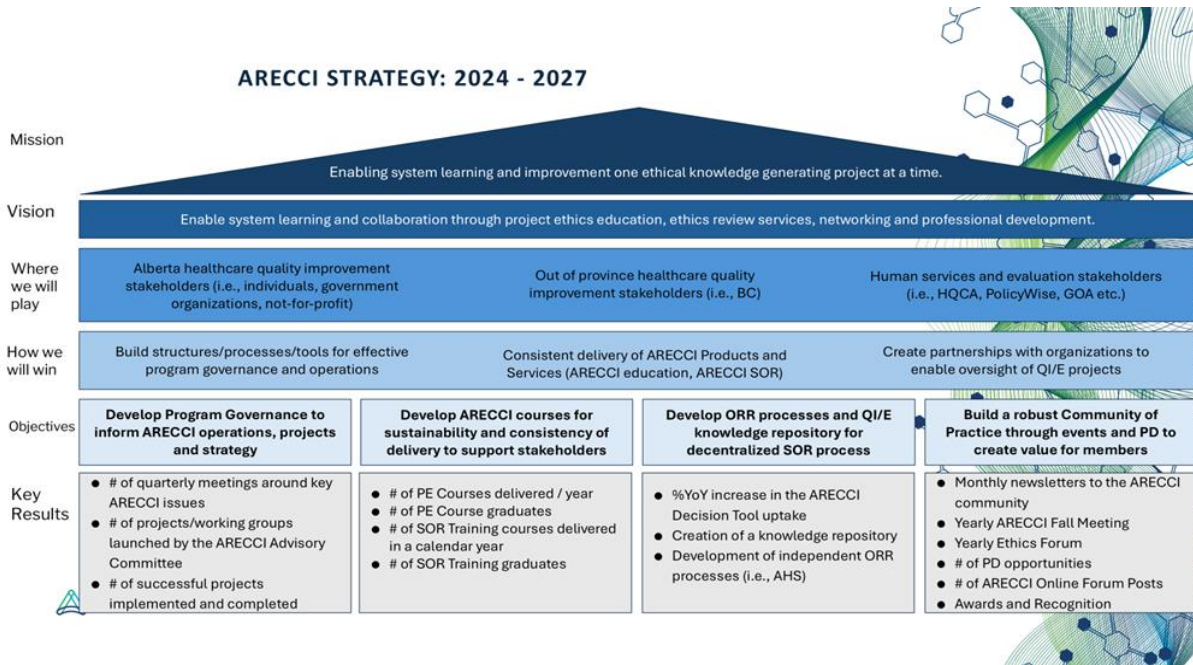
Organizational cultures are strengthened when people feel recognized and valued for their contributions. Day one concluded with an Awards and Recognition event where achievement, contributions, and commitment to excellence were celebrated. Details regarding the event can be found in Appendix 1 on page 37.

² University of Minnesota Extension. Benefits to consensus decision making. <https://extension.umn.edu/leadership-development/benefits-consensus-decision-making#:~:text=Definition%20of%20consensus%20decision%2Dmaking,to%20address%20all%20legitimate%20concerns.%20>

3. Strategy & Governance

3-Year Strategic Plan

Tammy Mah-Fraser offered a thorough examination of ARECCI’s history, future directions, and proposed next steps before seeking opinions from the meeting participants regarding ARECCI’s strategic direction.



The participants highlighted two key strategic priorities:

1. Identifying and managing risk is the highest priority. Additionally, it’s essential to establish a regular reporting mechanism that demonstrates the ethics risks that were mitigated because of the review process(es).
2. Agreed upon processes for ethics reviews of QI / E projects remain elusive largely because what constitutes an appropriate ethics review from this context remains unclear. Development of definitions, processes, and associated policies is high priority.

Accomplishments to Date

- Monthly newsletters
- Yearly fall meetings
- Professional development opportunities
- Online ARECCI learning platform (powered by THINKIFIC™) launched for the SOR community (as a starting point)
- Awards and recognition

Projects Underway

1. ARECCI Project Ethics (PE) Course
 - Engaging stakeholders and addressing feedback to meet stakeholder requirements.
 - Focusing on the ARECCI PE Course Foundational Concepts (Self-Directed Learning)
 - Developing content with stakeholders to meet learning objectives of various stakeholder groups.
2. ARECCI Second Opinion Reviewer (SOR) Training
 - Piloting course to address changing learning preferences.
 - Developing a mentorship program.
3. ARECCI Organization Recognized Review (ORR) Implementation and ACECCI SOR Processes
 - Process development underway.
4. ARECCI Community of Practice (CoP) Events
 - Quarterly
 - ARECCI Annual Fall Meeting – ongoing
5. ARECCI Community Engagement Tool
 - See page 12 of this report
6. ARECCI Ethics Forum Conference
 - Currently in the exploration and planning phase (see page 22 of this port)
 - Developing centralized knowledge repository of ARECCI projects.
7. ARECCI ORR Framework
 - Report Completed

2024 – 2025 Strategic Priorities

- Develop and implement ARECCI program and project governance model.
 - Identify an Advisory Committee
 - Draft a Terms of Reference or Charter for the Advisory Committee and obtain agreement on the terms provided.
 - Engage key organization and assess their interest in participating to shape the direction of ARECCI.
- Focus on ARECCI course sustainability and consistency
 - Launch the newly redesigned ARECCI PE Course
 - Launch ARECCI redesigned SOR training
 - Measure the number of PE courses deliver in a calendar year and
 - Establish key performance indicators associated with
 - the number of desired PE courses to delivery in a calendar year
 - number of PE course graduates
 - number of SOR training courses delivered in a calendar year
 - number of SOR graduates
- Develop ORR Processes and QI/E knowledge repository
- Build a robust Community of Practice (CoP)

Revisiting the 5 Primary Goals and Enabling Recommendations

Projects with ethics risks that slip through review processes have the potential to harm patients/participants. Consciously or unconsciously, researchers may consider their research

projects as QI/E simply to bypass the REB processes. Concerns expressed by stakeholders associated with the capacity, feasibility, acceptability, and the time commitment in undertaking the entire REB review process demonstrated the need to explore the QI/E process further. With ARECCI strategy in mind, Tammy Mah-Fraser asked the participants if the 5 primary goals and the operational and enabling recommendations as listed below remain relevant.

PRIMARY GOAL	OPERATIONAL & ENABLING RECOMMENDATIONS
1. Develop a common understanding & broad consensus on ethics reviews.	<ul style="list-style-type: none"> • Screen all projects to determine whether an ethics review is needed.
2. Increase the clarity / consistency / transparency / efficiency of ethics review processes.	<ul style="list-style-type: none"> • For the purposes of screening, first screen projects according to primary purpose.
3. Recommend an approach to answering: <ul style="list-style-type: none"> • What kind of investigation or project is it? • What process of ethics review should be used? • What level of review is appropriate for a particular project – full or expedited? 	<ul style="list-style-type: none"> • Then, after screening by purpose... • Screen projects according to level of risk • Determine need for full or expedited ethical review • Assess the degree of risk to all those involved.
4. Develop guidelines and tools to support implementation of recommendations by Alberta’s health researchers, managers, ethics boards, and other stakeholders.	<ul style="list-style-type: none"> • Build capacity and build on existing practices throughout the province. • Build on existing organizational structures for the design, implementation, and evaluation of these types of initiatives.
5. Inform the health authority, provincial, and federal polity related to ethics review processes (AHFMR, 2005, page 3-4).	<ul style="list-style-type: none"> • Implement in all organizations engaged in knowledge building projects and accompanied by evaluation and improvement initiatives at all levels of the system

The participants agreed that the primary goals and operational and enabling recommendations do indeed remain relevant and while there has been progress on actioning current goals, more remains to be done. Unaddressed priorities include but may not be limited to:

- the ability to query data,
- respond more efficiently and effectively to emerging trends,
- remain relevant in the changing world, and
- find and leverage expertise from outside of the ARECCI community.

To tackle those priorities and to strengthen organizational culture, the strategic plan, and associated governance processes, three components must be addressed:

1. Structural components
 - Organizational supports, policies, and processes
 - Defined roles and responsibilities of departments and staff and

- Provision of the necessary technology and infrastructure.
2. Resource components
 - Financial
 - Human (staff and skill levels)
 - Education, and
 - Ongoing professional development.
 3. Networking components
 - Creation of communication mechanisms that will enable an environment that blends formal and informal collaboration.
 - Assurance that there are consistent and ongoing opportunities for learning and sharing.

Strengthening ARECCI Governance: An Advisory Committee

Tammy Mah-Fraser explained how an Advisory Committee might support and strengthen ARECCI's governance in the future while helping to address the risks and gaps in current processes.

An ARECCI Advisory Committee will be an independent and non-partisan body with the objective to inform and to provide advice and recommendations to reshape the strategy, the projects, and other activities of ARECCI. Those activities may include but are not limited to:

- Identify and reach consensus on projects to be undertaken.
- Identify and address emerging issues and issues of common concern.
- Identify risks and issues and offer recommendations.
- Offer insights for developing best practices.
- Offer insight about strategies to enable growth, scalability, and sustainability.
- Support continuous learning.

Members of the Advisory Committee could arise out the current membership of ARECCI stakeholders as well as from other key stakeholders. Working groups have also been proposed, which can offer tremendous value in addressing operational concerns when they:

- Are project based and team structured.
- Leverage different disciplines and skillsets with a clearly articulated problem to overcome.
- Work to improve project turnaround time.
- Engage impacted stakeholders directly.
- Offer continuous learning.
- And, like the Advisory Committee – inform decision making.

Annamarie Fuchs, Facilitator for the ARECCI 2024 Fall Meeting and a credentialed Corporate Director (ICD.D) also offered a brief look at Advisory Committees from the standpoint of governance best practices in Canada.

Good governance is fundamental for growth and sustainable development, inclusiveness, shared decision making, engagement, accountability, openness, and transparency. In today's rapidly changing world, the need for unique and expert advice is emerging as a key

governance priority. In only the last decade, organizations have been challenged to respond to the following:

- ESG – Environment, Social, and Governance
- Diversity, Equity, Inclusion and now – Reconciliation, and Belonging
- Artificial Intelligence (AI)
- Cyber Security

These issues and more are prompting the evolution of governance systems and frameworks that stimulate leaders to embrace change and to adapt so that they may benefit from expert, independent, and unbiased advice that engages with and supports leadership.³

The International Risk Governance Council⁴ defines an emerging risk as one that is new or a familiar risk but in unfamiliar context or under new context conditions. Risk governance deficits are growing rapidly and can include issues such as missed opportunities, inefficient management measures, loss of public trust in how the organization works to reduce risk,⁵ inequitable distribution of risk and benefits between stakeholders, excessive focus on high profile risks while neglecting those with lower profiles or perceived significance, and failure to move away from ‘business as usual’ in order to trigger the right action.

Over time the wide range of issues that continue to complicate the governance landscape have made the use of Advisory Committees more and more attractive. For example, the Government of Canada’s Treasury Board Secretariat has established an Advisory Committee on Regulatory Competitiveness to make Canada’s regulatory system more competitive, more innovative, and more effective.⁶

By establishing functional governance systems that include an independent Advisory Committee, leadership can benefit from a vast array of independent expertise from new voices which can lead to improved decision making and increased opportunities for collaboration with new stakeholders and ultimately, greater innovation.

In context to ARECCI, enhancing a governance structure that includes an Advisory Committee is a collaborative and agile approach particularly if leveraging the well established (and supported) Community of Practice to:

- Address Issues of common concern
- Identify areas of risk and opportunity
- Offer insights around best practice
- Serve as key strategic partners
- Engage with ARECCI leadership and the ARECCI stakeholder community, ultimately allowing ARECCI to serve the community more broadly.

³ Thought Leadership Articles. The Evolution Between Governance Boards and Advisory Boards. 2023 October 11. [HTTPS://WWW.ADVISORYBOARDCENTRE.COM/INSIGHT/THE-RELATIONSHIP-BETWEEN-GOVERNANCE-BOARDS-ADVISORY-BOARDS/](https://www.advisoryboardcentre.com/insight/the-relationship-between-governance-boards-advisory-boards/)

⁴ <https://irgc.org/risk-governance/emerging-risk/>

⁵ <https://irgc.org/risk-governance/irgc-risk-governance-deficits/>

⁶ <https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/modernizing-regulations/external-advisory-committee-regulatory-competitiveness.html>

- Inform decision making
- Strengthen diversity
- Contribute to the creation of new partnerships

Takeaways

The healthcare environment is rapidly changing, both in Alberta and across the world. The speed of change is making it challenging to remain relevant, to identify and address risk, and to keep pace with emerging trends in QI/E projects. Concerns regarding the lack of widespread agreement about how to respond to these challenges.

The meeting participants agreed that there is value in creating an Advisory Committee but concerns about 'who' would or should sit on the committee remain. The ARECCI stakeholder community is small and more voices, broader expertise, and efforts to increase the size and the reach of the community will better serve to strengthen innovation and growth over time. The meeting participants recommended:

- An Advisory Committee is an ideal way to bring in new people who may not have preconceived ideas about ethics which may allow the inclusion of new and unbiased thinking.
- Consider reaching out to a broad network of potential Advisory Committee members.
- Artificial Intelligence (AI) expertise may be helpful.
- Find people with experience who have served on Advisory Committees in the past.
- Bring highly qualified people regardless – assure access to a range of expertise.
- Establish a clear Advisory Committee structure with a robust communication process.
- Think about remuneration.
 - There are many NFP boards as well as Agencies and Commissions with no remuneration beyond an honorarium and with expenses covered. Many people who have served in expert capacities or C-Suite executives are often seeking meaningful and context driven ways to give back to the community.

Action Items

1. Establish an independent Advisory Committee that is informed by the Community of Practice (CoP)
2. Develop Working Groups as needed – Project-based and team structured.

4. Current Projects

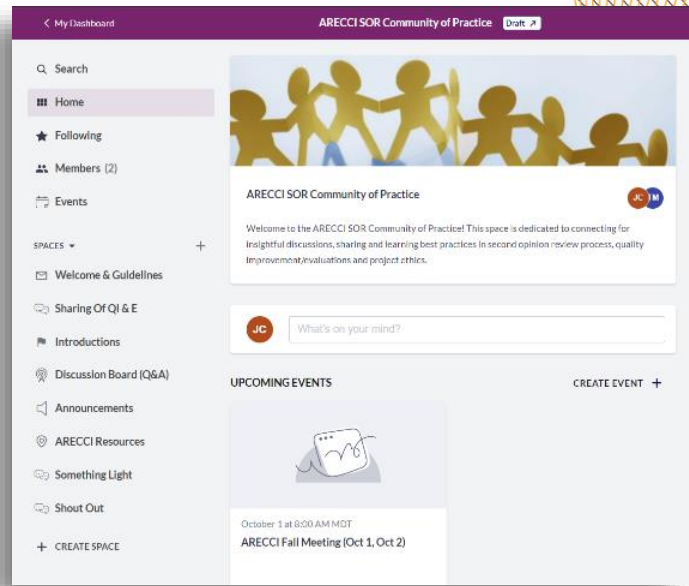
Community of Practice Engagement Tool

The meeting participants agreed that an Advisory Committee informed by a Community of Practice has the potential to strengthen ARECCI governance. In her presentation, Jamie Chong highlighted that to reinforce the work of the ARECCI Community of Practice (CoP), a dynamic online platform has been developed to promote and support interaction, collaboration, and

communication within and between members of the community. This new platform is a space where members of the community can connect and network, ask questions, participate in discussions, share ideas and updates, learn from each other, and offer support from anywhere they work and live.

The engagement tool (powered by THINKIFIC™) will enable ARECCI to

- Build a robust CoP.
- Build a sense of community by using online spaces.
- Allow the community to connect across geographic boundaries.
- Become more accessible to a wider audience.
- Enable peer-to-peer learning and sharing.
- Support engagement, collaboration, and participation.
- More effectively support and advocate for the ARECCI community.



Takeaways

Feedback of the tool from the meeting participants was positive with some caution expressed about ensuring balance between opportunities for widespread contribution and collaboration and the need to ensure strict privacy for SOR's who occasionally are called to discuss challenges that include identifiable information. The participants also agreed that anyone who has completed the SOR Training course would benefit from many of the discussions that take place in the CoP to support ongoing learning. The following questions and feedback arose.

- Should access to the CoP be closed or open? In other words, what privacy options need to be addressed? While it's important to achieve a balance between contributions and collaboration among members of the ARECCI community, there are times when discussions between members of the CoP are highly sensitive. In the case of SOR discussions for example, identifiable information is occasionally exchanged so it must be secure and available only to SORs.
 - However, anyone who has taken the SOR course would benefit from many of the discussions that take place which can contribute to ongoing learning. If set up with the appropriate 'nondisclosure' agreements, this level of discussion could offer another layer of ongoing professional development and support for the SOR community.
 - To address this concern, engagement guidelines have been posted on the community engagement site. By participating in the online community, members agree to abide by these guidelines.

- For Project Ethics, the group agreed that discussions and access to non-identifiable material should be shared as broadly as possible. This means of sharing may be the impetus that attracts people to ARECCI and to Project Ethics.
- The CoP is only as good as its consistent use. Innovation and even controversy are good for business, for growth, and scalability over time.
- Should the site be moderated? Moderation is difficult to sustain over time but in the early days, consistent moderation may spur conversation, manage expectations, and increase interest.

Action Items

1. Develop robust processes around the management of access, use, and storage of information.
2. A call was made for volunteers to review and test the site and the tool prior to its launch.

Project Ethics Course

The ARECCI Project Ethics Course is a practical course designed to help participants develop knowledge and skills related to project ethics and apply ethics considerations to a project they are currently working on. At the end of the course, attendees are expected to achieve an increased awareness of ethical risks in projects and have developed a structured approach to identifying and addressing ethics issues for project success. Robin Lau and Jamie Chong offered a detailed presentation about the Project Ethics course to date and the proposed redesign.

Background

There have been numerous versions of the ARECCI PE course developed over the years where continuous improvement has allowed ARECCI to respond to evolving stakeholder needs. The original course was a 1.5-day face-to-face workshop that focused on discussing why ethics reviews should be included in QI and Evaluation projects, how research and non-research ethics reviews compare and contrast, how risk should be handled, and where help can be accessed.

In 2021, ARECCI engaged Birgitta Larsson and Dale Wright to modernize and refresh the PE Course to respond to changing online learning needs to meet the necessary workstyle changes prompted by the COVID-19 Pandemic. The result of that work was the release of the ARECCI 2022 PE Course, a three-part course, supported by distance delivery over 4 weeks. Participants were required to complete all three components to receive a certificate of completion. The 2022 course encompasses the following:

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

In the 2022 course, participants were required to make use of a current project they were working on and use that project to apply their new knowledge and skills. Each course was limited to a maximum of 10 participants to meet the demands of the online format. The pilot project for this course included training for course facilitators which took place in the spring

of 2022. Challenges associated with this new format which prompted the need to revisit the program included:

- The 4-week timeframe was intensive for facilitators and required ongoing communication and coordination with course administrators.
- 15-20 hours of facilitation was needed
 - 1-2 hours for reviewing assignments
 - 8 hours for a full day workshop
 - 5 hours for one-on-one meetings with participants to discuss their projects.
- Participants came with every level of experience which meant that some were not able to contribute as fully as more experienced individuals and
- The limit of 10 participants (5 participants / 1 facilitators) didn't address the wait list that is becoming cumbersome to manage.

In the summer of 2023 and with the expressed need to expand the scale and reach of the ARECCI Project Ethics Course, ARECCI engaged an adult learning specialist, Marilynne Hebert to lead the shift of PE course onto a Learning Management System (LMS), THINKIFIC™.

The goal was to make the course applicable for all adult learners who come to the course with a range of project ethics experiences. The design under consideration consisted of an online self-learning module, making use of case studies to enhance understanding, followed by facilitated discussions led by experienced Second Opinion Reviewers (SOR's). Completion of all three course components (modules) is required to receive a certificate of completion. Transition to this new three-part series was completed at the end of 2023. Once the transition was complete, a structured survey collected 139 comments covering 13 categories from participants across all questions. 114 of the comments, or 82% of the total, were focused on the following categories.

THEME	FEEDBACK
Course Content	<ul style="list-style-type: none"> • Lack of education on <ul style="list-style-type: none"> ○ fundamental ARECCI principles ○ how to identify ethical risks in projects ○ questions in the screening tools & guideline tools ○ risks mitigation strategies ○ SOR and ORR processes. Missing facilitator / instructor guide
Learning Objectives	<ul style="list-style-type: none"> • Target audience not explicitly described Questions about whether the learning objectives for Modules 2 & 3 are attainable
Overall organization & flow	<ul style="list-style-type: none"> • The flow between scenario and questions needs improvement Need to revisit some scenarios / case studies to ensure inclusivity associated with cultural diversity.
Course Materials	<ul style="list-style-type: none"> • Inconsistency in formatting • Navigation buttons are confusing • The number of lessons is overwhelming.

Proposed Course Changes & Flow

After reviewing the feedback from both the 2022 and 2023 PE courses, it became clear that a 'one-size-fits-all' solution would likely not be possible. To that end, the following approach has been proposed for a redesigned ARECCI PE Course.

COURSE	FEEDBACK
Part One	<ul style="list-style-type: none">• Foundational course with foundational content and fully self-directed.• The target audience includes individuals at the entry level in quality improvement, evaluation, project ethics, or anyone from the public interested in learning about ARECCI and project ethics.• Part One is ideally suited to integrating into new hire orientation curriculums and to heighten awareness about ARECCI to a new population.• Anyone who does not need to apply the ARECCI process in their work, now or in the future, can take this course and consider it complete.
Part Two	<ul style="list-style-type: none">• Case studies where participants will learn to apply their foundational knowledge to real-world case studies.• This target audience includes individuals who are or may be required to use the screening and guideline tools, as well as applying ARECCI process to their future projects.• This will also attract individuals who are interested in learning about the contexts of the screening tool and guideline tool questions.
Part Three	<ul style="list-style-type: none">• A facilitated workshop conducted through an online platform.• This target audience includes Project Leads with active projects who wish to learn direct application of ARECCI process to their projects and complete a personal ethics review of their project by a facilitator who is a trained Second Opinion Reviewer.• This will be delivered as a workshop with group discussions, experience sharing and peer-to-peer learning.

Group Exercise and Feedback from the ARECCI Community for PE Course Part 1

Following the presentation of the proposed course redesign, the participants placed themselves in three groups to address questions associated specifically with the three chapters that make up Part One of the course. The purpose of this exercise was to gather feedback and suggestions for any additional topics or structural changes and content changes that may be needed to strengthen Part One and to help to shape Parts Two and Three. Participants were also asked to consider volunteering to be part of a review group to support revisions of draft content, pilot testing, and launch. Before launching into the group exercise, some general feedback from the participants included:

- Add a PowerPoint about how to prepare for a Project Ethics review.
- Provide an overview of how, what, and why to participate in a Project Ethics review.
- Demonstrate in an infographic or other format – the unique characteristics of various projects.
- For the public, offer a 5-minute video about ARECCI and how ARECCI supports public safety.
- Detailed feedback from the group exercise can be found in Appendix 2 on page 37

Takeaways

- Review of the entire proposed program redesign resulted in agreement by the meeting participants to continue developing the program in the manner described.
- After reviewing feedback from both the 2022 and 2024 PE courses, it became clear that a 'one-size-fits-all' solution may not be possible.
- A group exercise took place where the participants broke into three groups to provide in-depth feedback about the content, flow, design, and structure of Chapter 1 of the revised PE course. Detailed results can be found in Appendix 2 on page 39.

Action Items

1. Add a 'train-the-trainer' element as a fundamental addition to Part 3.

Pilot SOR Training Update

Birgitta Larsson provided an in-depth update of the Pilot SOR Training initiative. She explained that demand for trained Second Opinion Reviewers (SORs) is high which is evidenced by the ongoing delays in reviews. To address the ongoing delays and lack of available SOR's, the new SOR training pilot was launched. What is valuable with the new program is that the SOR training adapts the content from the PE course to apply a reviewer's lens to demonstrate how to review a project proposal. However, it was evident that the entire process needed to be reviewed to learn how to best meet the needs of the people served.

The original SOR program was delivered over two days of face-to-face training. Some of the challenges expressed included:

- The time commitment.
 - Review the content with a view toward decreasing the length of synchronous training.
- Strengthen the mentoring process. Mentors expressed that they felt lost and recommended that the mentoring processes be strengthened to be clearer and more intentional.
 - Mentors must be more intentional and explicit with expectations around meeting established processes.
 - The mentor/mentee pairing process must be more intentional as well – ideally pairing people from the same organization.
- Create an active Community of Practice to support the SOR program.

Redeveloped SOR Training Model

Birgitta Larsson and Sylvia Koso explained the processes involved in redeveloping the SOR Training Model. In the redesign of the training model, the first step was to clarify the SOR Candidate and Mentor Candidate requirements and to establish a structure that creates an environment where meaningful, guided and supportive mentoring can be provided by

experienced SORers. To that end, the SOR training was re-designed with a much weightier emphasis on the mentoring component.

The criteria for the entire program, including entry into Part 1 include:

- Must have completed the PE Course.
- Must have experience with extensive uses of ARECCI tools.
- Must have been part of at least one SOR Review.
- Must have a Mentor assigned before commencing the course.

The proposed redesigned SOR Training Program is offered in three parts:

- Part 1 has been redesigned as a self study module where the candidate reviews PE key concepts, ARECCI decision support tools, and their role in the SOR process. The candidate is guided through one review using a pre-established scenario. Finally, a series of reflective questions complete Part 1.
- Part 2 is a synchronous workshop focused on exploration of ethical issues and where diverse experiences are brought forward. The candidates start by reviewing Part 1 key concepts and the scenario with facilitator guidance. Any questions arising from Part 1 is addressed. The SORer role and process are introduced and described in detail, as well as the SORer relationship to the ORR process. Finally, the candidates review two separate scenarios (QI and Evaluation) from a SORer perspective. This component forms the bulk of Part 2.
- Part 3 is the mentoring phase. Shortly after completing Part 2, facilitators meet with the candidates and their mentors to confirm the progress and to determine if any further direction / support is needed. The duration of the mentoring phase is expected to be approximately 3-6 months. In this period, candidates must have participated in at least 3 SORs of which they have completed at least 1 SOR as the lead. The suggested progression is:
 - One completed by the Mentor with the candidate observing.
 - One completed jointly.
 - One completed by the candidate with the Mentor observing.

The next step will be to create a network of mentors who are available to mentor SOR candidates. The mentor/mentee pairing will be established before Part 1 starts and will continue until the training is complete. Considerations include:

- How to recruit mentors
- How to prepare the mentors to be the most effective (and how should they be supported.)
- Determine the time requirement, elapsed time requirement, and responsibilities of the mentor.
- Conversations between the mentor and mentee and joint decision-making will determine when the candidate is ready to go out on their own and start conducting independent second opinion reviews.
- A document called *SOR Training Part Three: Mentoring Process* has been developed and shared with ARECCI Program office. In addition to outlining and describing each element included in the mentoring process, it also contains Mentor/Mentee checklist for completion.

Additional Suggestions

Part 1 – Self Study

1. To connect Parts 1 and 2, candidates should submit the screening tool and reflection questions earlier. Initially 2 weeks was allocated to complete these two exercises. The candidates themselves suggested that this should be provided in advance of Part 2 (at least two weeks in advance) to allow them to familiarize themselves with the content.
2. Ideally the self study portion should be supported by the new LMS- THINKIFIC™ if possible.
3. Touching base with facilitators:
 - o There needs to be a scheduled one-hour connection with facilitators for a Q&A opportunity, half-way between Part 1 and Part 2 which allow the candidates to have reviewed the material and better understand the questions they need answered.
 - o Materials should be received by participants more than one week prior to each part of the training.

Part 2 – Synchronous Workshop

1. The greatest benefit was found when candidates had the opportunity to learn from each other; to hear different perspectives and how reviews are conducted as a ‘team.’ This strengthens the support in favor of maintaining synchronous delivery of Part 2.
2. A checklist and a schedule of events in a mentoring process should be introduced in more detail at end of Part 2.

Part 3 - Mentors

1. Most candidates require at least 3 months to complete the mentoring process to be ready to lead reviews.
2. Most organizations would benefit from having an external review completed to compare the different types of projects and associated processes.
3. Potential mentors could be found from reaching out to people who are retired.
4. Crossover mentoring (between and among different organizations) could be beneficial.
5. It would be helpful to establish contacts with Indigenous Elders.
6. A business case demonstrating the utility of ARECCI in supporting project ethics and tracking the types of projects reviewed by the SOR would be beneficial.

Takeaways

The meeting participants agreed unanimously that more mentors are needed to shore up and strengthen the SOR training program. When mentors are well grounded in Project Ethics (experience and methodology), they provide tremendous value. SORers don't have to be part of the organization. The key is that they understand context and they don't find themselves being prompted to provide methodological advice beyond what would affect ethics of the project. The group also agreed that creating 3 parts to the SOR training is ideal. What's most important is the ongoing support that will be required.

With the rise of projects associated with or influenced by AI, EDI, ESG, Truth and Reconciliation recommendations, protocols are becoming more and more unique and complex and the demand for SOR support for these types of projects is on the rise. SORers

and trainees all need additional training on emerging topics. Training may need to be contracted to external partners. Going forward, SORer's will require:

- External expertise and access to these experts through an available contact list. Examples of experts include but are not limited to Indigenous elders, AI experts, and methodological experts.
- Access to a well established, moderated and supported Community of Practice (CoP).
 - Develop a business case for ARECCI where SOR can be used internally (in organizations) to support the development of and commitment to systemic ethical oversight.
- Strengthened tracking processes where:
 - All applications for SOR reviews are centralized through the ARECCI program office.
 - All completed SORs are tracked.
 - ARECCI Program Office should develop a repository of completed reviews and other related essential data.
 - Provide a monthly or quarterly report of the number and types of SORs to strengthen a business case for growth.

Action Items

1. Task the CoP to tackle some of the continuing education needs that will arise out of emerging issues associated with AI, EDI, ESG, Truth and Reconciliation which will prompt the need to augment the training over time.
2. Access to external experts such as Indigenous Elders, AI experts, methodological experts for example will be necessary.
3. ARECCI must take the lead in re-igniting ARECCI's processes and value proposition. Start with identifying and tasking champions (existing SORs) to advocate for its the value in the organizations they serve.
4. Develop ARECCI promotional materials to share with the leaders of diverse organizations.
5. Provide a list (kept up to date) of:
 - SOR resources
 - Directories of specialists
 - Ideas and specific topics
6. Data custodians should provide information about data access for QI projects which may be more of an organizational operational issue. Ensure Project Leads are identifying any operational issues or gaps that exist in accessing data and work toward overcoming those issues. It is the duty of the Project Leads to determine any operational issues or gaps that exist in accessing data and work toward overcoming those issues.

5. New Initiatives

REB / ARECCI Process Mapping

Robin Lau underscored the thinking behind the process mapping exercise that took place in 2023 and the take aways that were collected.

The original Alberta Heritage Foundation for Medical Research (AHFMR) was established in 1980⁷ to support medical research and to address the ethics review gaps that are known to exist in QI/E/HHS projects. In 2010⁸, Alberta Research Council merged with several other research and development organizations to become Alberta Innovates Bio Solutions, Alberta Innovates Health Solutions, and Alberta Innovates Technology Futures. In 2016, the separate organizations were consolidated into 'Alberta Innovates.'

Since that time, challenges remain about how to consistently address gaps in oversight or approval with QI/H/HHS projects. Even though ethical risks do indeed exist, these projects aren't held to the same ethics standard for traditional research projects such as Randomized Controlled Trials (RCTs) which are much more rigorous. At the time of the 2024 Fall Meeting, there remained no broad consensus regarding the standardization or the extent to which ethics oversight should be applied to QI/E/HHS projects. However, with the scope and range of QI/E projects continuing to grow, it's important that clear guidelines, protocols, and ethics oversight processes be applied. To that end, a process mapping exercise was conducted in collaboration with the REBs (CHREB, HREB, and HREBA) to better understand ethics review processes in Alberta.

Takeaways

In addition to interest on the part of many of the meeting participants to receive copies of the process map which will be made available online, the following discussion took place:

- Increasing project complexity is an important consideration
- Ethics oversight for QI/E projects is inconsistent
- Decision making must be aligned and standardized
- Project planning and organizational sponsorship and oversight for QI/E projects is needed.
- Clarity between what is offered by REBs and ARECCI will improve project quality by seeking the appropriate ethics oversight in a timely manner.
- There remains a need for more robust professional development for SORs and ORRs.

Action Items

1. Create a shared understanding of the ethics environment for project leads by establishing revised processes for distinguishing the appropriate review process (REB and/or ARECCI).
2. Describe and provide examples of the type, scope, and nature of QI/E/HHS projects.

⁷ <https://era.library.ualberta.ca/communities/dcece9e1-4420-4743-ba8e-b1d74de7fae8>

⁸ <https://albertainnovates.ca/about/who-we-are/history-our-story/>

3. Create content on the ARECCI website that offers project information such as a suitable and manageable ethics review pathway as well as links to both ARECCI and REB resources.
4. Collaboratively explore issues impacting ethics reviews such as data custodians and data access for QI/E projects, ethics education sessions, and more.
5. Develop strategies and processes to better support stakeholders such as:
 - Triage processes for ethics review requests.
 - REB classification of QI/E/HHS projects.
 - QI/E/HHS project information sharing with REBs.

Proposed ARECCI Ethics Forum

In ARECCI's early days, an annual ethics forum was held to raise awareness of ethics issues that existed in non-research projects and to allow a space for professional development and networking among members of the ARECCI community. It was from those events that the Community of Practice (CoP) was born. The forums were also a place for trainees to present their projects and receive feedback from the ARECCI Community and the members of the Community of Practice (CoP).

Robin Lau posed the question to the meeting participants about whether an Ethics Forum should be organized and delivered with the primary objectives of promoting the value of learning health systems⁹ to create more robust processes that align science, informatics, and a culture of continuous improvement. The forum would also offer an environment for sharing project experiences and learnings, and as a setting for providing professional development opportunities. This forum, if consensus to proceed is received, would be provincial in scope and open to representation from a broad range of organizations.

Takeaways

Feedback was positive for the development and launch of an "Ethics" Forum. Some thoughts from the group included:

- Will this be much like the former "Quality Day" events?
- The scope of the audience will be a consideration.
- Mental Health and Addictions considerations are growing. Care will be needed to assure the use of the right language for the forum.
- Consider applying a theme for each year's forum where storyboards are presented based on the theme. Examples may include public health, home health, and more. This may make the forum more focused on health in general than on quality which will need to be considered.
- The forum could cover Health, QI, and Ethics.
 - If focused on "Ethics", then the forum could include different streams with healthcare being one of those streams.
 - If focused on "Project Ethics," there would not be a researcher focus.

⁹ <https://pmc.ncbi.nlm.nih.gov/articles/PMC9284922/>

- Other streams might be AI streams, topics / issues associated with data collection, and more.
- Carefully consider opportunities for the right keynote speakers.

Action Items

1. The group enthusiastically endorsed the idea of delivering an Ethics Forum.
2. Approach AI as a key theme for the forum and its impacts on QI/E/HHS processes.
3. Make the forum provincially based but with the understanding that there may be extra-provincial registrations that should be welcomed.

6. Professional Development

Artificial Intelligence (AI)

Artificial Intelligence can be defined as “the programming of computer systems to analyze, problem-solve, and make decisions just as a human would....it began as a means to use an algorithm to solve an ‘if this then this’ rule which then advanced into algorithms that can be personalized.”¹⁰

Facilitator Annamarie Fuchs offered a recent article from NBC News (January 14, 2023) that provided some background and context which initiated a robust conversation about the use and impact of AI.

“When people log in to Koko, an online emotional support chat service based in San Francisco, they expect to swap messages with an anonymous volunteer. They can ask for relationship advice, discuss their depression or find support for nearly anything else — a kind of free, digital shoulder to lean on. But for a few thousand people, the mental health support they received wasn’t entirely human. Instead, it was augmented by robots. In October 2022, Koko ran an experiment in which GPT-3 wrote responses either in whole or in part. Humans could edit the responses and were still pushing the buttons to send them, but they weren’t always the authors. About 4,000 people got responses from Koko at least partly written by AI, Koko co-founder Robert Morris said. The experiment on the small and little-known platform has blown up into an intense controversy since he disclosed it a week ago, in what may be a preview of more ethical disputes to come as AI technology works its way into more consumer products and health services. Morris thought it was a worthwhile idea to try because GPT-3 is often both fast and eloquent, he said in an interview with NBC News. “People who saw the co-written GTP-3 responses rated them significantly higher than the ones that

¹⁰ Rahman, V., Victoros, E., Ernest, J., Davis, R., Shanjana, Y., Islam, MR. *Impact of Artificial Intelligence Technology in the Healthcare Sector: A Critical Evaluation of both sides of the coin*. Clinical Pathology. 2024, January 22. <https://pmc.ncbi.nlm.nih.gov/articles/PMC10804900/>

*were written purely by a human. That was a fascinating observation," he said. Morris said that he did not have official data to share on the test. Once people learned the messages were co-created by a machine, though, the benefits of the improved writing vanished. "Simulated empathy feels weird, empty," Morris wrote on Twitter. When he shared the results of the experiment on Jan. 6, 2023, he was inundated with criticism. Academics, journalists and fellow technologists accused him of acting unethically and tricking people into becoming test subjects without their knowledge or consent when they were in the vulnerable spot of needing mental health support. His Twitter thread got more than 8 million views."*¹¹

Artificial Intelligence has already influenced our consumption of information and raised questions about ethics and accuracy. Information is more available and data management aids in improving productivity, but questions are beginning to arise around the diagnostic accuracy of some AI driven technologies where predictions are made without revealing how those conclusions were reached, leaving users concerned about their legitimacy. Chat GPT which is widely used, is believed by some to lack authenticity regarding the references that AI captures for medical articles. Furthermore, the use of AI Medical Scribe software is also on the rise to simplify demands on physician time in the clinic setting.

Data breaches also appear to be more likely when AI applications fill out Electronic Health Records because AI applications will capture much more sensitive information than when records are filled out by a human.

Ethics risks associated with AI include potential invasions of privacy associated with the practice of data scraping (large volumes of data captured from social media and other sites without permission). What's more, indiscriminate scraping can also result in risks associated with copyright infringement, plagiarism, and more. Further, when basing decisions on historical data, AI might generate assumptions about disease diagnosis or progression that are no longer accurate.

Despite these concerns, AI has considerable potential to positively transform the healthcare world if it is appropriately harnessed and regulated. Researchers see it as supporting and improving the work of health care analytics, which uses historical data to produce insights that can improve decision making and ultimately influence health outcomes. As AI becomes more prominent across the health system, members of ethics review committees will be called upon to consider the kind of ethics expertise needed to support decision making and adaptations in the work, particularly if they are tasked to conduct ethics reviews of AI driven medical devices.

¹¹ <https://www.nbcnews.com/tech/internet/chatgpt-ai-experiment-mental-health-tech-app-koko-rcna65110>

The question for discussion:

How do you see Artificial Intelligence coming alongside your work in project ethics, quality reviews, and evaluations?

A robust discussion followed:

- It is essential to consider where the health data is being stored. In Canada? Beyond?
- Conversations center around how human values will align with technology.
- Privacy Impact Assessments (PIA) ask questions about how long data is stored. In an AI world, this may be a much broader question that will require exploration of the approach and how to understand equity in accessing the tools and the data.
- From a patient perspective questions emerge such as how the data is collected, used, stored and what it will be used for in the future. Patients may also want to know if they have the right to change their minds about the use of their data.
- Physicians may have questions about how AI tools are used and how to update policies accordingly. The committee asked who should take on this task.
- When it comes to data scraping software, it is impossible to truly be able to protect privacy. There are bad actors everywhere.
- It's important to acknowledge that AI has simplified the analysis process.
- Humans have misunderstood each other for generations. A leap of faith may be needed to begin working in a world where AI becomes known as a key 'collaborator.' Humans will be tasked with incorporating human values into the right context and relevance.
- Consider using other data collection methods that aren't surveys. Examples include but are not limited to:
 - Electronic (digitized) data capture systems such as software that collects, stores, and manages data electronically.
 - Transactional tracking software that tracks what customers are using and use that data to make decisions about next steps.
 - Focus groups and interviews
 - Observational studies that measure how people interact with ARECCI's website and programs to capture information about user experience – which can be captured in real time.
 - Online tracking by implementing pixels and cookies that enable tracking of user online behavior to provide insight into what is of greatest interest.
 - Social media monitoring to better understand follower engagement.
- Incorporate AI in education to understand the most appropriate use of artificial intelligence.
- Quality based review pilot studies cannot capture context (i.e., emotion). In other words, don't be too quick to analyze data or accept analyses done by AI means.

Takeaways

- SOR training will need to include how to ask questions about the use of AI, how to record information from these sources, and protect privacy of sensitive health questions/answers.
- Data breaches from programs like MyChart for example can be largely avoided, but why are they asking for more information than needed/that we know is being recorded?
- REB: AI can create protocols, but we may not know about those protocols unless we are told about them. Level 2 data and beyond is given to Information Technology (IT) departments to conduct threat risk assessments.
- It's essential to ask whether screening questions were created by AI. If they were, we need to ask when and how project leads should declare this to reviewers or participants. Equity in the use and access of the tools is a concern. Adding statements to phone interviews can be overwhelming for patients and may require additional discussion or clarification.
- Use of Physician tools like AI scribe beg the question about where the data is being stored and for how long. Privacy Impact Assessments will be required to contemplate those questions.
- Legislation is not keeping up with innovation. Industry is leading in terms of pace, and it is largely unregulated.
- When achieving consent from patients, the consent process will need to describe how the data is being collected, stored, and used, whether it will be used for future studies, and whether patients will be permitted to change their minds in the future.
- Objective vs subjective data analysis. When scans are analyzed by AI one has ask about the quality of the data that was used to arrive at conclusions. One study demonstrated that when AI captured a "ruler" (straight edge) on a scan associated with cancer, the results of all scans containing visible rulers where therefore considered to be cancer.
- There are benefits to AI:
 - ChatGPT organizes data very quickly which allows the individual to spend far less time rearranging, thinking, or organizing information.
- Include other community members (government, places of worship, and more) in the creation and discussions surrounding policy development and implementation.

Finally, one individual reminded the group that we have misunderstood each other as humans for generations. A leap of faith may be needed to enable us all to better understand how to work alongside AI and to ensure we incorporate human values, context, and relevance.

Insight from the ARECCI Community: "Artificial Intelligence will never replace the need for ethics."

Action Items.

1. Add a question to the peer-review process to see if anything has undergone AI analysis.

Case Study: Indigenous Cultural Safety Considerations in the ARECCI Process

Jennifer Stieda and Fionna Blackman led a case study discussion focusing on a survey that was developed to assess the knowledge, attitudes, and behavior of staff around their understanding of Indigenous cultural safety. When addressing the inclusion of cultural sensitivity, trauma, racism and other sensitive topics in research, many avenues must be considered.

- Informed consent: Must articulate the purpose and content of the survey and address the possibility of triggers.
- Expertise: Who are the experts and what are their qualifications? Can there be one expert who represents different cultures? Within the Indigenous community for example, there is a vast array of cultural norms, practices, languages, and more.
- Belief, trauma, and emotions: How can we (or should we) remove beliefs, traumas, and emotions from the decision-making process when it comes to conducting ethical reviews?
- Trust is essential for culturally safe healthcare. Indigenous populations have a justifiably high level of mistrust of settler populations.

Second Opinion Reviewer Opinion & Example: Indigenous Cultural Safety Considerations

- Trust is essential for culturally safe healthcare.
 - Chapter 9 of the Tri Council Policy Statement on Ethical Conduct in Research: Research Involving first Nations, Inuit, and Metis Peoples of Canada¹² offers a framework for the ethical conduct of research involving Indigenous peoples. While it “is not intended to override or replace ethical guidance offered by Indigenous Peoples themselves, its purpose is to ensure to the extent possible, that research involving Indigenous peoples is premised on respectful relationships...and encourages collaboration and engagement between researchers and participants.”¹³

Takeaways

- Never lose sight of the fact that project participants can be vulnerable. Seek permissions as appropriate and allow the participants the feeling of safety and the time needed to respond accordingly.
- One question that was particularly thought provoking was “when do you ask about cultural safety – only with vulnerable populations?” Perhaps all discussions should recognize and address the possibility of cultural safety implications.

¹² https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html

¹³ https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter9-chapitre9.html

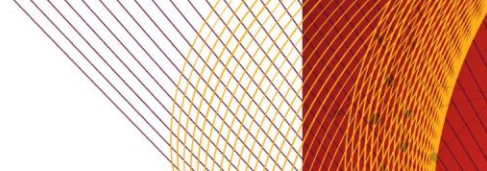
- If you ask a safety-oriented question such as “do you feel safe” it is essential to establish a means of addressing specific elements such as how the environment contributes to feelings of safety, whether people feel listened to and can express how they truly feel.
- A statement was included that said “I will prioritize Indigenous People’s health in my healthcare practice” which was a leading statement, making it obvious what the response should be. Leading questions skew the data because some people will feel that they need to respond in a socially appropriate way.

Action Items

1. Establish long term partnerships with Indigenous leaders and communities to build trust.
2. Include the opinions of vulnerable populations as early in the screening process as possible to ensure that inappropriate or triggering questions are removed from surveys or test designs.
3. Evaluate the intention of the reviewer or the designer and the experience of the target population as a fundamental part of the ethics review process.

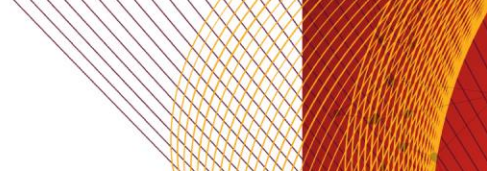
7. Updates from the ARECCI Community

ORGANIZATION	UPDATE
<p>BIM Larsson & Associates Doing SORs from the Outside.</p>	<ul style="list-style-type: none">• There are no well-established structures for conducting SORs within the consulting world.• Requests for ethical oversight are responded to as they come up.• We work with others through sub-contracting arrangements and bring a team together as the need arises.• Funds for projects are often limited and do not include time and effort to do ethical reviews (well).• Everyone agrees that there is a need to establish the appropriate rigor and flexibility in methodology to better serve Indigenous and EDI populations.• Truth and Reconciliation must be considered in all projects, and the ethical issues must be addressed in the right context. This also holds true for appropriately consider and respond EDI factors within evaluations.• Working with equity deserving populations is challenging and we need to ensure rigor, responsiveness, and relevance in how this work is designed and how the ethical implications are addressed.• Methodologies may need to be adapted.• What guides us:<ul style="list-style-type: none">▪ Ethical implications are top of mind as evaluations are becoming more and more intrusive▪ Must respond to issues as they arise (timely response is essential)▪ Must address issues with clients who may not understand the ethical implications that exist▪ ARECCI is slowly reaching into community organizations, and they are starting to explore how to address ethical implications of projects.▪ As organizations receive funding for pilots or projects, they reach out and ask for advice about how to conduct an evaluation. This discussion must include the identification of any the ethical issues that may exist.



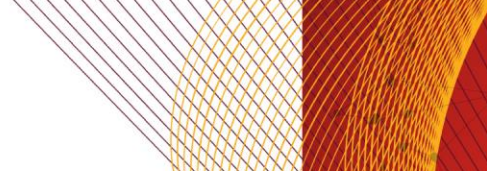
ORGANIZATION	UPDATE
University of Alberta HREB	<ul style="list-style-type: none">• Currently about 5,300 active files across 4 REBs with 1668 new applications in the past year, 2705 amendments and 4017 renewals.• REB's 1 and 2 review all qualitative and quantitative research across all disciplines• REB's 3 and 4 review all research that impacts AHS, Covenant Health, or involves the collection or use of health information as defined by the Health Information Act of Alberta.<ul style="list-style-type: none">▪ REB 3: Health Panel▪ REB 4: Biomedical Panel• Requests for review are received through the website where they are reviewed by the senior officer / REB Chair with a decision provided generally within 1-2 days. Two options exist<ul style="list-style-type: none">▪ Ethics review is required or▪ The project is outside the REB mandate.• The REB review process has two types of review streams: full board or delegated based on degree of risk. Researchers can expect a result within one month for a delegated review and within 6 weeks for a full board review.• Multicenter research now has a more streamlined approach for Category A, B, or C Involves review at their institutions and ours Duplication of process so – created 3 categories of research. See the slide• REBX Exchange is a multi-site neighborhood (application) that connects organizational enterprise systems for optimal efficiency in addressing multi-site human ethics applications. Average ethics review time is now down to 3 days compared with stand alone REB ethics applications that can take on average, 22 days. Participating institutions with more than 25,000 active studies underway now include:<ul style="list-style-type: none">▪ University of Alberta ARISE▪ University of Calgary IRISS▪ University of British Columbia RISE• Coming soon: a common consent template for U of A and U of C known as CHEER





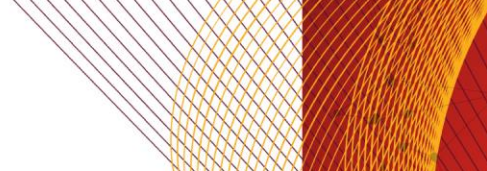
ORGANIZATION	UPDATE
University of Calgary CHREB	<ul style="list-style-type: none">• CHREB has authority for research ethics, not QA/QI• Jurisdiction includes the Faculties of Kinesiology, Nursing, and the Cumming School of Medicine at the University of Calgary. It also reviews research from other faculties where personal health information is sought as well as being the board of record for Mount Royal University projects seeking access to personal health information.• A Project Categorization Decision Tree for QA/QI/PE Versus Research is available on their website and a project categorization table that distinguishes the differences between QA/QI/PE offering indicators such as intent, motivation, and project/study design.• The decision support tools help the project leads to consider how best their undertakings should be categorized. However, for university affiliates, the final decision is made by the Research Ethics Board (REB). Only the REB can grant an exemption should one be required.• The Project Categorization Table was updated in 2024.• ARECCI provides a risk rating and screen review to evaluate whether it is QA/QI or research. The screening tool and risk rating are informative, not definitive.• The goal is for the decision to be made collaboratively, with everyone on the same page. In addition to considering the risk rating and screening tool, project leads are to provide a summary of their project and rationale for why they believe it to be QA/QI. An indication of support from the relevant clinical lead is also requested.• Where projects are determined to be QA/QI, a letter is sent exempting the project from REB review. Where the risk rating is high, they are encouraged to seek a SOR, but the REB does not have the authority to mandate this.• While there is no obligation on the part of project people to seek review, the CHREB cannot grant ethics reviews retroactively if it's found that a review should have been done. Warnings are clearly stated. Breaches of the University's integrity policy and legislation have considerable implications.• Comparison table: looking for BEST FIT• Distinction between QA/QI vs research, ethics review is different. QA/QI the lead researchers are not required to do an ethics review, second opinions for an ethics review are encouraged.
University of Lethbridge	<ul style="list-style-type: none">• Sylvia Koso is both Independent and affiliated with the University of Lethbridge where she teaches at two faculties





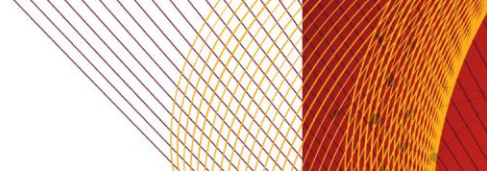
ORGANIZATION	UPDATE
	<ul style="list-style-type: none">• Also, a SORer where I conduct external reviews (about 4 per year) with completion of one community-based project as well.• Teach 3 courses where she intentionally mentions the importance of project ethics, program planning, and evaluation.• Also teach “advanced public health” which is the last course the students take before receiving their bachelor’s degrees.• Try to cover in 3 hours- as much of the PE course (level 1) as possible. The following is covered:<ul style="list-style-type: none">▪ Students are required to read the Harvey Grant case.▪ Discuss mitigation strategies for various identified risks▪ Assignment given• In the Advance Pub Health course –students become involved with real projects where they apply the tools.<ul style="list-style-type: none">▪ Focus on three key risks for the course▪ Mock proposals written where the three risks are identified with mitigation strategies applied• Encourage master’s & dissertation students to consider Research ethics and project / QA / QI project ethics processes.• Education piece – such as the PE course – is often missing at the university level.• Would love to see this as a credit course in advanced education.
Alberta Health Services	<ul style="list-style-type: none">• Clinician vs Researcher- the resources and timeline for ethics are different, increasing ethics processes are making it harder to complete.• AHS’s Project ethics website, particularly the landing page, is outdated.• With changes underway at AHS through the Refocusing of Alberta’s health system, it’s uncertain how AHS will approach ethics reviews and data sharing agreements.• Intake for SOR requests will have to adapt to serve the new four health organizations (Primary Care Organization, Acute Care Organization, Continuing Care Organization, and Recovery Alberta).• Currently offering an ARECCI Second Opinion Review





ORGANIZATION	UPDATE
Edmonton O'Day Primary Care Network	<ul style="list-style-type: none">• PCNs operate as individual businesses but provide similar services.• Mandate is to provide a group of physicians who join our organization with enhanced multidisciplinary services• Efforts have been underway to strengthen data informed decision making – creating standardization where possible• Have shifted to making robust data informed decisions that can spread and scale• Focus on responsible, ethics informed practice with a greater emphasis on planning how we manage our data• Created a medical home team – to physician clinics where they work on QA and QI projects and tapping into the PCN data AND the clinic specific data• Working to build ARECCI into every single project where ARECCI is introduced in our research and evaluation committee and where we are also creating more planned and responsible partnerships.• Front line team will require basic training. Then the objective is to spread training to all multi disciplinary team members• Teams work directly with physician clinics using data from PCNs and clinics to understand how best to support patients.• ARECCI is part of the charter and screening process for every project, in research and evaluation, and in establishment of new partnerships.
Interior Health B.C.	<ul style="list-style-type: none">• Have established an Interior Health Ethics Framework. Project ethics, business ethics, clinical ethics, public health ethics, and research ethics are all part of the same overarching ethics framework.• An associated policy (Project Ethics Policy) highlights the responsibility of quality improvement and program evaluation to project members so they can systematically apply ethical considerations to all projects involving people and their confidential information.• Have developed SOR & ORR processes and provide education for Improvement Consultants who are all required to become SORs.•• PE Education (Level 1 course and Level 2 course) are also embedded in the training of Improvement Consultants.• A SOR Review website containing available resources and a team workspace has also been developed





ORGANIZATION	UPDATE
	<ul style="list-style-type: none">• The QI Project Charter has ARECCI Guideline questions embedded.• A decision document enables people who need to know when they are required to use ARECCI tools how to proceed.• When a decision has been made to submit the project for a review, a standard Project Ethics Request for Review (SOR/ORR) has also been developed.
Alberta Innovates and HREBA	<p>HREBA- Health Research Ethics Board of Alberta</p> <ul style="list-style-type: none">• Alberta Innovates is not affiliated with the universities, AHS or Covenant.• HREBA reviews clinical studies and health studies by researchers not affiliated with the universities, AHS, or Covenant.• Cancer-based studies all go through HREBA even when they are based in the universities, AHS, or Covenant.• Go through UCalgary’s Institutional Research Information Services Solution (IRISS) system.



Takeaways

All presentations were received with interest and enthusiasm. During the discussion with Interior Health which offered a range of opportunities for organizations to consider how to standardize and blend best practices into a more comprehensive review process, questions arose about how to appropriately make use of ARECCI intellectual content, specifically whether organizations can adapt ARECCI intellectual content and deliver as their own. ARECCI leaders highlighted that any changes to content puts validation of the tools and materials in doubt. Interior Health folks explained that while ARECCI content isn't changed, it is augmented.

ARECCI people do not need to deliver the material. To scale and spread effectively, it is essential that ARECCI content be delivered by all trained organizational community members rather than only trained ARECCI staff. The development and adoption of the Learning Management System has been integral to supporting the kind of scale and spread that is needed.

Action Items

1. Organizations should come together to review the material and content to develop a shared understanding about any updates or adaptations that are needed.

8. Concluding Remarks

ARECCI accomplishments to date were made possible by ARECCI Second Opinion Reviewers and the Community of Practice. The ARECCI 2024 Fall Meeting fostered rich collaboration and provided an opportunity for input to strengthen our collective approach to project ethics, education and growth and scalability. The meeting provided valuable feedback on current and future initiatives:

- ARECCI Strategy (2024-2027),
- ARECCI Project Ethics Course,
- ARECCI SOR Training,
- ARECCI Community of Practice Engagement Tool,
- Ethics Process Mapping,
- Ethic Forum, and
- Case studies discussion on upcoming issues on AI and Indigenous Cultural Safety Considerations in the ARECCI Process

The theme, "Culture, Strategy and Change" reflects the current ecosystem with changes in the healthcare landscape and the development of 4 new agencies: Acute Care, Primary Care, Recovery Alberta and Continuing Care, and increasing complexity of QI/E/HHS projects. ARECCI will continue to support our valued stakeholders with project ethics decision support tools, education and review services to help minimize and mitigate risks to organizations, communities and patients.

In 2025, ARECCI will be guided by strategy which will be informed by an expert Advisory Committee and the establishment of project-based Working Groups. ARECCI is looking to increase the consistency and availability of ARECCI Education (ARECCI PE Course, ARECCI SOR Training), Community of Practice activities, engaging organizations to develop stronger supports (Organization Recognized Review) for ARECCI Second Opinion Review Requests and developing a knowledge repository of QI/E projects.

Thank you to all our ARECCI Community members who participated in the 2024 Fall Meeting, and we look forward to working with you in 2025 and beyond.

Appendix 1. Awards & Recognition

AWARDS & RECOGNITION	EVENT DETAILS (FALL 2024)	MEANING
Second Opinion Reviewer (SOR)	Tammy Mah-Fraser presented an SOR Pin to all SORs present during the dinner	The pin represents the ARECCI Second Opinion Reviewer community and recognition of your contributions as a SOR. We encourage you to wear the pin to ARECCI events, meetings, training and whenever you are meeting with project leads to review their projects.
Graduation		
SOR Graduation Ceremony	Mentors presented a certificate and the SOR pin to the mentees: Mentees graduated: <ul style="list-style-type: none"> • Erin Hay, • Naomi Usman, • Maarit Mackay & • A member of HQCA (not present) 	
Recognition		
Mentors	Tammy Mah-Fraser presented a Certificate and Tree of Life Metal Wall Art to the mentors Present <ul style="list-style-type: none"> • Brandi McCormack • Krista Brower Not Present: <ul style="list-style-type: none"> • Sarah Tilley • Markus Lahtinen 	Meaning of Tree of Life - The "Tree of Life" symbolizes growth, connection, and unity within a community. It represents how individuals within the community are interconnected, supporting one another and contributing to the overall health and vitality of the group.
Most Active Reviewer	Certificate and Tree of Life Metal Wall Metal Art. Brandi McCormack received the award and gift on behalf of Sarah Tilley who was not present.	
Most participations in working groups	Certificate and Tree of Life Wall Metal Art. Presented to: <ul style="list-style-type: none"> • Birgitta Larsson, • Silvia Koso, • Jennifer Stieda Not Present: Bonnie Lakusta	

AWARDS & RECOGNITION	EVENT DETAILS (FALL 2024)	MEANING
Token of Appreciation (bookmark)		
<p>Partners who participated in any working group in the last year i.e. ORR, PE Course review, ARECCI refresh website review, newsletter, REB/ARECCI Mapping Process</p>	<p>Presented to:</p> <ul style="list-style-type: none"> • Birgitta Larsson • Krista Brower • Silvia Koso • Jennifer Stieda • Markus Lahtinen • Stacey Page • Charmaine Kabatoff • Brandi McCormack <p>Not Present:</p> <ul style="list-style-type: none"> • Janine Engelhardt • Laura Schattle-Weiss • Kendra Malainey • Shelby Corley • Bonnie Lakusta • Andrew Ross • Flora Stephenson • Kim Stever 	

Appendix 2. Project Ethics Course, Part One

Group Discussion & Feedback. Chapter One

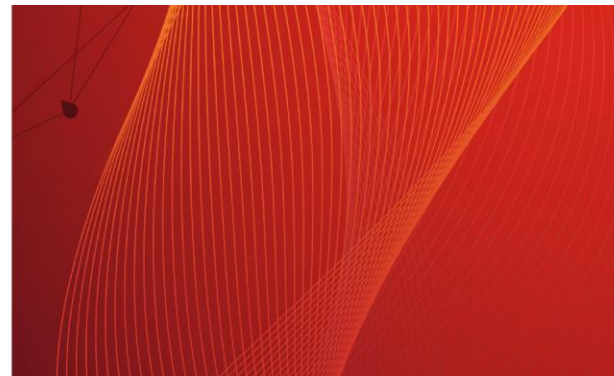
<i>What do you think of the topics for this chapter supporting foundational learning?</i>	<i>Suggestions (if any) of the flow or order of the topics</i>	<i>Suggestions for topics (if any) to be added in Chapter 1</i>	<i>What topics should be removed and why?</i>
<p>To better support foundational learning, frame the content and the experience in a way that participants understand that this is not just a 'hoop to jump through' but a value add to the project manager.</p> <p>Make the thinking exercise a value-add proposition to the attendees.</p> <p>Provide ways to enable participants to defend their choices and to think more deeply.</p>	<p>Take "Introduction to Decision Support Tools" from Chapter Two and move into Chapter One</p> <p>Chapter 1, #4: "Primary Purpose of a Review"</p> <ul style="list-style-type: none">• How to define• How to determine• Why this is a tool that enables more in-depth project management thinking. <p>Chapter 1, #5 "Characteristics between research and other types of projects. Remove "commonalities" and highlight what makes project types unique.</p>	<p>Primary Purpose – ensure this is very clearly communicated in terms of conversation, context, and negotiation.</p> <p>In project ethics we are looking for 'best fit' and to understand 'primary purpose.'</p> <p>Subjectivity of ethics – need to help people understand they must be comfortable in the grey areas. Also need to explain that sometimes projects go through tools more than once.</p>	<p>Rather than framing the material in terms of the commonalities, highlight what element are unique and then describe the characteristics of each so they can be easily identified.</p>

Volunteers available to help:

Develop content and/or materials for Part 1

Review and test the course in the LMS prior to launch

Andrew Ross



Chapter Two

<i>What do you think of the topics for this chapter supporting foundational learning?</i>	<i>Suggestions (if any) of the flow or order of the topics</i>	<i>Suggestions for topics (if any) to be added in Chapter 1</i>	<i>What topics should be removed and why?</i>
<p>The topics support foundational learning. Some suggestions in the next column are suggested.</p> <p>The tone overall should be to explain why reviewing project ethics is important and what the consequences can be if this step is not done.</p> <p>Assume no knowledge on the part of participants and develop material accordingly.</p> <p>Talk about the purpose and the utility of the quizzes Consider the audience (i.e. General public versus decision makers.)</p> <p>Could develop an informational video or presentation or infographic.</p> <p>Consider resources / materials – provide pdfs of flow charts and key points.</p>	<p>Introduce the decision support tools in Chapter One.</p> <p>Reorder the sections in Chapter two in the following manner: #1. Identifying Ethical Risks and include a section “how to complete a project where the risks are found in a project. #2. Ethical Review #3. Introduction to Decision Support Tools</p>	<p>In the ‘resources’ section add more materials such as infographics, key contents, and self reflection.</p> <p>Add information about a project charter and identification of risks (see IH training adaptation.)</p> <p>Add information about why as a project lead project ethics reviews are important.</p> <p>Discuss how to incorporate PE review when leading a project.</p>	<p>Introduce the tools in Chapter One and remove from Chapter Two. Then refer to the tools only briefly in Chapter 2</p>
<p><i>Volunteers available to help:</i></p>			

Develop content and/or materials for Part 1
Review and test the course in the LMS prior to launch

Kriste Brouer, Jennifer Stieda
Kriste Brouer, Jennifer Stieda

Chapter Three

<i>What do you think of the topics for this chapter supporting foundational learning?</i>	<i>Suggestions (if any) of the flow or order of the topics</i>	<i>Suggestions for topics (if any) to be added in Chapter 3</i>	<i>What topics should be removed and why?</i>
<p>Provide examples of things that have gone wrong – real life experiences. Add a personal reflection section after the quiz.</p> <p>To support foundational learning, explore empathy and perspective – ask “how would you feel if...?”</p> <p>Reflective learning questions to capture learning might support foundational learning – application of knowledge to experience.</p> <p>Empathy – “why is this training or PE even an issue?” or “why do we do this?” Take real life experience with ethics issues and share – human beings have experienced the consequences of ethics issues / failures / gaps.</p> <p>The training needs to drive home the point that PE reviews are better for everyone!</p>	<p>Introduce the decision support tools in Chapter One</p> <p>#2 in Chapter 3: “relationship between risk level and review type’ should be in Chapter 2</p> <p>Move #3 SOR to #2</p> <p>Move #4 ORR to #3</p> <p>#2. Relationship between risk level and review type should be in Chapter 2.</p>	<p>Talk about consequences of not doing PE reviews and how project ethics review strengthens the project.</p> <p>Explain why we are even talking about project ethics – in other words, ask the question “why does this matter?”</p> <p>Add a reflection to connect what the person learned with how they feel about ethics.</p> <p>Make sure the project and risk level diagram is included in chapter 3. Make the three levels of risk very succinct.</p> <p>Make sure the consequences of NOT doing an ethics review is discussed.</p>	<p>Be cautious about the content given that Part One can include the public.</p>
<i>Volunteers who are available to help:</i>			
<p>Develop content and/or materials for Part 1</p> <p>Review and test the course in the LMS prior to launch</p>	<p>Naomi Usman</p> <p>Naomi Usman</p>		

Appendix 3. Project Ethics Program Guide

DRAFT: ARECCI PROJECT ETHICS COURSE PROGRAM GUIDE

Program Overview

The ARECCI program courses are designed to help participants develop knowledge and skills related to project ethics in quality improvement and evaluation and apply the ethics considerations to a project they are currently working on.

The ARECCI Project Ethics Course is divided into three distinct parts, each designed to focus on a specific group or target audience.

Each part is delivered separately allowing flexibility for participants. Upon completing all three parts, participants will have developed skills in developing a structured approach to identifying and addressing ethics issues for their project to ensure project success.

Part 1 – Foundational

Delivery Method:	Self-directed. Online through Learning Management System.
Duration:	Approximate 2.5 hours
Goals:	<ul style="list-style-type: none">• Build foundational knowledge in project ethics and ARECCI principles laying the foundation for Part 2 & 3• Meet the increase demand of PE Course by making it available to a wider group of audience through a scalable, consistent and cost- efficient method• Promote and build awareness of the ARECCI program
Target audience:	Entry level to quality improvement/evaluation, ARECCI and project ethics and public that like to learn about ARECCI and project ethics.
Learning Objectives:	By the end of this course, participants will be able to: <ul style="list-style-type: none">• Understand ARECCI's historical development and ethical principles• Differentiate Between types of ethics and projects• Recognize and apply the six ethics principles to knowledge-generating projects• Recognize various ethical risks and vulnerabilities in projects, and develop strategies for assessing, minimizing, and mitigating these risks.
Program Format	Part 1 is a self-paced learning delivered through a Learning Management System (LMS) platform with a blend of presentation slides with voiceovers, self-reflection exercises, quizzes for assessment and additional resources to support learning. Key topics covered will be broken down into three chapters. Pre-requisite course for Part 2 & 3.

Part 2 – Case Studies (Proposed)

Delivery Method:	Self-directed. Online through Learning Management System.
Duration:	To Be Determined
Goals:	<ul style="list-style-type: none">• To reinforce the foundational PE concepts and gain deeper understanding of ARECCI process and principles through practical and applied methods using real-world case studies/structured scenarios.

	<ul style="list-style-type: none"> ○ Practical - Learn how to complete screening and guideline tool questions. ○ Applied <ul style="list-style-type: none"> ▪ Learn how to identify ethical risks, analyze complex scenarios and develop risk mitigation strategies. ▪ Learn how to apply theory and concept to actual contexts ● Sustainable and scalable - The ability to accommodate increasing demand and a wider group of participants by making it accessible without increasing burden on facilitator, administrative costs and logistical constraints.
Target audience:	<p>Individuals who are or may be required to use the screening and guideline tools, as well as applying ARECCI process to their future projects.</p> <p>Individuals who are interested in learning about the contexts of the screening tool and guideline tool questions.</p>
Learning Objectives:	<p>By the end of this course, participants will be able to:</p> <ul style="list-style-type: none"> ● Understand the contexts of screening and guideline tools questions and use both tools together to identify and assess ethic risks for their project. ● Analyze project outcomes and explore alternative strategies.
Program Format	<p>Proposed: Part 2 is a self-paced learning delivered through a Learning Management System (LMS) platform with a blend of self-paced learning and case studies. Participants must complete Part 1, and this will be pre-requisite to Part 3.</p>

Part 3 – Workshop (Proposed)

Delivery Method:	Workshop (Instructor-led through online platform)
Duration:	To Be Determined
Goals:	<ul style="list-style-type: none"> ● Connecting learning to current project ● Stimulate discussion, explore different viewpoints and approaches among experienced project leads ● Receive direct feedback from instructor
Target audience:	Project leads with active projects who wish to learn the direct application of ARECCI process to their projects and complete an ethics review of their project by an instructor who is a trained Second Opinion Reviewer.
Learning Objectives:	<p>By the end of this course, participants will be able to:</p> <ul style="list-style-type: none"> ● Apply learning to real project through group discussion and instructor feedback ● Develop actionable strategies to mitigate and manage ethic risks for their project. ● Build community support through peer-to-peer learning and experience sharing.
Program Format	Proposed: Part 3 is an instructor-led workshop delivered through an online platform with a blend of case studies, group discussions, experience sharing, guidance and feedback provided by instructor of personal's project. The workshop will have a limit on the number of participants.

Appendix 4. Feedback from the ARECCI Community



Prior to the 2024 Fall Meeting, a survey was sent out to introduce some entertaining icebreaker opportunities. The survey also sought ARECCI stakeholder input on a question that offered an opportunity to do some blue sky thinking:

“If there were no budget or resource constraints, what ideas would you offer about what’s possible? Share innovative ideas about what the ideal ARECCI program and Community of Practice would look like.” the following suggestions were offered.

What follows is a sampling of the feedback that was gathered.

- Re-visit the way the screening tool was developed including the scoring to establish whether there are any additions or updates.
- To ensure clarity of purpose:
 - Hold, at minimum, quarterly regular meetings organized by the ARECCI office.
 - Establish a monitored and managed virtual forum/place/space for timely guidance on ethical issues.
 - Provide targeted professional development opportunities for members to have time (and support) from their organization to be active participants.
- The process could / should be completely integrated into organizations at all levels.
 - Alberta Innovates should be available to provide support, but my organization should take ownership of the day to day.
- Create opportunities for a growing, more collaborative community with new members who will bring new ideas and approaches.
- Create an engaging environment for collaboration by organizing more social events. Schedule frequent brainstorming sessions in unconventional ways that might include some physical activity. Use some type of ‘soft brain’ stimulation to enhance the release of dopamine and cortisol which occurs whenever there’s rigorous activity involved. That’s where our brains come alive!
- Quarterly virtual Community of Practice (CoP).
 - A planned topic with time to chat about concerns, learnings, and new challenges.
 - Ensure that there isn’t a great deal of preparation required to organize or attend.
 - Simplify the screening questions and guidelines to make it easier for people to complete.

- Make education accessible and not overly time consuming.
- I like that much of the new education will be offered online and asynchronous. I am concerned about people moving through the entire process though.
- The Community of Practice (CoP) should meet at designated intervals with a mailing list of SOR's and be a requirement. Perhaps create a designation or a credential for SORs as a means for people to advance the work.
- The work should be fully funded, supported, and championed by leaders in our organizations and supported by Alberta Innovates. I would ideally love to see this rolled out across all teams and portfolios.
- We need to promote widespread use of ARECCI tools in organizations, i.e. increase effort into raising awareness/education and knowledge.
- Nationwide standard for ethics review on QI/E projects
- ARECCI should be mandatory in healthcare.
- Create an ARECCI 'Program Manual' for organizations to implement and adapt within their networks and to context. Have this manual describe 'ideal roles' and who should be trained. Align these training recommendations with an ARECCI calendar that would offer consistent access to training and support.
- Provide a small stipend for people who are currently volunteering to sustain and scale the work. REB reviewers are remunerated, and this should be a standard that extends to the ARECCI program volunteers. It's a small token of appreciation for the work that we do.
- More effort is needed to raise awareness and knowledge so that there is more widespread use of ARECCI tools in organizations.

Appendix 5. 2024 Meeting Participant List.

Name	Organization
Tanaya Badgandi	Alberta Innovates
Fionna Blackwell	Interior Health
Krista Brower	PCN
Rakhi Chandra	HREBA
Jamie Chong	Alberta Innovates
Annamarie Fuchs	Facilitator
Erin Hay	Edmonton O-day'min Primary Care Network
Charmaine Kabatoff	HREB
Silvia Koso	Independent/ Lethbridge Polytechnic
Birgitta Larsson	Independent/Larsson
Robin Lau	Alberta Innovates
Maarit MacKay	AHS
Tammy Mah-Fraser	Alberta Innovates
Karena Mallett	HREBA
Brandi McCormack	AHS
Cristian Neves	Alberta Innovates
Amanda Nolet	Alberta Innovates
Stacey Page	CHREB
Andrew Ross	AHS
Jennifer Stieda	Interior Health
Naomi Usman	Edmonton O-day'min Primary Care Network



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Managed by

