

AL 1600 – (Project Ethics Policy)

1.0 PURPOSE

This policy outlines the responsibility of Project Leads and project members to systematically apply ethical considerations to quality improvement and program evaluation projects involving people or their confidential information. The intention is to protect both people and Interior Health from ethical risk throughout all phases of a project.

2.0 DEFINITIONS

TERM	DEFINITION
ARECCI	An acronym created by Alberta Innovates-Health Solutions which stands for “ A pRoject Ethics Community Consensus Initiative ”. It is sometimes used interchangeably with the term “Project Ethics”.
ARECCI Decision Support Tools	Two web-based decision-support tools developed by Alberta Innovates-Health Solutions to assist leaders and organizations with identifying the purpose of their project (Research, Quality Improvement or Evaluation) and the ethical risk associated with non-research projects. They are the ARECCI Guidelines for Quality Improvement and Evaluation Projects and the ARECCI Ethics Screening Tool.
ARECCI Ethics Guidelines Tool	On-line ethics decision-support tool which helps integrate six areas of ethical considerations into projects from the planning phase to reporting out at completion of the project.
ARECCI Ethics Screening Tool	On-line ethics decision-support tool which helps sort projects into their most likely category (research or non-research), determines the category of ethical risk and appropriate level of ethical review.
Confidential Information	Whether oral, written, electronic or film, includes the following: <ol style="list-style-type: none"> a) personal information about any individual that includes their: <ul style="list-style-type: none"> • name, address or telephone number; • race, national or ethnic origin, color, or religious beliefs or associations; • age, gender, sexual orientation, marital status or family status; • Personal Health Number (PHN), identification number, symbol or other particular assigned to them; • fingerprints, blood type or inheritable characteristics; • health care history, including a physical or mental condition, diagnosis, or disability; • information about their educational, financial, criminal or employment history; • personal views or opinions, except if they are about someone else; and • anyone else’s opinions about themselves.

Policy Sponsor: VP, Medicine & Quality	1 of 7
Policy Steward: Executive Director Quality and Patient Safety	
Date Approved: October 27, 2014	Date(s) Reviewed-r/Revised-R: September 2022(R)



AL 1600 – (Project Ethics Policy)

	<p>b) business information collected or created by Interior Health that exists regardless of form and includes, but is not limited to:</p> <ul style="list-style-type: none"> • information provided to Interior Health by an external vendor or service provider which, if disclosed, would harm the business interests of the third party; • information prepared as part of pending or ongoing litigation, law enforcement investigation, quality assurance review, Workers Compensation Board or Ombudsman investigation; • information related to credentialing, discipline, privilege, quality assurance reviews, and external review of quality of care; • in-camera deliberations of Interior Health where such topics as • budget strategies, personnel, labor relations, land acquisitions, or litigation may be discussed; • unpublished statistical information and internal correspondence related to organizational initiatives; and • information supplied in confidence to a mediator or arbitrator to resolve or investigate a labor relations dispute. <p>c) all information that, if disclosed without authorization, could be prejudicial to the interests of Interior Health and associated individuals or agencies; and</p> <p>d) organizational business information that would harm Interior Health’s financial interests and/or information that relates to the management of Interior Health that has not yet been implemented or made public; such as information that identifies the security architecture and infrastructure of the organization’s information systems.</p>
Organization’s Recognized Review (ORR)	The highest level of systematic ethical review for non-research projects scoring 47 or more “Definitely greater than minimal risk” on the ARECCI Ethics Screening Tool.
Program Evaluation	Systematic collection and analysis of information about a program’s activities, characteristics and outcomes to make judgments about the program, improve program effectiveness, and/or inform decisions about future programming.
Project	An initiative or collaborative endeavor with a defined purpose/aim that is organized and implemented to monitor, assess and improve the quality and safety of current and future systems of care. Examples of projects where this policy may apply are seen in (and not limited to) quality improvement, evaluation, needs assessments, health innovation and knowledge translation.
Project Ethics	Integration of ethical considerations from the planning to the reporting stages (from the beginning to the end) of a project.
Quality Improvement	Any process that from an individual and/or population perspective and from a health system perspective that improves the respect, safety, accessibility, appropriateness, effectiveness, equity and efficiency of a health care system.

Policy Sponsor: VP, Medicine & Quality	2 of 7
Policy Steward: Executive Director Quality and Patient Safety	
Date Approved: October 27, 2014	Date(s) Reviewed-r/Revised-R: September 2022(R)

AL 1600 – (Project Ethics Policy)

Risk	A probability or threat of damage, injury, liability, loss or any other occurrence to participants and/or information that is caused by external or internal vulnerabilities and may be avoided through pre-emptive action. Risks are usually considered something to be controlled and minimized if they cannot be eliminated.
Second Opinion Review (SOR)	Appropriate type of ethical review of a project scoring 8-46 “Somewhat more than minimal risk” on the ARECCI Ethics Screening Tool.

3.0 POLICY

The IH Ethics Framework supports employees, medical staff, and patient and family project partners in identifying and addressing ethical issues. Projects that do not require research ethics approval still involve people or their information and can have similar risks to research studies. This policy outlines the responsibility of quality improvement and program evaluation Project Leads and project members to systematically apply ethical considerations to projects involving people or their confidential information undertaken by IH employees, students, external consultants, patient and family project partners, or medical staff in the course of their employment, contractual, or student obligations (See Appendix A: [Decision Support Tool: When to use the ARECCI Guidelines and Screening Tools](#)).

3.1 Ethical Review

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

3.2 Roles and Responsibilities

Project Leads or team member(s) ensure projects are reviewed for their level of ethical risk according to the Project Ethics Procedures (see Section 4.0). Professional judgement is required in interpreting the results. Those responsible will plan appropriate mitigation strategies before involving participants. The Project Sponsor will assume any ethical risk associated with the project on behalf of the organization. The decision to proceed with a project is the responsibility of the Project Team and Sponsor.

3.3 Compliance

The Project Team is expected to comply with all IH policies, procedures and guidelines for the release of confidential information. This includes information for education, teaching, research, quality improvement, or other secondary purposes outlined in policy [AR0400 Privacy and Management of Confidential Information](#).

Policy Sponsor: VP, Medicine & Quality	3 of 7
Policy Steward: Executive Director Quality and Patient Safety	
Date Approved: October 27, 2014	Date(s) Reviewed-r/Revised-R: September 2022(R)

AL 1600 – (Project Ethics Policy)

4.0 PROCEDURES

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

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

Policy Sponsor: VP, Medicine & Quality	4 of 7
Policy Steward: Executive Director Quality and Patient Safety	
Date Approved: October 27, 2014	Date(s) Reviewed-r/Revised-R: September 2022(R)

AL 1600 – (Project Ethics Policy)

and Screening Tools), Project Charter, data collection tools, and any other supporting documentation. If the Project Team has completed a Project Charter or other Interior Health tool that has the six ethical considerations embedded within it, completing the ARECCI Guideline tool is not required.

4.5.1 Once the guidelines are completed and the team is ready for the review, contact projectethics@interiorhealth.ca for assistance.

5.0 REFERENCES

1. [ARECCI: A Project Ethics Community Consensus Initiatives](#)
2. Alberta Innovates. (2017). ARECCI Ethics Guideline Tool. Retrieved from albertainnovates.ca/w_p-content/uploads/2017/11/ARECCI-Ethics-Guideline-Tool.pdf
3. Alberta Innovates. (2017). ARECCI Ethics Screening Tool. Retrieved from <http://www.aihealthsolutions.ca/arecci/screening>
4. ARECCI Project Ethics Reference Guide, Alberta Innovates-Health Solutions, August 2013
5. [AR0400 Privacy and Management of Confidential Information](#)
6. BC Patient Safety & Quality Council. BC Health Quality Matrix [Internet]. 2020. Available from: <https://bcpsqc.ca/matrix>

Policy Sponsor: VP, Medicine & Quality	5 of 7
Policy Steward: Executive Director Quality and Patient Safety	
Date Approved: October 27, 2014	Date(s) Reviewed-r/Revised-R: September 2022(R)

AL 1600 – (Project Ethics Policy)

APPENDIX A: Decision Support Tool: When to use ARECCI Guidelines and Screening Tools

**IH Project Ethics Decision Support Tool
When to use the ARECCI Guidelines and Screening Tools**

Purpose of this tool: Research projects in IH that involve people or their information must be reviewed by Research Ethics Board (REB). Similar risks exist for quality improvement and program evaluation projects involving people or their information. IH has a project ethics policy (AL1600) that requires screening of all non-research projects that involve people or their information.

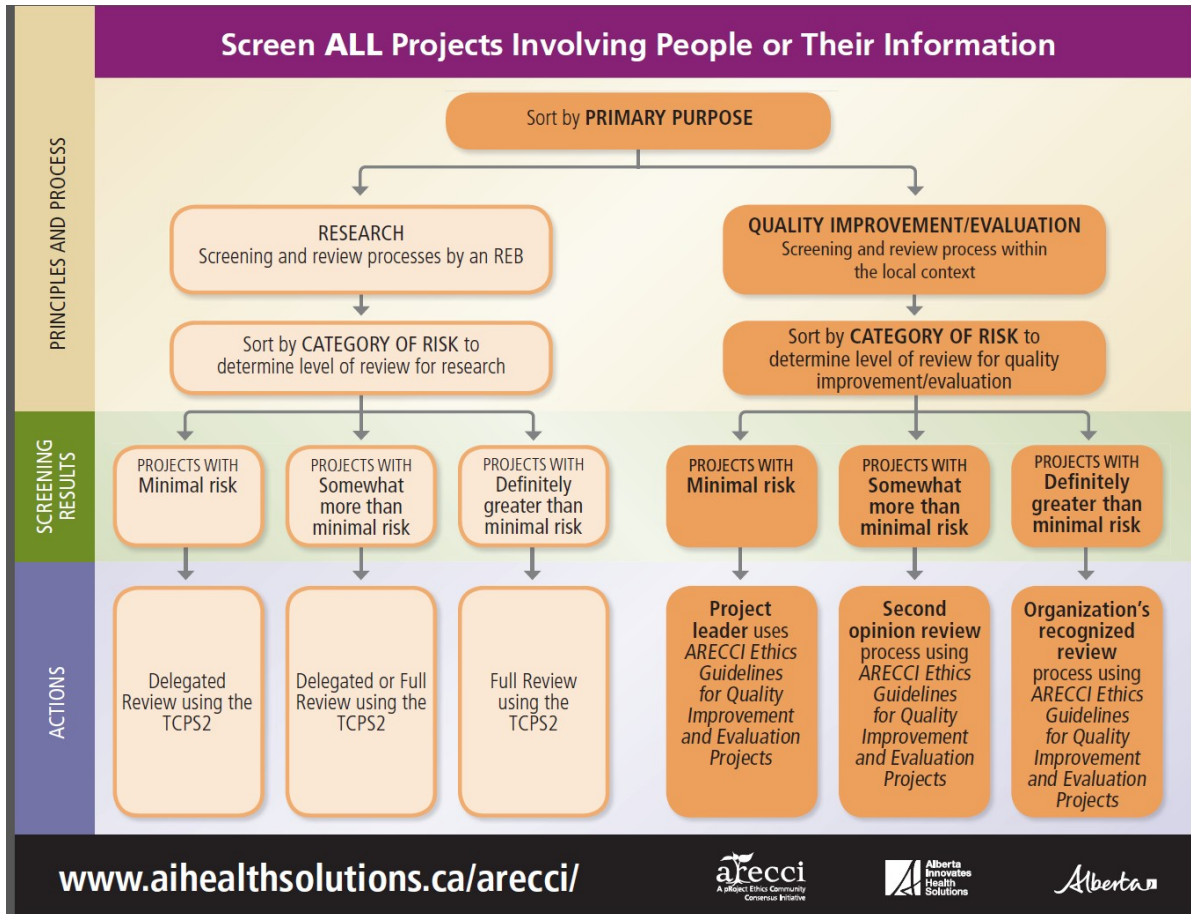
Please answer the pre-screening questions below and follow the prompts to determine if you need to complete the ARECCI guidelines and screening tool for your project.

	Yes	No
1. Does your quality improvement or evaluation project involve people or their information? If you selected YES – please continue to question 2 If you selected NO – ARECCI is not required no need to continue below	<input type="checkbox"/>	<input type="checkbox"/>
2. Does your quality improvement or evaluation project involve:	Yes	No
A. A Critical Incident Review?	<input type="checkbox"/>	<input type="checkbox"/>
B. A PSLS event/investigation?	<input type="checkbox"/>	<input type="checkbox"/>
C. A Quality Review of a specific case?	<input type="checkbox"/>	<input type="checkbox"/>
If you selected NO to all of the above – please continue to question 3 If you selected YES to any of the above – ARECCI is not required, please follow appropriate process		
3. Does your quality improvement or evaluation project include data collection or measurement (beyond what is currently monitored by the program or service) of a targeted audience through:	Yes	No
1. Survey	<input type="checkbox"/>	<input type="checkbox"/>
2. Observation	<input type="checkbox"/>	<input type="checkbox"/>
3. Focus Group	<input type="checkbox"/>	<input type="checkbox"/>
4. Interview	<input type="checkbox"/>	<input type="checkbox"/>
5. Chart Review (Paper or electronic)	<input type="checkbox"/>	<input type="checkbox"/>
6. Administrative Data Review (Strategic Information reports, document review, PSLS)	<input type="checkbox"/>	<input type="checkbox"/>
If you selected YES to any of the above – please use the ARECCI Guidelines and Screening Tools If you selected NO to all of the above – ARECCI is not required		

AL 1600 – (Project Ethics Policy)

APPENDIX B: ARECCI Process Flow Chart

Source: Alberta Innovates – Health Solutions



Policy Sponsor: VP, Medicine & Quality	7 of 7
Policy Steward: Executive Director Quality and Patient Safety	
Date Approved: October 27, 2014	Date(s) Reviewed-r/Revised-R: September 2022(R)