

**Is this a research project or a quality improvement initiative?**

**Guidelines for Researchers**

Distinguishing between research and quality improvement (QI) can be unclear when beginning a new project. This document serves as a tool to help researchers/physicians/clinicians/staff to determine in which category their project lies. It should be noted that in some cases, initiatives that are predominantly QI may have elements that make them fall under research.

Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research, and do not fall within the scope of REB review (TCPS2, 2018). For further information, please consult Article 2.5 of the TCPS2 (2018).

Upon consulting this document, the principal investigator (PI), who is the lead researcher on the given study, should submit a protocol/summary of the project to the Research Ethics Board (REB) Office ([rebsubmissions@ontarioshores.ca](mailto:rebsubmissions@ontarioshores.ca)) for Chair and Coordinator review. The final decision of whether a project requires REB approval lies with the REB Chair and Coordinator. If the project is deemed as QI, the REB will provide a letter to the PI regarding the review and subsequent exemption of REB review.

**Research vs. Quality Improvement**

	<b>Research</b>	<b>Quality Improvement</b>
<b>Purpose</b>	An investigation to establish/determine facts, reach conclusions, and contribute to new or existing knowledge	To implement knowledge, or evaluate or improve a process/program
<b>Design</b>	Follows an approved, rigid protocol, with no unapproved deviations	An adaptive process
<b>Mandate</b>	Activities that are not mandated, but of interest; knowledge seeking to answer a question	Activities that are mandated or a part of regular operations; knowledge seeking to improve ongoing activities
<b>Risks</b>	May put patients at risk, with consent	No risk to operations or individuals involved (exception: possible privacy/confidentiality concerns for patients' data)

<b>Benefits</b>	Intention for research conclusions to benefit future patients, may or may benefit current patients	Intention for direct benefits to a process or system, may or may not benefit patients
<b>Analysis</b>	Use statistical analyses to prove or disprove hypotheses	Compare process or system to established standards or standards desired to achieve
<b>Effect on program/practice</b>	Findings are generally not expected to immediately affect or change practice	Findings of study are expected to directly, and quickly affect institutional practice
<b>Publication/Presentation</b>	General intent to publish findings	May be an intent or not intent to publish, but intent to share insights with colleagues and organization

*The table above is based on information from the Ottawa Health Science Network, adapted from: The Ethics of Using QI Methods to Improve Health Care Quality and Safety (Human Subject Research vs. Quality Improvement)*

To further determine if the project is research or quality improvement, answer the questions below based on the summary of your project.

If you answer YES to any of the questions below, your project is considered research. Please submit your full REB application to the REB Office at [rebsubmissions@ontarioshores.ca](mailto:rebsubmissions@ontarioshores.ca).

Does your project:

1. Develop or test the efficacy of an intervention that has not been studied before, or test new hypotheses that build on and are beyond the current knowledge in the specific area?
2. Have an assignment of patients/service providers into different treatments or procedures (such as randomization)?
3. Include a control group in which the study intervention is withheld to allow for assessment of efficacy?
4. Blinding patients/caregivers/practitioners to any element of care or assessment?
5. Prospective evaluation of a drug, device, or procedure not currently approved by Health Canada?

If, based on the above, it is still unclear if whether your project is research or QI, use the following questions to generate responses to submit to the REB to help assist in assessing the category the project.

1. Is the primary intent to generate information to provide feedback to the institution?
2. Is the project testing a hypothesis, or replicating/building on another researcher's study?
3. Will the project establish clinical practice standards where none exist, or will provide revisions in existing standards?

Information in this document is based on information adapted from the Ottawa Health Science Network Research Ethics Board: Is Your Project Research or Quality Improvement? Guideline and Checklist

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4. Is the project funded (by such as a sponsor or granting agency) that is provided with the intent to conduct research or has commercial interest in the results of the activities?
5. Does it test interventions or care practices/treatments that are not yet standard?
6. Will the project require informed consent from patients for practices/treatments that are outside the standard care?
7. Is the risk to patients separate from the daily/standard care they are receiving?
8. Is the primary purpose, or general intent to produce publication(s) for a research journal?

Please use the questions above to generate a response and consult with the REB Office on the above, along with submitting your proposal summary/protocol for review.

To supplement your proposal summary/protocol, you may choose to use the ARECCI screening tool to determine any areas of ethical concern, which is used to address the gap between QI and research, and provide the REB Office with your screening tool results. More information can be found here: <https://albertainnovates.ca/programs/arecci/>.

**Please note:** a QI project may change over time and may move to be considered research. When you experience any changes to the project, please refer to this document to reassess the need for REB review, and submit to the REB if you are uncertain.

### What if I want to publish results from my QI project?

Inherently, QI is done for components of improvement and shared learning, and is therefore entirely appropriate to disseminate QI successes, including through internal and external channels to the home organizations, such as presentations at meetings and publications in journals. Therefore, the intent to publish the findings of a QI project does not require REB review, if the publication does not refer to the QI activity as research and is made clear that the publication is a result of a quality improvement initiative.

If you would like to publish, and the project is determined as QI prior to its start, the REB will issue the PI letter stating the exemption from REB review. This may be something as required by the journal as evidence of exemption.

For any questions or if you require a consult with the REB Office, please contact [rebsubmissions@ontarioshores.ca](mailto:rebsubmissions@ontarioshores.ca).