Ottawa Health Science Network Research Ethics Board/
Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa

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Is your project Research or Quality Improvement? Guideline & Checklist

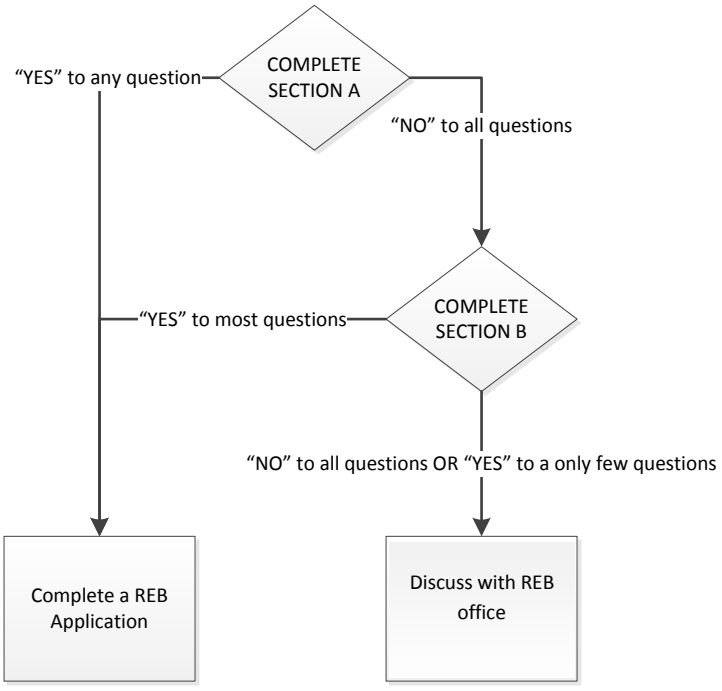
Purpose:

There can be confusion distinguishing between Quality Improvement (QI) and research. The guideline and checklist are tools to help staff/physicians/researchers determine in which category their project lies. It should be noted that in some cases, initiatives that are predominantly QI may have certain elements that make them fall under research. Upon completion of the checklist, the project lead should submit, along with a 1 page summary of the project, to the OHSN-REB Research Ethics Coordinator for Chair review. The final authority as to whether a project requires REB approval always lies with the REB Chair/Vice-Chairs. A copy of the REB letter with the final determination will be shared with the Quality Office for their records.

This Applies To:

Physicians, staff (including staff acting as investigators outside the institution), fellows, residents, volunteers, and students.

Checklist: Does Your Project Require OHSN-REB Review



Characteristics of Research and Quality Improvement Projects

	Clinical Research	Quality Improvement
Purpose	A systematic investigation to establish facts, principles or contribute to generalizable knowledge	To implement knowledge, evaluate or improve a process or program through established/accepted standards
Design	Follows a rigid protocol that remains unchanged	Adaptive, iterative design
Mandate	Activities not mandated by institution	Activities are mandated by institution as part of operations
Starting point	Knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis with the intention of contributing to generalizable knowledge	Knowledge-seeking is integral to ongoing management system for delivering health care
Population	Usually involves a subset of individuals and specific sample size	Includes information on all affected by process or program change receiving
Benefits	May or may not benefit current subjects; intended to benefit future patients	Immediately and directly benefits a process, system or program; might or might not benefit patients
Risks	May put subjects at risk with consent	No increased risk to patients, with exception of possible patients' privacy or confidentiality of data
Data collection strategy	Systematic data guided	Systematic data guided
Testing or Analysis	Statistically prove or disprove hypothesis	Compare program, process or system to established standards
Effect on program or practice	Findings of the study are generally not expected to immediately affect or change practice	Findings of study are expected to directly and immediately affect institutional practice
Adoption of Results	Dissemination of results may require more time	Dissemination of results occurs rapidly and adopted into local care delivery
Endpoint	Answer a research question and/or invite critical appraisal of that conclusion by peers through presentation.	Improve a program, process or system
Publication/Presentation	Intent to publish generally presumed at the onset of the project	Intent to publish may or may not be presumed at the onset of the project but QI practitioners are encouraged to share systematic reporting of insights

The table above is based on information adapted from:
The Ethics of Using QI Methods to Improve Health Care Quality and Safety[1]
Human Subject Research – vs. – Quality Improvement[2]

Checklist: Does Your Project Require OHSN-REB Review?

Project Title:

Answer the questions with a "YES" or a "NO".

SECTION A - **If you answer "YES" to <u>any</u> of the questions in this SECTION A, your project is research. Proceed to submit an REB application through the IRIS system.**	**Yes**	**No**
1. Develop or test the efficacy of a new intervention that has not been studied before, or test hypotheses about issues that are beyond the knowledge of current science?		
2. Prospective assignment of patients/providers into different procedures or therapies (such as randomization).		
3. A control group for whom the procedure or therapy or study intervention is withheld to allow an assessment of its efficacy.		
4. Blinding caregivers to any element of care.		
5. Prospective evaluation of drug, procedure or device not currently approved by Health Canada		
6. Exploring a previously unknown phenomenon with a marketed or approved product (i.e. off label use of a drug/device)		
7. National or provincial registry/database from which a hypothesis will be tested?		
SECTION B - **Continue with the questions in SECTION B below to further assist us to make the determination whether your project is "quality improvement" versus "research requiring REB review".**		
Project Purpose	**Yes**	**No**
a. Is the primary intent of the project to generate information to feedback to the institution?		
b. Test a hypothesis or replicate another researcher's original study?		
c. Establish clinical practice standards where none are already accepted or lead to revisions in practice standards?		
Funding	**Yes**	**No**
d. Is the project funded by an entity (such as a sponsor or granting agency) that makes clear its mission to conduct research, or has a commercial interest in the results of the activity or are funds being requested from institution to support the activity?		
Project involvement	**Yes**	**No**
e. Testing an intervention, care practices or treatments that are not standard		
Project Design	**Yes**	**No**
f. Is the project designed around a fixed protocol not allowing for frequent changes?		
Consent	**Yes**	**No**
g. Will the activity require voluntary informed consent for interventions that are not part of standard clinical care?		
Risks	**Yes**	**No**
h. Is the risk to the participants separate from what is involved in the care they are receiving?		
Publication of Project	**Yes**	**No**
i. Is the primary purpose of the project to produce results for publication in a <u>research</u> journal?		

Please submit the completed checklist and your proposal/protocol to rebadministration@ohri.ca for review as instructed by following the diagram on page 1.

Note: It's very easy for your QI project to slip into something that might be considered research as it changes over time. Each time that your project changes, it is recommended you refer to this checklist to reassess the need for REB review/approval, and submit to the REB for re-evaluation if uncertain.

What if the project is determined to be QI and you might wish to publish?

Intrinsic components of QI are shared learning, therefore it is entirely appropriate to disseminate and replicate QI successes, including through channels that are external to an organization. This may include presentations at meetings and publications in professional journals. Therefore, the mere intent to publish the findings of a QI project does not obligate REB review, if the publication does not refer to the activity as research and makes it clear the publication is the result of a quality improvement initiative.

Any investigator whose project is determined to be Quality Improvement prior to its start, will be issued a letter to state the REB waived its review and the project is REB exempt. If you are interested in having your project published, the journal may request this evidence of REB exemption. The process may be referred to in the methodology section of your paper, and/or the checklist may be submitted for their review. Please note, OHSN-REB does not retroactively review projects that have already been completed.

Investigator's Declaration:

I confirm that the information answered above is a true and accurate reflection of my project.

- If the project is determined to be research, I will submit an application to the OHSN-REB for review and approval.
- For projects determined to be a quality improvement occurring at the University of Ottawa Heart Institute, I will ensure my project has been **registered** with the Quality Office at quality@ottawaheart.ca.
- For projects determined to be quality improvement occurring at TOH, I will ensure to contact the Quality Office for more information at quality@toh.ca**.**

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Name (Please Print)

_____ _____
Signature Date

Name of supervisor, if applicable

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Name (Please Print)