



Determining if a Project is 'Research' or 'Quality Improvement/Quality Assurance'

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1. PURPOSE

The purpose of this guideline and checklist is to provide a tool to help staff, physicians, and researchers determine in which category their project lies. It should be noted that in some cases, initiatives that are predominantly Quality Improvement (QI) may have certain elements that may require Research Ethics Board (REB) approval. For example, intention to publish. The final authority as to whether a project requires REB approval always lies with the REB Chair/Vice-Chairs/Delegate. For help determining if a study is 'QI' or 'research', please contact the REB Office.

2. Definitions: RESEARCH vs QI PROJECTS

Are you doing research or quality improvement? Please review the table below and consider where your project and work is most aligned.

Research	Quality Improvement
A systematic investigation which aims to increase the sum of knowledge. It usually involves the testing of a hypothesis or theory	A systematic approach to review or evaluate practices and procedures in order to identify possible improvements and to provide a mechanism for bringing them about
Follows a rigid protocol	Adaptive
Activities are not mandated by institution	Activities are mandated by institution as part of operations
There is a research question or hypothesis, with the intention of contributing to generalizable knowledge	Information is integral to ongoing management system for delivering health care. QI compares current practice with current standards/best practices
Usually involves a specific sample size or target population. Research often will have a defined "end-point" which is researched when an adequate sample size has been obtained	Includes information on all affected by a process or program
May or may not benefit a patients, or future patients	Directly benefits a process, program or system' might or might not benefit patients
Research results are generally for "external" information	QI results are generally for "internal" information
Research results are published universally to share the knowledge with a wide user base of persons	QI requires the participation of site-specific people and departments. The data relates only to the specific site or area

3. CHECKLIST

The following checklist can assist in determining if the project is considered 'research'. If any of the follow applies to the project it is would meet the requirement for REB approval and should be submitted to the REB for review to the ethics inbox at ResearchAdmin@msh.on.ca.

Step 1: Will the project:

- Produce results for publication in a research journal
- 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?
- Assign patients/providers into different procedures or therapies (such as randomization)
- Contain a control group for whom the procedure or therapy or study intervention is withheld to allow an assessment of its efficacy
- Be used for evaluation of a drug, procedure or device not currently approved by Health Canada
- Create a registry or database
- Test a hypothesis or answer a research question
- Funded by an entity (e.g., Sponsor or granting agency)
- Test an intervention, care practices or treatments that are not standard of care (e.g., new drug or medical device)
- Involve any voluntary informed consent for interventions that are not part of standard of care, including interviews or questionnaires
- Involve some harm to patients or participants a part of the project that is not standard of care, but resulted from the intervention

Step 2: If the answer to any of these questions is yes then consider submitting your work to REB for approval. If your project is QI it still should be conducted according ethical standards ensuring privacy, confidentiality, and consent where relevant for all patients.

Step 3: If the project is considered 'research', follow the steps outlined by the REB on how to submit a study for review. Please visit the [REB website](#) or ACORN page for details.

4. REVISION HISTORY

Effective Date	Summary of Changes
11 May 2021	Document creation
19 Aug 2021	Amendments (Brand/logo)

5. REFERENCES

<https://hireb.ca/guidelines/quality-assurance/>
<http://www.ohri.ca/ohsn-reb/forms/Checklist%20Research%20or%20QI%20-%20revised%20November%20202016.pdf>