

Title	Guidelines for Determining if a Project is Research or Quality Improvement
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1.0 PURPOSE

The purpose of this guideline is to assist individuals in differentiating between projects that constitute Quality Assurance/Quality Improvement (QA/QI), Program Evaluation (PE), and Research, and to determine when submission to the Osler Research Ethics Board (REB) is required.

The Tri-Council Policy Statement 2 (TCPS 2) defines research as: *“An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term “disciplined inquiry” refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.”*

As per TCPS2 Article 2.5, *“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 for the purposes of this Policy, and do not fall within the scope of REB review.”*

Some projects that do not meet the definition of research, however, often use methods commonly used in research. The final authority as to whether a project requires REB approval always lies with the REB Chair/Vice-Chairs/Delegate.

If your project does qualify as Quality Improvement, Quality Assurance or Program Evaluation (QI/QA/PE) but you later wish to publish your findings, journals will often ask for a letter from the REB that the project was exempt from review. Therefore, if publication is a possibility, you should apply to the REB for an exemption **before** the project begins

For confirmation from the REB as to whether a particular project is exempt, you may forward the completed checklist below, along with a summary of your project, to the REB requesting an exemption. **Please note that the REB only issues exemption letters prior to the initiation of a project, and not after its completion.**

2.0 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

Research	Quality Improvement
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	practices Includes information on all affected by a process or program
May or may not benefit a patient, 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

3.0 INSTRUCTIONS FOR REQUESTING AN EXEMPTION

Before beginning your project, please review the definitions, comparison table, and checklist below to determine whether your project aligns more closely with Research or Quality Improvement/Quality Assurance (QI/QA) or Program Evaluation.

If, after completing the checklist, you are unsure if your project qualifies as QI/QA/PE, you must submit the following items to the REB Inbox (WOHSREB@Williamoslerhs.ca) for an exemption determination:

1. Completed QI/QA/PE Determination Checklist (Appendix A)

All sections of the checklist must be completed.

The checklist assists applicants in evaluating the purpose, design, and methods of their project and demonstrating alignment with QI/QA/PE criteria.

2. A Project Summary

The summary must include enough detail for the REB to understand the project.

Applicants should include the following:

- **Purpose of the project:**
Describe the local process, workflow, or program being evaluated or improved.
- **Methods and approach:**
Explain whether the project uses adaptive or iterative QI methods (e.g., PDSA cycles) or performance monitoring practices. Identify any standards or benchmarks being used for comparison.
- **Scope and participants:**
Describe who is included in the project.
- **Intended use of results:**
Who the data will be shared with (e.g., communicated back to the person or unit responsible for the program/product/service, shared more broadly to the academic or hospital community)
- Confirmation that you will not be including the data, or analysis based on the data, in any research publications.

If your project is QI/QA/PE it still should be conducted according to ethical standards ensuring privacy, confidentiality and consent where relevant for all patients.

Important note about publication:

The possibility of future publication **does not make a project research**. QI/QA/PE projects may be published; however, many journals request confirmation that the project did not require REB review. Therefore, if publication is possible, applicants should request an exemption **before starting the project**.

Submission requirement:

Exemption determinations are made **only before** a project begins. Completed checklists and project summaries must be submitted to the REB for review and confirmation.

4.0 FREQUENTLY ASKED QUESTIONS:

1. *Is publication the deciding factor between Research and QI/QA/PE?*

No. QI/QA projects can be published. The defining feature of research is the intent to generate new or generalizable knowledge, not whether results are published.

2. *If I intend to publish results of my QA/QI/PE project, do I require Osler REB approval?*

No. The mere intent to publish the findings of a QA/QI project does not obligate REB review. In the publication you would need to make it clear the publication is the result of a QA/QI initiative. The Osler REB suggests that before project implementation, you consider contacting the journal you will target for publication and determine whether they require an exemption letter from the Osler REB ethics as a condition of publication.

3. *Can a QI project involve data collection or analysis?*

Yes. QA/QI/PE frequently involves performance data, workflow metrics, or compliance measurement. This does not automatically make it research.

4. *Who makes the final determination?*

Only the REB Chair/Vice-Chairs/Delegate can issue a final decision on exemption. The checklist is a tool to support, not to replace REB assessment when required.

5. *Can I get an exemption letter after the project is done?*

No. Exemptions can only be issued before the project begins. You must determine the purpose of your project at the beginning of your project. If a researcher knows at the outset that the project will be done for both QI and research purposes, Osler REB approval is required.

6. *I collected data for a QA/QI/PE project. I would now like to use the data for research. Can I use it?*

No. This would be considered secondary use of information and may require REB review in accordance with TCPS (article 2.5, 5.5A, 5.5B). Please submit an Osler REB application.

7. *My research project involves collecting anonymous information from participants. Do I need ethics approval?*

Yes. Collection of anonymous information for research purposes requires ethics approval, unless you are observing individuals in a public place in a way that does not require their active participation.

5.0 OTHER QI VS RESEARCH TOOLS AND EDUCATIONAL RESOURCES

This guideline has been informed by, and benefited significantly from, the external guidelines and educational tools listed below. The following external resources provide additional guidance on distinguishing between Quality Improvement (QI), Quality Assurance (QA), Program Evaluation (PE), and Research. These are provided for educational purposes only. The Osler REB remains the final authority on project classification.

[ARECCI Ethics Screening Tool: ARECCI helps project leads address and mitigate ethical risks by providing decision support tools, training opportunities, and project ethics consultation.](#)

[Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans, December 2022.](#)

[HIREB Non-Research Activities \(e.g., Quality Improvement\)](#)

[Ottawa Health Science Network Research Ethics Board: Is your project Research or Quality Improvement? Guideline & Checklist](#)

[Toronto Metropolitan University: Guiding Questions to Determine Whether Your Research Requires Ethics Approval](#)

[Western University: Distinguishing Between Quality Assurance/Improvement, Program Evaluation & Research](#)

Appendix A: QI/QA/PE or Research Determination Checklist

Preliminary Questions	Yes	No
Will or has an application been made to a research funding agency (e.g. CIHR, NSERC, SSHRC) for a grant or award that requires REB approval?		
Does the project involve use of a drug, device, or health product under Health Canada or FDA regulations or guidelines?		

If you answered **YES** to any of the above questions, your project will require Osler REB approval.

If you answered **NO** to all questions, continue to the next group of questions below.

Questions about your project	Yes	No
Is the purpose to evaluate or improve an existing process, workflow, or program within our organization?		
Will the project adapt or change as we learn more (e.g., iterative cycles like PDSA)?		
Is the project using existing, evidence-based practices or standard procedures?		
Is the primary goal to improve a local system, process, or program rather than to create new knowledge?		
Will the results mainly be used internally to guide operational improvement?		

If you answered **YES** to any of the above questions, your project is likely not research and is QI/QA or PE.

If you answered **NO** to all questions, continue to the next group of questions below.

Questions about your project	Yes	No
Is the primary purpose to generate new or generalizable knowledge? (knowledge meant to apply outside our organization)?		
Will this project test a new or unproven intervention, tool, or method?		
Does the project involve a comparison of different groups, protocols, sites, or interventions and/or control groups?		
Will the project use a specific sample size, defined study population, or endpoint?		
Will the project follow a fixed, formal protocol that should not be altered during the study?		

If you answered **YES** to any of the above questions, your project is research and will **require Osler REB approval**. Please connect with the [Osler REB](#) for any additional support or consultations.

Please follow the steps outlined by the Osler REB on how to submit a study for review. Please visit the [Osler REB website](#) for details.