

Guidance Document	Distinguishing Between Quality Assurance/Improvement, Program Evaluation & Research
Effective Review	HSREB/NMREB
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Introduction

This guideline is to assist researchers in differentiating between projects that are considered quality assurance/improvement (QA/QI), program evaluation (PE) versus those that are considered research and whether submission to Western's Research Ethics Board (REB) is required. Although the three fall on a continuum, when in doubt, the Researcher must confirm with the REB as to whether ethics approval is required. The intent to publish results does not distinguish activity as research as findings of QA/QI and PE are often published. The REB WILL NOT provide ethics approval retroactively; the onus is on the Researcher to obtain the necessary approvals.

Definitions

Often, organizations will use a variety of methods to improve their functioning and performance. The methods are applied in the normal course of their operations. In accordance with the Tri-Council Policy Statement 2, QA studies are "*program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes...*" (Article 2.5). Conversely, research is defined as "*an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.*" (Article 2.1). It should be noted that in some cases, some initiatives that are predominantly QA/QI and PE may have certain elements that make it fall under research. Upon completion of the checklist, if there is still uncertainty, the researcher should request guidance from the REB.

Please refer to the chart below to determine whether your project is QA/QI and PE or research

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?		
Are there local policies that require the project to have REB approval?		

If you answered YES to any of the above questions, you will require Western REB approval.
If you answered NO to all questions, continue to the next group of questions.

Questions about your project	YES	NO
Is the primary purpose to contribute to a growing body of knowledge on a topic?		

Is the project designed to answer a specific quantitative or qualitative research question or to test a hypothesis?		
Is there an attempt to remove bias from the project: For instance: Will you randomize participants to groups? Is there an attempt to “blind” or conceal group allocations to the project team?		
Does the project involve a comparison of different groups, protocols, sites, or interventions and/or control groups?		
Is the project designed to support generalizations beyond the project setting and participants?		
Does the project involve additional burdens beyond what would be normally expected or experienced during standard care, program participation, or role expectations? For instance, physical, social (loss of status/reputation, loss of privacy information) or psychological/emotional (feeling uncomfortable, embarrassed, upset), legal		
Will the data be able to identify a participant from the project’s results?		
Does the project infringe on rights, privacy, and reputation of participants?		

**If you answered YES to any of the above questions, you will require Western REB approval.
If you answered NO to all questions, continue to the next group of questions.**

Questions about your project	YES	NO
Is the primary purpose of your project to develop a better practice within your setting?		
Does the project involve a continual process of gathering and monitoring data within the project setting?		
Is it possible that most participants will benefit by project participation?		
If there was no potential for publication or if there was no potential to apply the results elsewhere, would the project still be done within your setting?		
Is terminology of purpose specific to a particular program/setting as opposed to general wording (rural vs. urban populations)		

**If you answered YES to any of the above questions, your project is likely QI
If you answered NO to all questions, you may require Western REB approval**

Common Questions

Do QA activities occurring at Western University require approval from Western's REB?

No, provided that activities are not research and that you are a legal custodian of any personal health information that will be used in the project. In accordance with PHIPA, the legal custodian is a person or organization who has custody and control of personal health information. If the Researcher is utilizing patients at St. Joseph's Health Care or Lawson Health Science Institute, they are the Health Information Custodians and the Researchers are the agents of the personal health information (Section 44 of PHIPA Act).

According to the TCPS: "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." (Article 2.5)

Are QA activities governed/regulated by a non-research body?

Yes. These activities will raise ethical issues that should be guided by a body other than an REB. This guidance will depend on your project setting and professional or disciplinary associations.

I'm not sure if my project is QA or research. Can I determine this after I begin my project?

No. Research requires REB review and approval before the research begins. Western REB will never give approval after methods are initiated. 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, Western REB approval is required.

If I intend to publish results of a true QI project, do I require approval from Western's REB?

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. If a journal requests ethics approval documentation, you would explain that these activities do not require institutional ethical review under Article 2.5 of the TCPS. Furthermore, in the event that you wish to publish, a notation that your project was determined to be QA/QI by the completion of this checklist can be included in your methodology section of your paper and submitted for review (if the journal requests further documentation).

The Office of Human Research Ethics suggests that before project implementation, consider contacting the journal you will target for publication and determine whether they require ethics review as a condition of publication.

I collected data for a QA project. I now would 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). Complete a Western REB application.

References

ARECCI Ethics Screening Tool developed by the Alberta Research Ethics Community Consensus Initiative (ARECCI) Network (2005, revised 2008)

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.

Fraser Health, BC, Research and Evaluation.

Differentiation of Research, Quality Improvement and Program Evaluation.

http://www.fraserhealth.ca/about_us/research.-program-evaluation-%26-quality-improvement/

Queen's University, Quality Assurance/Quality Improvement Guidelines

<http://www.queensu.ca/ors/researchethics/GeneralREB/PoliciesandProcedures/GREBQAQIGuidelines0322013final.pdf>

University of British Columbia, BREB Frequency Asked Questions

<http://www.research.ubc.ca/ore/breb-frequently-asked-questions>

PHIPA

<http://www.ontario.ca/laws/statute/04p03>