

Guidance Document	Distinguishing Between Quality Assurance/Improvement, Program Evaluation & Research
Effective Review	HSREB/NMREB
Version Date	March 9, 2021

Introduction

This guideline is to assist researchers in differentiating between projects that are considered quality assurance/improvement (QA/QI) or a 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 since the findings of QA/QI and PE projects are often published. The REB WILL NOT provide ethics approval retroactively for projects that have started or that have already been conducted; therefore, the onus is on the Researcher to obtain the necessary approvals beforehand.

If you are requesting the Office of Human Research Ethics to provide a formal notification indicating that the project IS or IS NOT considered research, there is an online QA/QI/PE application form in WREM that you must submit for review.

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 via submission of the QA/QI/PE application form in WREM.

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

Preliminary Questions	YES	NO
Is the primary purpose of this project to contribute to a growing body of knowledge on a topic?		
Is the project designed to support generalizations beyond the project setting and participants?		
Will the results be applicable outside of the context you are studying?		
Is the project designed to answer a specific quantitative or qualitative research question?		
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, 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
Will you randomize participants to groups, use “blinded” outcome assessors, conceal group allocations from any study team member, or employ advance statistical techniques such as (but not limited to) regression in an attempt to remove bias or confounding?		
Does the project involve additional burdens beyond what would be normally expected or experienced during standard care, program participation, or role expectations?		
Will the data be able to identify a participant from the project’s results?		
Does the project infringe on rights, privacy, and/or reputation of participants?		
Does the project involve a comparison of different groups, protocols, sites, or interventions and/or control groups?		
Is this project funded by a research funding agency that typically requires REB review/approval (e.g. CIHR, NSERC, SSHRC)?		

If you answered YES to any of the above questions, you will likely require Western REB approval. If you are still unsure, continue to complete the QA/QI/PE form within WREM where more information can be provided for the OHRE to review. These responses can be reviewed and used to determine whether you must complete an HSREB or NMREB Initial Application form.

Please also continue to the next section of questions.

Questions about your project	YES	NO
Is the primary purpose of your project to develop a better practice within your setting (i.e., advancing the organization)?		
Does the project involve a process of gathering and monitoring data within the project setting and/or as part of the regular mandate of the organization?		
Is it expected that participation in this project will lead to a better experience (e.g., within the organization), either for the participants themselves or for other people in the future (e.g., patients/clients/employees, etc.) who would be impacted by the project outcomes?		
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?		

Does the language used in the project description refer specifically to features of a particular program, organization, or locale, rather than using more general terminology such as rural vs. urban populations?		
--	--	--

If you answered NO to any of the above questions, you will likely require Western REB approval. If you are still unsure, continue to complete the QA/QI/PE form within WREM where more information can be provided for the OHRE to review. These responses can be reviewed and used to determine whether you must complete an HSREB or NMREB Initial Application form.

Common Questions

Do QA/QI/PE 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 London Health Sciences Centre, 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/QI/PE 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/QI/PE 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 not 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 QA/QI/PE and research purposes, Western REB approval is required.

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

No. The mere intent to publish the findings of a QA/QI/PE project does not mandate REB review. **The expectation of the REB is that, in the publication, you would need to make it clear the publication was the result of a QA/QI/PE initiative (i.e., in the Title and/or the Abstract) and that, because of this, no REB approval was sought or obtained.** This makes the project’s design transparent to the editors and the readers.

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/PE by the completion of this checklist should be included in your methodology section of your paper and submitted for review (if the journal requests further documentation).

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

In general, the REB requires investigators to consider the research potential of QA/QI/PE projects BEFORE they start. If it is thought that a QA/QI/PE project may ultimately also be used for research purposes, we ask investigators to complete an REB submission ahead of the project's start. On rare occasions, the usage of data originally collected for QA/QI/PE projects may be considered as secondary use of information. This would require REB review in accordance with TCPS (article 2.5, 5.5A, 5.5B).

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>