

Queen's REB Guidelines on Quality
Assurance (QA)
Quality Improvement (QI) and
Program Evaluation (PE)

Queen's REB Guidelines on Quality Assurance (QA), Quality Improvement (QI) and Program Evaluation (PE)

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Inquiries and permission requests for commercial use may be directed to:

Queen's University
Vice-Principal Research
Research, Compliance, Training, and Ethics
355 King Street West
Kingston, Ontario
K7L 2X3
chair.greb@queensu.ca, hsreb@queensu.ca
[Research Compliance, Training and Ethics](#)

Queen's University is situated on [traditional Anishinaabe and Haudenosaunee Territory](#).

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Purpose

The purpose of this guideline is to:

- Provide clear guidance on what qualifies as a Quality Assurance (QA), Quality Improvement (QI) and Program Evaluation (PE) studies.
- Provide clear guidance on what QA/QI/PE studies require REB approval.

Background

QA, QI and PE studies are projects undertaken to assess the performance of a program, organization, group, faculty, or department. QA/QI projects are conducted internally and for operational and/or administrative purposes. QA is a process used to ensure services are meeting quality standards. QI is a continuous improvement process focused on processes and systems. PE is an evaluation of a program focused on weaknesses, strengths and room for growth or improvement.

Do QA/QI/PE studies require REB review and oversight?

QA/QI/PE studies do not require REB Review Per [TCPS 2 2022 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.”

Article 2.5 refers to assessments of the performance of an organization or its employees or students, within the mandate of the organization, or according to the terms and conditions of employment or training. Those activities are normally administered in the ordinary course of the operation of an organization where participation is required, for example, as a condition of employment in the case of staff performance reviews, or an evaluation in the course of academic or professional training. Other examples include student course evaluations, or data collection for internal or external organizational reports. Such activities do not normally follow the consent procedures outlined in this Policy.

Does my project qualify as QA/QI/PE?

In order to determine whether your study qualifies as QA/QI/PE refer to the [ARECCI \(Alberta Research Ethics Community Consensus Initiative\) guidelines and screening tool](#). The ARECCI Screening tool helps to determine the level of risk of your project, the types of ethical risks and the appropriate type of ethics review. You will be given a score: Yellow (score 0-7), Orange (score 8-46) and Red (score greater than 47).

Formal exemption from the REB

Queen's HSREB and GREB recommend the submission of all QA/QI/PE studies regardless of the ARECCI score. However, if a score of:

- Yellow is achieved and a formal exemption from the REB is not required, and no further follow-up is required. Reminder: some publications require a formal REB exemption letter.

Important note: REB approval cannot be obtained retrospectively.

- Orange is achieved, submit a Quality Initiative Screening Tool application in TRAQ. The REB will review the application and determine if the study meets the requirements for REB exemption. The REB will issue a formal exemption letter. However, if the study has been determined not to meet the REB exemption criteria, the application will be withdrawn, and the researcher will be asked to submit the appropriate GREB or HSREB application form in TRAQ.
- Red is achieved, submit the appropriate GREB and HSREB application form in TRAQ, as this study has not been deemed as a QA/QI project and is in fact research that requires REB review.

Publication of a QA/QI/PE study

Dissemination of QA/QI findings through external channels is permitted, but it must be specified that the study was conducted for QA/QI purposes and that results must not be generalized (i.e. applied outside of the organization for which the QA/QI study was conducted). Please note that if you intend to publish the results of a QA/QI project, a note explaining that the project was determined to be QA/QI should be added to the methodology section of the published paper. It is recommended that if you intend to publish that you seek formal exemption OR request approval by the REB.

Use of data collected for a QA/QI/PE study for future research

Per TCPS 2022: If data are collected for the purposes of such activities but later proposed for research purposes, it would be considered secondary use of information not originally intended for research, and at that time may require REB review in accordance with this Policy. Refer to Section D of Chapter 5 of the TCPS 2 for guidance concerning secondary use of identifiable information for research purposes. If you do intend to use data collected for QA/QI study for research then please apply submit an GREB or HSREB application form for REB review.

Access Personal Health Information for QA/QI/PE studies

As long as anyone who accesses Personal Health Information (PHI) for QA/QI purposes is authorized as a legal custodian or agent of health data, and as long as all relevant institutional data protection, privacy, and confidentiality policies/guidelines are followed, access to PHI is permitted. Please note, accessing a patient's chart for the purposes other than for clinical purposes requires consent from the patient (even for QA/QI/PE studies).

Important information

QA/QI projects, although not considered research as defined by the TCPS 2 2022, are still expected to be conducted professionally and ethically, in accordance with the core principles of the TCPS 2 2022.

These core principles include:

- Protecting the interests of the participants.
- Respecting free and informed consent and voluntary participation.
- Respecting privacy and confidentiality.

If you are unsure whether or not your project qualifies as a QA/QI project or if you have any questions please contact HSREB or GREB at HSREB@queensu.ca and chair.greb@queensu.ca.