Distinguishing Between Quality Assurance/Improvement, Program Evaluation & Research

YU HUMAN PARTICIPANTS REVIEW COMMITTEE (HPRC) GUIDELINES

Preamble:

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 York University's HPRC is required. Although the three fall on a continuum, when in doubt, the researcher must confirm with the Office of Research Ethics (ORE) as to whether ethics approval is required.

Definitions:

QA, QI and PE studies are 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. Their primary purpose is to provide information for decisions to improve some aspect of care or service delivery in a particular location. PE is an evaluation of a program focused on weaknesses, strengths and room for growth or improvement. **For QA, QI, and PE studies, the results are not intended to be generalizable beyond the study site and often only benefits the immediate participants**.

On the other hand, a research study is defined as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation." (TCPS2 Article 2.1). The primary purpose is to expand a body of knowledge via the discovery of new facts, development of new theory and/or the collection of information. **Research is specifically designed to produce results that can be assumed to apply beyond the individual participants in the specific study with the clear intent of scientific generalizability**.

Ethics review for QA/QI/PE studies:

Provided that activities are not research and that they do not you include any personal health information that will be used in the project[1]; QA/QI/PE studies do not require HPRC Review. As per TCPS2 (2022) Article 2.5:

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[1] Please note, accessing a patient's chart for purposes other than clinical purposes requires consent from the patient even for QA/QI/PE studies.

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"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."

However, researchers should note that some projects that are predominantly QA/QI and PE may have certain elements that make them fall under research and may require ethics review.

If it is expected that a study will serve two purposes – both as QI/PE and research – then the study must undergo research ethics review before it commences. The HPRC 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.

Does your project qualify as QA/QI/PE?

Please refer to the chart below[2] to determine whether your project is QA/QI and PE or research. You can also refer to the ARECCI (Alberta Research Ethics Community Consensus Initiative) guidelines and screening tool for further assistance.

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?		

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[2] Taken from Western University Guidelines "Distinguishing Between Quality Assurance/Improvement, Program Evaluation & Research"

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If you answered YES to any of the above questions, you will require research ethics 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 research ethics approval.

Please also continue to the next section 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?		
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?		

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Questions about your project	YES	NO
Does the project infringe on rights, privacy, and/or reputation of participants?		
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?		

If you answered NO to any of the above questions, you will likely require research ethics approval. If you are still unsure, please contact ore@yorku.ca with your inquiries.

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 HPRC.

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

The HPRC requires investigators to consider the research potential of QA/QI/PE projects **BEFORE** they start. If researchers think that a QA/QI/PE project may also be used for research purposes, an ethics application must be submitted for review and approval ahead of the project's start. **On rare occasions**, the usage of data originally collected for QA/QI/PE projects (including anonymous) may be considered as secondary use of data, however this is carefully determined by the HPRC on a case-by-case basis. This would require HPRC review in accordance with TCPS2 (article 2.5, 5.5A, 5.5B). Researchers would be required to consider the sensitivity of the data, provide a strong rationale as for the use of QA/QI/PE data to be used for research purposes, and also address related consent issues.

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Sources:

Alberta Research Ethics Community Consensus Initiative (ARECCI) Network - ARECCI Ethics Screening Tool

Dalhousie University - Guidelines for Differentiating among Research, Program Evaluation and Quality Improvement

Queen's University - Quality Assurance/Quality Improvement Guidelines

University of Guelph - Is my work Quality Assurance / Quality Improvement / Program Evaluation or is it research?

University of Alberta - Differences Between Research, Quality Assurance + Quality Improvement

Western University - Distinguishing Between Quality Assurance/Improvement, Program Evaluation & Research

Developed: April 2024

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