

Guidelines for differentiating between Quality Assurance (or Program Review) and Research

Introduction

These guidelines are intended to guide researchers and evaluators as they determine whether their proposed activity constitutes research or quality assurance (QA)/program review (PR), and therefore whether it requires HREB review or is exempt.

[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.”

Responsibility

It is the responsibility of the individual administering the information gathering techniques to ensure that appropriate judgement has been reached in regard to the requirement for HREB review. If your study is not research and does not require ethics review, it is still your moral imperative to ensure the respect for human dignity and to adhere to ethical standards, all relevant University Policy, and any other applicable standards of conduct associated with the activities or profession of practice. If your study requires HREB review, it is the responsibility of the researcher to obtain ethics clearance prior to beginning the research (MRU POL 585-1 - Ethics in Research Involving Human Subjects). Retroactive ethics clearance cannot be granted.

Performance reviews or studies that contain an element of research in addition to assessment may need ethics review. Some projects are not easily characterised as quality assurance/program review or research, nor is there any simple rule or single characteristic that differentiates quality assurance and research studies. The HREB views these types of studies as existing on a continuum.

QA/PR vs Research

The Mount Royal University HREB has identified three dimensions as important to differentiating quality assurance studies and program review from research studies:

I. *What is the goal of the study?*

QA/ PR

Primary goal is to evaluate the functioning of an organization, institution, or system with the goal of:

- monitoring quality of the output or operation itself
 - justifying or assessing the need to introduce, continue, eliminate, or modify an existing program, organization or service
- improving service delivery, organizational efficiency, etc.
- accreditation and/ or the development of standards.



Research

Purpose is to expand a body of knowledge via the discovery of new facts, and/or the collection of information.

Application

[TCPS2, Application of Article 2.5](#) “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 review, 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.”

II. Who will be the consumer of the study’s findings?

QA/ PR

Primary consumer is the organization, institution, or system that is being evaluated.

Research

Primary consumers are scholars, practitioners, or organizations other than the ones comprising the immediate affiliation of the researcher and/ or participant.

Application

QA/PR results may be published or presented in a public forum as long as the primary goal remains that of QA/PR. As an example, if the University Bookstore conducted a survey to gather information about customer satisfaction, the results and/or methodology may also be of interest to other bookstores.

III. What is the focus of the research question?

QA/ PR

Primary research focus is the organization, institution, or system.

Research

Primary research questions address issues, concerns, ideas, and questions that extend beyond the immediate organizational or institutional context.

Summary

Would a participant in this study reasonably expect that the primary purpose of the data he/she contributes will be for the monitoring, oversight, or improvement of the organisation that has solicited the information and with whom the person is currently affiliated as a client, patient, stakeholder, employee, student, etc.? If so, you are likely doing QA/PR.



Does your study require review by HREB?

Clearly, there is not a set of defining characteristics that discriminate program evaluation from research and many projects will contain an element of both. If the study contains an element of research, the HREB should review it. In contrast, if the primary purpose of the study is quality assurance or program review, the study is exempt from review. To assist researchers in making this determination, we have provided the checklist below. The items near the top of the list should be given more weight than the items near the bottom.

Note that if the information collected for the purposes of process improvement will also be used for the purposes of research, the study falls within the scope of TCPS2. This is considered secondary use of information and at that time the study may require HREB review.

[TCPS2, Application of Article 2.5](#) *“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 for guidance concerning secondary use of identifiable information for research purposes.”*

If a researcher knows at the beginning of a study that it will serve two purposes – quality assurance and research – then the study must undergo HREB review before it commences. If the study you are undertaking is a borderline case, or if you are still unsure and would like a more formal opinion from the HREB, please contact the Research Compliance Officer at 403-440-8470 or hreb@mtroyal.ca.



Checklist

	QUESTION	ANSWER	IMPLICATION
1.	Is the study funded by a peer-reviewed, research funding agency, such as CIHR, NSERC, or SSHRC?	Yes	The project requires HREB review
2.	Would the study still be done at your site, even if there were no opportunity to publish the results?	Yes	The project is very likely to be QA/PR
3.	Is the study designed to test or develop an explicit hypothesis or theory?	Yes	The project is very likely to be research
4.	Do the planned procedures deviate from normal operation, service delivery, client care etc.? That is, does the study involve an intervention or impose any additional/substantial burdens on participants beyond what would be normally be expected?	Yes	The project is likely to be research
5.	Does the statement of the purpose of the study refer explicitly to the features of a particular program, organization, or region as opposed to using more general terminology such as urban vs rural populations?	Yes	The project is likely to be QA/PR
6.	Is the primary goal of the study to provide an aid for decision making within your institution?	Yes	The project may be QA/PR
7.	Does the study involve a comparison of multiple sites?	Yes	The project may be research

Risk

If you are conducting a QA/PR study with vulnerable populations, such as children, or collecting personally sensitive information, your QA study may be above “minimal risk”. These studies still fall outside of the mandate of HREB, however the Board would be happy to review or provide advice for conducting the study ethically. ARECCI (a project of Alberta Innovates Health Solutions) provides a useful risk filter to classify minimal risk and above-minimal risk studies:

<http://www.aihealthsolutions.ca/arecci/screening/23635/17db2fe50e21a0e6e8c9b2d97f24637b>

(Step 3, Risk Filter)



Sources

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www.ahfmr.ab.ca

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Lynn, J. 2004. When does quality improvement count as research? Human subject protection and theories of knowledge. Quality and Safety in Health Care 13:67-70.

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