Guidelines for Differentiating
among
Research, Program Evaluation and Quality Improvement

Introduction

This document is intended to guide researchers and evaluators (including students) as they determine whether their proposed activity constitutes research, program evaluation, or quality improvement, and therefore whether it requires research ethics review or is exempt.

The *Tri-Council Policy Statement (TCPS2) Ethical Conduct for Research Involving Humans* governing research ethics in Canada requires that while research must undergo research ethics board review, program evaluation and quality improvement/assurance studies do not fall under the auspices of the TCPS or institutional Research Ethics Boards (REBs).

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.*"

Clarity in distinguishing research, program evaluation and quality improvement is scarce. This document aims to help fill that gap.

Some projects are not easily characterized nor is there any simple rule or single characteristic that differentiates quality improvement, program evaluation and research. Quality improvement and program evaluation activities that contain additional research components will need research ethics review. Intent to publish results does not distinguish activity as research; findings of quality improvement and program evaluation projects are often published.

TCPS2, Article 2.1 Application: "*For the purposes of this Policy, 'research' is defined as an undertaking intended to extend   knowledge through a disciplined inquiry or systematic investigation.*"

If a researcher knows at the outset that a study will serve two purposes – it is intended both as quality improvement/program evaluation and research – then the study   must undergo research ethics board review before the study commences. If information collected for quality improvement or program evaluation is later proposed for a research purpose, this falls within the scope of TCPS2 as secondary use of data, and at that time the study requires REB approval.

TCPS2 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."*

It is when inquiry is primarily intended for program evaluation / quality improvement, but results and/or process will be disseminated beyond the institution, that it is most difficult to distinguish research from PE/ quality improvement. It is the responsibility of the individual engaging in data gathering to use good judgment with regard to the requirement for REB review. This document is intended to help researchers with that decision-making. Think through the questions below with respect to the project to see if the proposed inquiry falls mostly or entirely in the program evaluation or quality improvement columns, or mostly or entirely in the research column. If the latter, it probably requires REB review.

Guiding questions to distinguish research, program evaluation and quality improvement:

RESEARCH	PROGRAM EVALUATION	QUALITY IMPROVEMENT
1. Is the *intent* of the activity to extend or expand knowledge on a topic in which the methods, results, and conclusions of the activity meet scholarly standards within the relevant discipline?		
☐ Yes. Designing the activity such that the investigative approach and outcomes would withstand scrutiny of peers and experts in the applicable discipline or field is integral to the success of the activity.	☐ No. There is no intent or need for the results or information collected to meet scholarly or academic standards in the related field. The activity is locally focused, and broad acceptance of the methods, results, and conclusions are not likely to be relevant in determining the success of the activity.	☐ No. The intent is not for the results or information collected to meet scholarly or academic standards. The focus of the activity is to improve a feature or design of a specific product or service.
2. Does the lead investigator have the authority or mandate to implement changes as a result of the study?		
☐ No. The investigator does not have the authority or mandate to implement changes to the phenomenon, program, or service under investigation.	☐ Yes. The study is being undertaken by someone with the authority or mandate to identify problems or areas of improvement that can or will be implemented because of the study.	☐ Yes. The study is being undertaken by someone with the authority or mandate to identify problems or areas of improvement that can or will be implemented because of the study.
3. Is the project primarily designed to test a specific hypothesis, answer a specific quantitative or qualitative question?		
☐ Yes. The study has a clearly stated research question, related to theory and existing literature in the field. May test specific hypotheses through measurement of specific	☐ The question is likely to be along the lines of How is X working? What happens when we do Y? It seeks to assess how well a program innovation or aspect is working, or	☐ If there is an explicit study question it is likely to be along the lines of How is X working? Or What happens when we do Y? The question relates to an existing practice,

variables, or seek to understand a phenomenon. Some qualitative research seeks to develop theory through rigorous data interpretation and analytical frameworks. Research questions are usually posed in such a way that they are as open to disproving as proving a phenomenon.	determine the need for program change.	or application of processes already shown to be effective elsewhere.

4. What is the role of theory?

☐ The goal of research is to develop and/or test theory and theoretical propositions for the purpose of extension beyond the immediate case, site or sample. The specific context is simply one possible operationalization of a theory, or site to test or develop theory or knowledge.	☐ The focus is to evaluate a particular program that may or may not be based on a specific theory. Theory may be used to design a program, but testing or developing theory is not the goal of the study. Sometimes evaluation frameworks are being tested.	☐ The focus is on improving the program or service rather than evaluating any underlying theory. It is assumed the program will continue; the question is how to make it better. Organizational theory may be used to support the implementation of changes.

5. Are the results intended to be transferable (generalizable) beyond the particular population or sample?

☐ 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, or transferability, the project design includes precise and defensible techniques for sampling and data collection and analysis. With qualitative research, the intent is to produce knowledge that may apply to similar populations. Study site is often described in general terms, rather than by the name of the program or organization.	☐ The language used in the project may specifically name a particular program or process, or a particular organization, setting, or service. The results are not intended to be generalizable beyond the study site. Producing and sharing learnings from a project for potential adaptation to other contexts is not the same thing as seeking to produce results that will be generalizable or transferable. The results, or the process, may later be published or presented, usually descriptively.	☐ The language used in the project may specifically name a particular program or process, or a particular organization, setting, or service. The results are not intended to be generalizable beyond the study site. Producing and sharing learnings from a project for potential adaptation to other contexts is not the same thing as seeking to produce results that will be generalizable or transferable. The results, or the process, may later be published or presented, usually descriptively.

6. Is the primary purpose of the project to produce the kind of results that could be published in a research journal?

☐ 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. Expanding knowledge in the field is accomplished mainly through scholarly publication or presentation to external scholarly groups.	☐ The primary purpose is to produce findings that can be used to improve practice or service delivery within an organization or setting; to evaluate the functioning of an organization, institution, or system in order to justify or assess the need to introduce, continue, eliminate, or	☐ The primary purpose is to provide information for decisions to improve some aspect of products or service delivery in a particular location. To evaluate the functioning of an organization, institution, or system in order to monitor the quality of the output or operation itself, or for

	modify an existing program; to inform decisions about future programming; to aid accreditation and/or the development of standards. Sharing by publication is a secondary goal.	accreditation and/or the development of standards. To assess an existing practice or the impact of implementing practices already shown effective in the literature. Sharing by publication is a secondary goal.
7. Who is the primary audience for your results?		
☐ Primarily scholars, practitioners, or organizations well beyond the ones comprising the immediate affiliation of the researcher and/or participant.	☐ Primarily, the organization, institution, or system that is being assessed. Others may have interest in the results or process, but are not the primary target audience.	☐ Primarily, the team, organization or system that is being assessed. Others may have interest in the results or process, but are not the primary target audience.
8. Who is likely to benefit from the results?		
☐ There may not be any benefits to the actual research participants. The knowledge is intended to have future benefits for similar individuals, as well as benefits for those who wish to apply the research findings and/or theory developed. The time frame for benefit can be quite long. The body of evidence to inform practice/policy develops gradually, usually with multiple studies.	☐ Participants or future program participants are intended to benefit directly from findings produced, through improved services or service delivery. Can change practice in the local setting immediately.	☐ Participants or future users of the service or product are likely to benefit from findings produced, through improved program design and implementation, and identifying efficient, benefits and risks. Can change practice in the local setting immediately.
9. Where will participants come from?		
☐ Participants would be expected to meet inclusion criteria such that they would be able to respond to study stimuli or answer questions in a way that could contribute to answering the research questions. They would not necessarily need to have involvement with the program or service being studied. May involve a comparison of multiple sites and/or the use of control groups.	☐ Participants normally come only from the setting being evaluated. Having participants from outside the project setting would not make sense because another setting would not deliver services in the same way. Participants' inclusion is by virtue of their association with the program or setting under study.	☐ Participants would need to meet a certain profile or inclusion criteria so they can respond to study stimuli, questions, or interventions in the same way as someone using the service or product under investigation.
10. Would the project still be done even if the results might not be applicable anywhere else?		
☐ No. The specific setting is usually representative of a *type* of site. The intent is to produce results that apply more broadly.	☐ Yes. The primary intent is to produce information for use by that specific program, institution, organization or system. Dissemination of results more broadly to help	☐ Yes. The primary intent is to produce information for use by that specific team, organization or system. Dissemination of results more broadly to help inform others is

	inform others is only a secondary benefit.	only a secondary benefit.
11. Is the current project part of a continuous process of gathering or monitoring data within an organization?		
☐ No. The project may be part of a program of research, but is not part of ongoing assessment of program changes.	☐ Yes. Projects would often be part of an ongoing assessment of program effectiveness, changes and innovations.	☐ No. Usually the focus is on time-limited projects that target service, product or process improvements. Projects are often initiated in response to issues and trends or through monitoring of program outcomes.

After you answer the questions in the table, if you are still unsure whether your proposed project requires research ethics board review, please contact the research ethics office at ethics@dal.ca. Include a one-page description of the proposed project, the potential benefits, the research instruments and the answers to the above questions. When in doubt, an application for research ethics review is recommended.

Please note that all projects benefit from applying the core research ethics principles of respect for persons, concern for welfare, and justice. Whether or not your project is characterized as research, you are encouraged to adhere to ethical standards as well as any professional or practice standards of conduct.