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CFREB Scholarship of Teaching Learning (SoTL) Guidelines for Research, Program Evaluation, and Quality Improvement

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Introduction

This document is intended to guide educators, curriculum designers, and researchers as they determine whether their proposed Scholarship of Teaching & Learning (SoTL) activity constitutes research, quality assurance (QA), or quality improvement (QI), and therefore whether it requires research ethics review or is exempt.

Research, quality assurance (QA), and quality improvement (QI) are all systematic investigations that involve data, use scientific methods, and can be broadly considered science. Examples of research can include, but are not limited to, projects funded through the SoTL teaching and learning grants stream or other research streams, and graduate and undergraduate theses. Examples of quality assurance and quality improvement projects include curriculum review, and program and course innovation. Depending on the intentions, scope, data collected, and plans for dissemination, many projects could fall into one or more of these categories. This guide is intended to help distinguish between these different types of activities in order to determine if a project needs research ethics review.

The Tri-Council Policy Statement 2 (TCPS2) governing research ethics in Canada suggests that while research must undergo ethical review, program evaluation and quality improvements studies do not fall under the auspices of the TCPS2 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.”* Because of this, it is important to distinguish the differences between research, program evaluation and quality improvement. An incorrect determination, whether intentional or otherwise, may result in a violation of the University policy on integrity in scholarly activity and where applicable, the Health Information Act of Alberta. It is equally important to understand the distinction prior to initiating the project. The CFREB cannot issue retroactive ethics approval.

Some projects are not easily characterized, nor is there any simple rule or single characteristic that differentiates QI, QA and research. The CFREB views these as existing on a continuum. Quality improvement and program evaluation activities that contain additional research components may need ethics review. Intent to publish results does not distinguish an activity as research; findings of QI and QA are often published in QI / QA specific journals. 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 QI/QA and research – then the study must undergo research ethics review before it commences. If information collected for QI or QA is later used for research purposes, the research may fall within the scope of TCPS2 as secondary use of data, and at that time the study would normally require REB review. 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 QA/QI, but results and/or process will be disseminated beyond the institution, that it is most difficult to distinguish research from QA/QI. It is the responsibility of the individual engaging in data gathering to use good judgment regarding the requirement for CFREB review. This document and the guiding questions provided (**pages 3-7**) are intended to help with that decision-making. Think through the questions below with respect to the project, to see if the proposed inquiry falls mostly/entirely in the QA or QI columns, or mostly/entirely in the research column. If the latter, it probably requires REB review.

In thinking about the questions on **pages 3-7**, particularly consider:

● Whether or not the participants in the study would reasonably expect that the primary purpose of the data they contribute will be for the monitoring, oversight, or improvement of the organization that has solicited the information, and with whom the person is currently affiliated as a student, patient, stakeholder or employee.

● Is dissemination beyond the institution a secondary purpose – would the study be done regardless of dissemination, to meet internal needs?

● Does the study draw on routinely collected data, rather than gathering new data?

● Is the work applying or testing an evaluation framework, rather than developing or testing theory about a substantive area?

If the answer is yes to these questions, your project is likely program evaluation or quality improvement, not requiring REB review.

Projects deemed to be quality improvement or program evaluation and therefore outside of REB mandate, should still be conducted with respect for human dignity adhering to ethical standards as well as any professional or practice standards of conduct. All projects involving institutional data or collection

of data from students, staff, or faculty must also follow legal and privacy regulations. Please contact foip@ucalgary.ca if you have questions about the legal and privacy regulations.

Please note that the REB is the final authority as to whether or not a project requires ethics review and approval. *"When in doubt about the applicability of this Policy to a particular research project, the researcher shall seek the opinion of the REB. The REB makes the final decision on exemption from research ethics review."* (TCPS2 – Article 2.1). If you are still unsure whether your activities require CFREB review after completing the guiding questions (pages 3-7), you can consult with the CFREB on your project through completing this online form. Depending on the nature of the study, the CFREB will either request the completion of an ethics application or provide a determination that the study is exempt from CFREB consideration.

All projects on campus must also follow legal and privacy policies. Please see guidelines and policies at https://www.ucalgary.ca/legal-services/access-information-privacy. It is your responsibility to consult with legal services regarding questions related to your project (foip@ucalgary.ca).

Guiding Questions

	RESEARCH	QUALITY ASSURANCE	QUALITY IMPROVEMENT
1**. Is the project primarily designed to test a specific hypothesis or answer a specific quantitative or qualitative question?**	Has a clearly stated research question, related to theory and existing literature in the field. May test specific hypotheses through measurement of specific variables, or seek to understand a phenomenon. Some qualitative research seeks to develop theory through rigorous data interpretation.	The question is likely to be along the lines of How is X working? Or What happens when we do Y? Seeks to assess how well a program innovation or aspect is working, or determine the need for program change.	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? Or What are the needs of participants? The question relates to an existing practice, or application of processes already shown to be effective elsewhere.
2. **Would the data be routinely gathered anyway, as part of organizational operations, regardless of this project's intent?**	Typically research requires novel data collection. In secondary data analysis, the data is already available, and the research asks of it new questions, beyond the purpose for which the data was gathered.	<u>Typically</u> uses data already being gathered for program purposes or generated by participants, and where participation is required. Student evaluations and coursework, satisfaction surveys, patient outcome	<u>Typically</u> uses data already being gathered for program purposes, and where participation is required. Student evaluations and coursework, satisfaction surveys, patient outcome assessments, data for

		assessments, data for internal or external organizational reporting – data collection normally conducted in the ordinary course of the operation of an organization or program.	internal or external organizational reporting – data collection normally conducted in the ordinary course of the operation of an organization or program.
3. **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 scientific publication.	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 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. This work would occur regardless of whether the results are shared externally.	The primary purpose is to provide information for decisions to improve some aspect of care 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 accreditation and/or the development of standards. To assess an existing practice or the impact of adapting or implementing practices or techniques previously described in other contexts. Sharing by publication is a secondary goal. This work would occur regardless of whether the results are shared externally.
4. **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 organization, institution, or system that is being assessed. Others may have interest in the results or process, but are not the primary target audience.
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	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	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

	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.	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.	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. **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.	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 or participant experience rather than evaluating any underlying theory. It is assumed the program will continue after the evaluation; the question is how to make it better. Organizational theory may be used to support the implementation of changes.
7. **Does the project impose additional burdens on participants beyond what would normally be expected or experienced during the course of care, program participation or role expectations?**	Participation must be voluntary because those participating will be involved in activities which are in addition to routine care, program provision, or role performance.	Participants continue to engage in routine care, program provision, or role performance. There <u>may</u> be additional information gathering, such as an assessment of satisfaction with ongoing services.	Participants continue to engage in routine care, program provision, or role performance. There may be an innovation to service or delivery, but it typically applies to everyone. Burdens on participants are those that clients, patients, students, employees or other service users would routinely experience.
8. **Is there an assumption of benefit?**	No – In research, no benefits are assumed. Research questions must be posed in such a way that they are as open to disproving as proving benefit. Benefit is genuinely in question. ("If we knew what we were doing we wouldn't call it research" attributed to Albert Einstein.)	Yes – the program and its services are presumed effective, although through PE programs found to be not beneficial may be discontinued. In evaluation program innovations, it is assumed the changes will be at least as beneficial as existing practice.	Yes – interventions or services delivered are presumed effective, not experimental. It is assumed the changes will be at least as beneficial as existing practice.

9. **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 participants are intended to benefit from findings produced, through improved services or service delivery. Can change practice in the local setting immediately.	Participants or future participants are likely to benefit from findings produced, through improved program design and implementation, and identifying participant needs, efficiency, benefits, strengths, weaknesses, and risks. Can change practice in the local setting immediately.
10. **Where will participants come from?**	May involve a comparison of multiple sites and/or the use of control groups.	Controls may be used, such as those who did or did not experience a program innovation, but 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. Controls are not likely to be used.
11. **Would the project still be done even if the results might not be applicable anywhere else?**	No – in research the specific setting usually is a 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 inform others is only a secondary benefit.	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 inform others is only a secondary benefit.
12. **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 changes and innovations.	No – usually the focus is on time- limited projects that target service or process improvements. Projects are often initiated in response to issues and trends identified in the literature, by participants, or through monitoring of program outcomes.
13. **Is external funding required?**	Usually research requires a separate source of funding, although some research is unfunded. Funding may be from an external granting agency or an internal grant	No, funding for Program Evaluation is typically budgeted for within an institution's operating budget.	Possibly , funding for QI initiatives is typically budgeted for within an institution's operating budget, but internal and external grants may provide support for

	competition for research only.		innovation and re-design of programs.
14. **Will you randomize participants into different groups?**	Yes for randomized trials OR will design strategies to match the targeted population.	Unlikely, only if an experimental or quasiexperimental design can be used.	No
15. **How will you analyze data?**	With inferential statistics to test for significant differences or correlations, descriptive statistics or a qualitative methodology that can compare and contrast qualitative data.	Quantitative (inferential and descriptive analysis) and qualitative data may be used.	With descriptive statistics that demonstrate change/trends.
16. **How will you determine how many participants to include?**	Typically, the research subjects must reflect the characteristics of the total population being studied. Controls may also be required.	Sample size will depend on the number of program participants and to what degree it is necessary to determine the success of the program can be attributed to the program itself versus confounding factors.	Will use a convenience sample of participants exposed to the practice (i.e., small sample size, but large enough to observe change; depends somewhat on size of practice).
17. **Is Research Ethics Board Approval Required?**	Yes – REB approval is required of all research.	No	No

Source (with some modifications)

University of Alberta Research Ethics Office. Guidelines for Differentiating among Research, Program Evaluation and Quality Improvement. https://www.ualberta.ca/research/media-library/reo/human-ethics-files/forms-files/guidelines-for-differentiating-among-research.pdf