

Determining Whether a Project is Research or Quality Improvement, Quality Assurance, Program Evaluation, or Curriculum Development

BACKGROUND:

Projects at Bruyère Health that qualify as research must be reviewed and approved by the Bruyère Health REB. Under the Tri-Council Policy Statement 2 (TCPS 2), research is defined as:

...an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. The term “disciplined inquiry” refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.

However, the TCPS 2 specifically exempts the following types of projects from REB review, so projects of these kinds do not need REB review and approval:

Quality assurance and quality improvement studies [QA and QI, program evaluation [PE] activities and performance reviews, or testing within normal educational requirements [curriculum development or evaluation], 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.

These latter types of activities often employ methods commonly used in research. The Bruyère Health REB has the final authority to determine whether a project qualifies for exemption as QI, QA, or PE. The purpose of this guideline is to aid researchers, physicians, staff and students to help determine into which category their project fits.

HOW DO I DETERMINE WHETHER MY PROJECT IS QI/QA/PE OR RESEARCH?

QI/QA/PE initiatives are systematic, data-guided activities designed to bring about immediate improvements in health care or other service delivery in particular settings. Research studies are intended to create new knowledge that can be generalized to other populations and settings.

Although intentions can be mixed, it is the **primary** intent of the developers of the project that determines whether a project is research or QI/QA/PE. Is the primary intention to create knowledge for the benefit of the broad scientific or scholarly community (research), or does the project intend primarily to benefit the local institution and the people it serves (QI/QA/PE)?

CHARACTERISTICS OF RESEARCH AND QI/QA/PE PROJECTS

	Research	QI/QA/PE
Definition	A systematic investigation to establish facts, principles or generalizable knowledge that involves human participants, including patient data and biological materials.	An activity where the primary purpose is to monitor, evaluate or improve the quality of services delivered by an individual or organization.
Intent of Project	To answer a question or test a hypothesis with the intention of contributing to generalizable knowledge.	Intent of project is to improve a practice or process within a particular institution, or specified group of institutions, or ensure it conforms to

		expected norms.
Design	Designed to develop or contribute to generalizable knowledge; may involve randomization of individuals to different treatments, regimens, or processes; or novel research ideas supported by literature search.	Not designed primarily to develop or contribute to generalizable knowledge; generally does not involve randomization to different practices or processes.
Mandate	Activities generally not specifically mandated by the institution or program.	Activities mandated by the institution or clinic as part of its operations.
Population	Usually involves a subset of individuals and specific sample size. Universal participation is not expected; generally, statistical justification for sample size is used to ensure significant endpoints can be met.	Information on all or most receiving a particular treatment or undergoing a particular practice or process expected to be included; exclusion of information from some individuals may significantly affect conclusions.
Effect on Program or Practice	Findings of the study are generally not expected to directly or immediately affect institutional or programmatic practice.	Findings of the study are expected to directly affect institutional practice and identify corrective action(s) needed.
Benefits	Participants may or may not benefit directly. A benefit, if any, to individuals may be incidental or delayed.	Participants continuing to use tested services are expected to benefit directly from changes or refinements to the services.
Adoption of Results	Dissemination of results may require more time.	Dissemination of results may occur rapidly and are intended to be adopted into institutional program(s).
End Point	Answer a research question, and/or invite critical appraisal of that conclusion by peers through presentation.	Improve a program, process, or service; implement, monitor and sustain program improvement.
Publication/Presentation	Intent to publish or present is generally presumed at the outset of project as part of professional expectations, and/or obligations; and usually occurs in research/scientific publications, grant proposals, or other research/scientific forum. Results are expected to contribute to generalizable knowledge by filling a gap in scientific knowledge or supporting, refining, or refuting results from other research studies.	Intent to publish or present generally not presumed at the outset of the project; dissemination of information often does not occur beyond the institution evaluated, but may occur in quality improvement publications/forums. When published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge.

PART 1 – “Yes” answers tend to indicate Research and not QI/QA/PE

1. Is the project/study being presented to the public, colleagues, the institution, your department or others (including students) as a “research” project: that is, do you consider the project research?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. Is the project funded by (or being submitted to) a grant/award competition from a funding agency that requires research ethics review?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3. Does the project involve randomization to compare interventions with participants, or use other sampling techniques to divide participants into different groups?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

4. Does it involve a control group for whom the procedure or therapy or study intervention is withheld to allow an assessment of its efficacy?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5. Does the project intend either to test a novel intervention, drug, device, treatment or program, or test hypotheses about issues that are of broad interest, or beyond the knowledge of current science?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6. Does your project involve a prospective evaluation of drug, procedure or device not currently approved by Health Canada?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7. Is your project exploring a previously unknown phenomenon with a marketed or approved product (i.e. off-label use of a drug/device)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8. Is the project design and methodology rigorous enough to support statistical generalizations beyond the particular population that will participate in the project?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
9. Will your project be blinding caregivers to any element of care?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
10. Is there a national or provincial registry/database from which a hypothesis will be tested?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
11. Is the project designed to support generalizations that go beyond the particular population the sample is being drawn from?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12. Is the primary purpose of the project to produce the kind of results that could be published in a research journal?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
PART 2 – “No” Answers tend to indicate Research and not QI/QA/PE		
1. Is the project intended primarily to develop a better practice within your organization or setting?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. Is the current project part of a continuous process of gathering or monitoring data within an organization?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3. Would this project still be done at your site even if the results might not be applicable anywhere else?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Still have questions?

Please contact the REB office:

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