CONJOINT HEALTH RESEARCH ETHICS BOARD (CHREB)
Research Services Office
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COMPARISON OF THE CHARACTERISTICS OF RESEARCH and QUALITY IMPROVEMENT/QUALITY ASSURANCE/ PROGRAM EVALUATION ACTIVITIES

Under the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), quality assurance, quality improvement and program evaluation activities do not constitute research and do not fall within the scope of REB review (see Article 2.5). As stated by the Panel on Research Ethics, publishing or otherwise disseminating the results of an activity is not a factor that determines whether the activity is research or not (see Scope Interpretation 7). Determining whether a project meets this exemption can be difficult.

The table below is intended to help determine whether a project is best categorized as research or QA/QI/PE. It is meant as a guideline only. Where the primary intent of project is best categorized as research, it must be submitted for REB review. Where it is best categorized as QA/QI/PE, it may be exempted from the research ethics review requirement. Exemptions are granted by the REB, the onus is on the project lead to consult in advance of project implementation. Research ethics approval cannot be granted for work already undertaken.

Please note, research conducted without ethics approval is a breach of the University of Calgary's research integrity policy and may result in significant sanctions. Further, inappropriate access of personal health information may result in penalties under the Health Information Act (HIA) of Alberta.

	RESEARCH	**QUALITY IMPROVEMENT/ QUALITY ASSURANCE/ PROGRAM EVALUATION**
INTENT	Intent of project is to develop or contribute to generalizable knowledge (i.e., the knowledge gained is intended at the outset to be applicable in settings beyond the local practice context). This includes, but is not limited to, testing hypotheses.	Narrow in scope, the intent of project is to improve a specific practice, process or program within a particular institution/facility or to ensure it conforms to expected norms. Results of the project are not

		applicable to other processes or programs within the same or at other institutions/facilities.
MOTIVATION FOR PROJECT	The occurrence of the project may be used for professional advancement (obtaining grants, seeking tenure, students identifying their involvement as research experience on resumes/CVs, etc).	Project occurs regardless of whether individual(s) conducting it may benefit professionally from conducting the project. Those involved in the project do not identify their involvement as a professional accomplishment but rather a component of their job duties.
DESIGN	The project is designed to develop or contribute to generalizable knowledge or provide greater insight into an issue. All study designs (case control, cohort, qualitative, etc) may be considered as research, particularly those projects involving randomization of individuals to different treatments, regimens, or processes.	Given its narrow scope, the project is not designed to develop or contribute to generalizable knowledge. QI/QA/PE projects generally do not involve randomization to different practices or processes.
MANDATE	The project is not mandated by the institution, facility, clinic or program.	The project falls under the mandate or authorization of the institution, facility, clinic or program as part of its normal business operations.
EFFECT ON PROGRAM OR PRACTICE EVALUATED	There is no specific organizational or institutional directive that the findings of the project are expected to immediately affect institutional or programmatic practice. However knowledge gained from the project may inform improved practice (e.g. health services research that addresses efficiency, effectiveness, appropriateness, patient safety, etc).	Findings of the project, through organizational or institutional directives, are expected ***to directly and immediately*** affect practice. Those conducting the project are required to implement corrective action(s) as needed. Those involved in the project are, by the nature of their position, responsible for mandating and orchestrating the required change in practice.

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POPULATION	The project may involve a subset of individuals, the results from which are extrapolated (i.e. generalizable) to a larger population. In this case, statistical justification for sample size is used to ensure endpoints can be met. Health services research, particularly that which uses data derived from administrative health care databases, may include an entire population of individuals rather than a subset.	Information on all or most receiving a particular treatment or undergoing a particular practice or process is expected to be included in the project. Exclusion of information from some individuals may significantly affect conclusions.
BENEFITS	Participants may or may not directly benefit from the project. Benefit, if any, is incidental or delayed in time.	Participants are expected to directly benefit from the project, given that the results of the project will be implemented immediately by those conducting the project.
DISSEMINATION OF RESULTS	The intent to publish or present the project results is presumed at the outset of the project as part of professional expectations or obligations. Dissemination of project results usually occurs in research/scientific publications or other research/scientific fora. The project results are expected to develop or contribute to generalizable knowledge by filling a gap in scientific knowledge or by supporting, refining, or refuting results from other research studies.	The intent to publish or present is generally not presumed at the outset of the project. Dissemination of project results typically does not occur beyond the institution/facility/program/clinic that was evaluated. Dissemination of project results may occur in *quality improvement* publications/fora. When published or presented to a wider audience, the intent is to suggest potentially effective models, strategies, assessment tools or to provide benchmarks or base rates rather than to develop or contribute to generalizable knowledge.

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FUNDING	Usually research requires a separate source of funding, although some research is unfunded. Funding may be from an external granting agency or an internal research grant competition. Acceptance of any research funding to conduct the project (grants, studentships, etc) necessitates labelling the project as research.	Funding for QI/QA/PE projects typically is budgeted for within an institution/facility/program's operating budget, given that the project should be mandated by the institution, facility, clinic or program as part of its normal business operations.
IMPACT ON PRACTICE	Project results will contribute to the scientific body of knowledge which collectively adds to evidence that will inform practice/policy, including quality health services delivery. Project results will change practice/policy slowly as multiple studies may be needed to validate the results, and those conducting the project are generally not in a position to immediately mandate and implement practice/policy change within an institution/facility/program/clinic.	Project results will immediately change practice/policy within an institution/facility/program/clinic. Those conducting the project, by the nature of their job duties, are required to immediately mandate and implement the practice/policy change.
USE OF PLACEBO	Use of placebo may be planned as part of the project methodology.	A placebo would NOT be used as part of the project methodology.
DEVIATION FROM STANDARD PRACTICE	The project methodology may involve significant deviation from standard practice (e.g. a novel treatment).	The project methodology is unlikely to involve significant deviation from standard practice.