

Quality Improvement vs. Research: Do I Need REB Approval?

As per TCPS 2, research involving living human participants or human biological materials requires ethics review and approval by an REB before the research commences.

HOWEVER, *quality assurance and quality improvement studies, 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 (Article 2.5).*

So... how do I know if my project is considered research or QI?

	Your project is most likely RESEARCH if...	Your project is most likely QI if...
Purpose	It is designed to develop or contribute to generalizable knowledge	It is designed to implement knowledge or to assess a process or program
Design	It follows a rigorous protocol that remains unchanged throughout the research. It likely involves comparison between multiple sites, control sites and/or control groups	It has an adaptive or iterative design. It likely refers to a specific program, organization or region
Benefits	It is intended to benefit future participants (it may or may not benefit current participants)	It directly benefits a process, system or program (and may or may not benefit participants)
Risks	It may pose a risk to participants	It does not increase risk to participants, with the exception of risks to privacy or confidentiality
Endpoint	It answers a specific research question or tests an explicit hypothesis	It improves a program, process or system
Analysis	It will statistically prove or disprove a hypothesis	It will compare a program, process or system to previously established standards

If you are still unsure whether or not your project is considered research or QI, seek a second opinion! Connect with Graham at campbg4@mcmaster.ca or consult HiREB for guidance at www.hireb.ca

I want to publish the results of my project. Does that make it research (and subject to REB review)? No.

Publishing or otherwise disseminating the results of an activity is not a factor that determines whether the activity is research or not. Publishing the results of a quality improvement study may inform other work, but does not alter the main purpose for which the study was conducted.

I collected data as part of a QI initiative, but now I want to use it in research. Do I need REB approval? Maybe.

If data are collected for the purposes of QI but later proposed to be used for research purposes, it is considered secondary use of information not originally intended for research, and at that time may require REB review.

My project is QI and does not require REB review. Do I still need to follow TCPS 2 guidelines? Yes...mostly!

Researchers are expected to adhere to applicable parts of the TCPS and its Policy, which establishes principles to guide the design and ethical conduct of research, including participant confidentiality. Certain policies, like obtaining informed consent from participants, are not applicable to quality improvement work.