

How to determine Research vs Quality Improvement projects: A Guideline and Checklist

Purpose:

Differentiation between a research study and a quality improvement (QI) project can be difficult and confusing, as both involve implementing a change to address a problem and there can be overlap between their technical definitions. As such, guidelines and tools can be a helpful way for people to determine which category a project falls into. Upon completion of this checklist the user will be able to distinguish if the presented proposal is QI or research. QI will have and will not have certain elements that make it able to be exempt from an ethics review^{1,2}.

Characteristics of Research and Quality Improvement Projects:

	Research	Quality Improvement
Purpose	A systematic investigation to establish facts, principles or contribute to generalizable knowledge.	To implement knowledge, evaluate or improve a process or program through established/ accepted standards.
Design	Follows a rigid protocol that remains unchanged. Utilizes amendments.	Adaptive, iterative design with PDSA Cycles.
Mandate	Activities not mandated by institution.	Activities are mandated by institution as part of operations.
Starting Point	Knowledge-seeking is independent of routine care and intended to answer a question of test a hypothesis with the intention of contributing to generalizable knowledge.	Knowledge-seeking is integral to ongoing management system for delivering health care.
Population	Usually involves a subset of	Includes information on all

	individuals and specific sample size.	affected by process or program change receiving.
Benefits	May or may not benefit current subjects; intended to benefit future patients	Immediately and directly benefits a process, system or program; might or might not benefit patients
Risks	May put subjects at risk with consent	No increased risk to patients, with exception of possible patients' privacy or confidentiality of data. Consent not always needed.
Data Collection Strategy	Systematic data guided	Systematic data guided
Testing or Analysis	Statistically prove or disprove a hypothesis	Compare program, process or system to establish standards
Effect on program or practice	Findings of the study are generally not expected to immediately affect or change practice	Finding of the study are expected to directly and immediately affect institutional practice
Adoption of Results	Dissemination of results may require more time	Dissemination of results occurs rapidly and adopted into local care delivery
Endpoint	Answer a research question and/ or invite critical appraisal of that conclusion by peers through presentation	Improve a program, process or system
Publication/ Presentation	Intent to publish generally presumed at the onset of the project	Intent to publish may or may not be presumed at the onset of the project but QI practitioners are encouraged to share systematic reporting of insights

The table above is based on information adapted from: The Ethics of Using QI Methods to Improve Health Care Quality and Safety³ & Human Subject Research – vs. – Quality Improvement⁴

References:

1. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.
2. Ottawa Health Science Network Research Ethics Board
3. Lynn, J., Baily, M. A., Bottrell, M., Jennings, B., Levine, R. J., Davidoff, F., ... & Agich, G. J. (2007). The ethics of using quality improvement methods in health care. *Annals of internal medicine*, 146(9), 666-673.
4. DHA Human Research Protection Program. (2013). *Issue: Human Subject Research versus Quality Improvement Activity* [PDF]. Retrieved from <https://health.mil/Reference-Center/Fact-Sheets/2015/10/13/Human-Subjects-Research-versus-Quality-Improvement-Activities>.

Consideration	Question	Yes ✓	No ✓
PURPOSE	Is the primary aim or motive of the project either to: <ul style="list-style-type: none"> Improve care right now for the next patient seen? <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> Improve operations or efficiency? 		
RATIONALE	Is there sufficient evidence for, or acceptance of, this mode or approach to support implementing this activity or to create practice change, based on: <ul style="list-style-type: none"> literature, consensus statements, or consensus among clinician team? 		
METHODS 1	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes?		
METHODS 2	Do the methods include any of the following? <ul style="list-style-type: none"> Control group Randomization Fixed protocol 		
RISK	Is the risk related to the project minimal and no more than usual care (including the unavoidable minimal risk in implementing any changes made in processes of care)?		
PARTICIPANTS	Will the activity only involve participants (patients, parents, or WDMH or partners staff) who are ordinarily seen, cared for, or work in the setting where the activity will take place?		
FUNDING	Is the project funded by any of the following? <ul style="list-style-type: none"> An outside organization with an interest in the results A manufacturer with an interest in the outcome of the project relevant to its products A non-profit foundation that typically funds research, or by internal research accounts 		
<p>If all of the check marks are inside the shaded gray boxes, then the project is very likely QI and not human subjects research. Projects that are not human subjects research do not need review by the REB.</p> <p>Note: Each time the project changes it is recommended to refer back to this checklist and reassess the need for an ethics review if uncertain if still a QI project.</p>			

Checklist: *

*The table above is adapted from: Children’s Hospital of Philadelphia Research Institute - IRB

An inquiry can be made by email to the WDMH ethics committee by emailing research@wdmh.on.ca

Characteristics of a QI project that do not determine the need for REB Review:

- Intent to publish – both QI and research may be published.
- Process of data collection – both QI and research may include prospective or retrospective data collection and may collect data on living/deceased individuals.

Clarifications for publishing QI work:

- Do not refer to QI projects as research in publications or presentations.
- If the project was not submitted to the REB for determination, the following statement may be included in the manuscript:
“This project was undertaken as a Quality Improvement Initiative and as such does not constitute human subjects research.”
- If the project was reviewed by the REB and was determined not to be human subjects research, the following statement can be included in the manuscript:
“This Quality Improvement Initiative was reviewed and determined to not meet the criteria for human subjects research by the Winchester District Memorial Hospital Research Ethics Board.”

Declaration

- I confirm that the information answered above is true and is an accurate reflection of the project.
- If the project is determined to be a quality improvement project, it will be exempt from an ethics review/ approval process.

Name (Printed)

Signature

Date