

# Is it Research? Or is it Program Evaluation?

The Research Ethics Board (REB) at St. Joseph’s Care Group is governed by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2014 (TCPS2). The policy states that:

*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 (Article 2.5).*

However, it can be difficult sometimes to determine whether a project is research or program evaluation/quality improvement. This document is intended to help you identify whether an activity is research or program evaluation/quality improvement, and thus whether your project requires review by the REB or is exempt.

## CHECKLIST

**To begin...**

	Yes	No
If your project is funded, is REB review required by the Funder?	<input type="checkbox"/>	<input type="checkbox"/>
Does your project involve use of a pharmaceutical device, drug or natural health product under Health Canada Food and Drug Act regulations or guidelines??	<input type="checkbox"/>	<input type="checkbox"/>

If you have checked “**Yes**” for either of these questions, your project requires REB review. Information about applying to the REB and all forms can be found at: <http://sjcg.net/departments/research-services-ethics/reb.aspx>.

If the answer is “**No**” to both of the questions, please complete the checklist on the following page to see if your project is research or program evaluation/quality improvement. Check “N/A” if neither statement applies to your project.

If you have trouble completing the checklist, please feel free to contact Carrie Gibbons (Manager, Research Ethics & Library Services at 346-3697 or [gibbonsc@tbh.net](mailto:gibbonsc@tbh.net)).

	Check Column 1 if <i>this</i> best describes your project...	Check Column 2 if <i>this</i> best describes your project...	N/A
<b>Aim</b>	Systematic investigation to establish facts/principles/ general knowledge <input type="checkbox"/>	Monitors/evaluates/improves quality of healthcare in a given context <input type="checkbox"/>	<input type="checkbox"/>
	Tests a hypothesis or establishes a clinical practice standards where none are accepted <input type="checkbox"/>	Assesses or promptly improves a process/program/system; or improves performance as judged by accepted/established standards; integral to hospital operations <input type="checkbox"/>	<input type="checkbox"/>
	Answers a research question <input type="checkbox"/>	Improves a program/process/system <input type="checkbox"/>	<input type="checkbox"/>
	Is an untested intervention for purposes which include not only improving the quality of care but also collecting information about client outcomes to establish scientific evidence to determine how well the intervention achieves its intended results <input type="checkbox"/>	Comprises a range of activities conducted to assess, analyze, critique, and improve current processes of health care delivery <input type="checkbox"/>	<input type="checkbox"/>
<b>Review</b>	Independent, peer review conducted of the proposal <input type="checkbox"/>	No independent, peer review conducted of the proposal <input type="checkbox"/>	<input type="checkbox"/>
<b>Risk</b>	May place clients at risk and stated as such <input type="checkbox"/>	Does not increase client's risk, with exception of possible privacy/confidentiality concerns <input type="checkbox"/>	<input type="checkbox"/>
<b>Consent</b>	Participation is optional and informed consent is required <input type="checkbox"/>	Participation is an expected part of receiving health care <input type="checkbox"/>	<input type="checkbox"/>
<b>Design</b>	Follows research design leading to scientifically valid findings (e.g., a randomized controlled trial) <input type="checkbox"/>	Uses quality improvement methods (e.g., Plan-Do-Study-Act cycle) aimed at producing change within the organization <input type="checkbox"/>	<input type="checkbox"/>
	Literature review and critical appraisal conducted <input type="checkbox"/>	A review of what similar programs/institutions has been done; no full literature review <input type="checkbox"/>	<input type="checkbox"/>
	Assignment of the intervention(s) is random; clinical uncertainty as to whether treatment is advantageous to the client <input type="checkbox"/>	Intervention is specific to the needs of the client and is used to produce the best outcome given the knowledge available <input type="checkbox"/>	<input type="checkbox"/>
	There is a control group <input type="checkbox"/>	There is no control group <input type="checkbox"/>	<input type="checkbox"/>
	Intervention delivery is blinded (i.e., client and/or staff do not know who is receiving the intervention) <input type="checkbox"/>	Intervention is not blinded <input type="checkbox"/>	<input type="checkbox"/>
	Designed to contribute to generalizable knowledge and may or may not benefit clients <input type="checkbox"/>	Designed to promptly benefit a process/program/system; may or may not benefit clients <input type="checkbox"/>	<input type="checkbox"/>
<b>Audience</b>	Primary audience for findings is external (e.g., publication in a scientific journal or conference) <input type="checkbox"/>	Primary audience for findings is internal or local <input type="checkbox"/>	<input type="checkbox"/>
	New knowledge is generalizable (e.g., applicable outside the local context) <input type="checkbox"/>	New generalizable knowledge is not an expected outcome <input type="checkbox"/>	<input type="checkbox"/>

## Interpreting the results:

If you have **only** checked boxes in the **Column 2**, your project is program evaluation or quality improvement and does **not** require REB review and approval.

If you have checked **any** boxes in **Column 1**, your project may be research. Please contact Carrie Gibbons (email. [gibbonsc@tbh.net](mailto:gibbonsc@tbh.net), tel. 346-3697) to discuss next steps.

Another interesting resource that you may want to review is the [A pRoject Ethics Community Consensus Initiative \(ARECCI\) Ethics Screening Tool](#). This tool was designed “to provide practical “on the ground” decision-support assistance to project leaders and teams” who are trying to distinguish research and program evaluation/quality improvement.

## FAQs

### What about students doing research or program evaluation at SJCG?

Students are frequently involved in research and program evaluation/quality improvement initiatives at SJCG. The findings from such work may also comprise a component of a student’s course work (e.g., thesis, project). It is essential that students receive appropriate supervision from SJCG staff as these projects are designed and implemented. REB approval may be required, especially in cases when data will be leaving SJCG. Students may also require approval from the REB at their institution.

### What if an external agency is conducting an evaluation of a program at SJCG?

The REB does not review program evaluation activities. In this case, it is the responsibility of managers/directors at SJCG to ensure that data will be used and shared appropriately.

### What if I collect information about my clients now to evaluate my program but think that I may use the same data in the future to answer a research question?

This would be considered the secondary use of data or using “*materials originally collected for a purpose other than the current research purpose.*” As stated in TCPS2:

*REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generative identifiable information (Article 2.4).*

If data collected from clients may be used for secondary analyses (i.e., to answer a research question), this should be reviewed with clients when data are initially collected. It is the responsibility of SJCG staff to ensure that programs adhere to SJCG policies and procedures regarding the confidentiality and privacy of client data (these can be found on the iNtranet). If there is the possibility that individuals could be identified in the secondary analysis, REB review may be required. Please contact Carrie Gibbons (email. [gibbonsc@tbh.net](mailto:gibbonsc@tbh.net), tel. 346-3697).

## Sources used in developing this document included:

Baily, M.A., Bottrell, M., Lynn, J., Jennings, B. (2006). The Ethics of Using QI Methods to Improve Health Care Quality and Safety. *Hastings Center Hastings Center Report*, 36(4), S1-40.

Bellin, E., Neveloff Dubler, N. (2001). The Quality Improvement–Research Divide and the Need for External Oversight. *American Journal of Public Health*, 91(9), 1512-1517.

Cambridge Health Alliance. *Quality Improvement (QI) versus Research – Researcher Guidance*. Retrieved from: <http://www.challiance.org/Academics/QIvsResearch.aspx>

Grand River Hospital. (2010). Research versus Quality Improvement Guideline. Retrieved from: <http://www.grhosp.on.ca/research/research-versus-quality-improvement>

Pinard, M. (2007). *Quality Improvement and Research: Sick Kids' Harmonized Review Process*. Retrieved from: <https://www.sickkids.ca/pdfs/Research/REB/12408-SickKidsQIOversightFeb07.pdf>

Research Compliance Office – Stanford University. Quality Assessment and Quality Improvement (QA/QI) FAQs. Retrieved from: [http://humansubjects.stanford.edu/research/documents/qa\\_qi\\_faqs\\_AID03H16.pdf](http://humansubjects.stanford.edu/research/documents/qa_qi_faqs_AID03H16.pdf)

Research Ethics – Dalhousie University. *Guidelines for differentiating among Research, Program Evaluation and Quality Improvement*. Retrieved from: [https://www.dal.ca/content/dam/dalhousie/doc/research-services/Guidelines%20research%20PE%20QI%20\(28%20Nov%202013\).pdf](https://www.dal.ca/content/dam/dalhousie/doc/research-services/Guidelines%20research%20PE%20QI%20(28%20Nov%202013).pdf)

St. Joseph's Health Centre Toronto. (2014). Research versus Quality Improvement Guideline & Checklist. Retrieved from: <http://www.stjoestoronto.ca/wp-content/uploads/2016/01/SJHC-REB-Research-vs.-QI-Guideline-Checklist-July-24-2014-2.doc>

Wichita Medical Research and Education Foundation – Wesley Medical Center. Quality Improvement versus Research Instructions and Clinical QI Worksheet. Retrieved from: <http://www.wichitamedicalresearch.org/wmrefscientificreviewcommittee/procedureguide/d101947.aspx>