**Quality Assurance (QA) and Quality Improvement (QI) Studies**

**What is QA/QI?**

Quality Assurance and Quality Improvement (QA/QI) studies are projects undertaken to assess the performance of a program, organization, group, faculty, or department. QA/QI projects are conducted internally and for operational and/or administrative purposes.

**Although QA/QI studies might use methods and techniques similar to those traditionally employed in research (e.g., surveys, interviews, data analysis, etc.), they are used exclusively for management, assessment, or improvement within an organization.** QA/QI activities are designed solely for internal purposes, with no intention for external application or distribution. Examples of QA/QI projects may include performance reviews, course evaluations, or data collection for internal organizational reports.

QA/QI studies are listed in the [**Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2014)**](http://www.pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html)under **Activities Not Requiring REB Review**. As the TCPS2 states:

*“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.”* (TCPS 2 2014, Article 2.5.)

**ARECCI Guidelines and Screening Tools**

In order to determine whether your study qualifies as QA/QI, please refer to the ARECCI (Alberta Research Ethics Community Consensus Initiative) Guidelines and Screening Tool, both of which are available online for public use [through a creative commons license](https://creativecommons.org/licenses/by-nc-nd/4.0/).

1. [Introduction: ARECCI Ethics Guidelines for Quality Improvement and Evaluation Projects](https://albertainnovates.ca/our-health-innovation-focus/a-project-ethics-community-consensus-initiative/faq-arecci/)
2. [Researcher Instructions: ARECCI Ethics Guideline and Screening Tool](https://albertainnovates.ca/our-health-innovation-focus/a-project-ethics-community-consensus-initiative/arecci-ethics-guideline-and-screening-tools/)
3. [The ARECCI Ethics Screening Tool](https://albertainnovates.ca/our-health-innovation-focus/a-project-ethics-community-consensus-initiative/arecci-ethics-guideline-and-screening-tools/)

**QA/QI FAQs**

1. **If my project is determined to be QA/QI, can I still publish or disseminate my findings?**

Yes. Dissemination of QA/QI findings through external channels is permitted, but it must be specified that the study was conducted for QA/QI purposes and that results must not be generalized (i.e. applied outside of the organization for which the QA/QI study was conducted). For example, QA/QI findings and successes may be presented in meetings or published in professional journals as long as all publications and presentations clearly refer to QA/QI studies as QA/QI studies (i.e. rather than as research). Please note that if you intend to publish the results of a QA/QI project, a note explaining that the project was determined to be QA/QI should be added to the methodology section of the published paper. In addition, no generalizations can be made about the study outside of the scope of QA/QI for that specific organization. For further information on the publication of QA/QI studies, please refer to the [SQUIRE (Standards for Quality Improvement Reporting Excellence) guidelines](http://squire-statement.org/index.cfm?fuseaction=Page.ViewPage&PageID=471).

1. **Can I determine whether my project is QA/QI or research *after* I have begun my project?**

No. HSREB Ethics Clearance must be issued before a research project has begun and will not be issued retroactively.

1. **I collected data for a QA/QI project and would now like to use this data for research. Is this permitted?**

Yes - The use of QA/QI data for a research project would be considered a secondary use of information, and **would require REB review prior to the use data for research purposes**.

1. **Can I access Personal Health Information for QI projects?**

Yes – as long as anyone who accesses Personal Health Information (PHI) for QA/QI purposes is authorized as a legal custodian or agent of health data, and as long as all relevant institutional data protection, privacy, and confidentiality policies/guidelines are followed, access to PHI is permitted.

1. **Can I access data from Shared Health Systems for QI projects?**

No. Shared Health Systems (e.g., Connecting Ontario, OLIS, cCHN, HDIRS, IAR, etc.) are not to be accessed for use in QA/QI studies.

**Important Considerations**

* QA/QI projects, although not considered research as defined by the TCPS 2 2014, are still expected to be conducted professionally and ethically, in accordance with the [core principles of the TCPS 2](http://www.pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html) 2018. These core principles include: protecting the interests of the participants, respecting free and informed consent and voluntary participation, and respecting privacy and confidentiality.
* If data collection occurs as part of a QA/QI project and that data is ***later proposed for research purposes***, this would be considered secondary use of information not originally intended for research, and would require REB review. Secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose (see TCPS 2 2014, Chapter 5, Section D). When secondary data can be linked to individuals, and when the possibility exists that individuals can be identified in published reports or through data linkage, additional considerations may need to be made regarding participant consent requirements ([TCPS 2 2018 Article 5.5A & 5.5B](http://www.pre.ethics.gc.ca/eng/tcps2-eptc2_2018_chapter5-chapitre5.html)).
* Queen’s University will not grant retroactive ethics clearance of a study.
* **If you are unsure whether or not a project qualifies as QA/QI and will be exempt from review, you should seek the opinion of Jennifer Couture, the Ethics Compliance Advisor, before initiating the project. Jennifer can be reached by email at: jennifer.couture@queensu.ca, or by phone at: 613-533-6000 ext. 78223.**

**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. Quality Improvement Projects, American Society of Clinical Oncology (ASCO), 2018.
3. Posterboards from IHI's 27th Annual National Forum on Quality Improvement in Health Care, School Resources, Institute for Healthcare Improvement, 2018.
4. ARECCI Ethics Screening Tool developed by the Alberta Research Ethics Community Consensus Initiative (ARECCI) Network (2005, revised 2008).
5. Research vs Quality Improvement Guideline & Checklist, St. Joseph’s Health Centre Toronto, July 24, 2014.
6. Revised Standards for Quality Improvement Reporting Excellence, SQUIRE 2.0, 2017 SQUIRE.
7. Distinguishing Between Quality Assurance/Improvement & Research, Western University, 29MAY2015.
8. REB Quality Improvement/Quality Assessment (QA/QI) Tool, North York General Hospital, August 2016.