**RESEARCH VERSUS QUALITY ASSURANCE/IMPROVEMENT (QA/QI) SCREENING TOOL**

The following document is designed to help you determine if your project is considered research requiring Research Ethics Board (REB) review or a QA/QI project that is exempt from REB review and approval at the McGill University Health Centre (MUHC). The document also describes the process that must be followed to request an REB exemption letter for a QA/QI project.

**IMPORTANT**

This tool is meant for REB exemptions requests for projects that are quality assurance/improvement.

For questions related to exemptions for ***other*** types of projects, contact the MUHC REB directly ([reb@muhc.mcgill.ca](mailto:reb@muhc.mcgill.ca)).

**1. Why is deciding if a project is research or QA/QI important?**

Research involving human subjects must undergo REB review and approval; as per Article 2.5 of the Tri-Council-Policy Statement (TCPS2, 2022) QA/QI projects do not.[[1]](#footnote-1)

**2. What is the difference between research and quality improvement?**

**Research** is defined as: “an undertaking intended to extend knowledge through a disciplined inquiry and or systematic investigation. The term disciplined inquiry refers to an inquiry that is conducted with the expectation that the method, results and conclusions will be able to withstand the scrutiny of the relevant research community.”[[2]](#footnote-2) Research aims to produce generalizable knowledge by answering a specific research question or testing a hypothesis via scientific methods.

**Quality assurance/improvement projects** aim to introduce changes that will lead to improved patient outcomes (health), system performance (care) and/or professional development. Often, QA/QI projects seek to implement already-established best practices. QA/QI projects may use established methods (e.g., Plan-Do-Study-Act cycles) and generally do not place any additional burdens on participants other than what is expected during standard care or practice.

Research and QA/QI exist on a continuum. **Some projects may contain features of both research and QA/QI that can make it difficult to distinguish clearly between one and the other.** This screening tool was designed to help you make this determination.

**3. Can a retrospective chart review be considered a QI project and be exempted?**

The objective and intent of a project being determining factors, it is helpful to complete the screening tool when a project requires access to patients’ health records. Often, this type of project will be considered a health records research (HRR) project and will need to be submitted for approval by the REB using [Nagano](https://nagano.muhc.mcgill.ca/login) and the HRR protocol template available [here](https://muhc.ca/sites/default/files/users/user291/HHR_Template%20Protocol_v2025-02-05.docx).

**4. Do I automatically need REB review if I intend to publish?**

No, “intent or ability to publish findings are not factors that determine whether an activity is research requiring ethics review.” [[3]](#footnote-3)

**5. What can I do if I am not sure whether my project requires REB review?**

The Centre for Applied Ethics has created a Research versus QA/QI Screening Tool to help you determine whether a project requires REB review.

This tool may help you if:

1. You are uncertain as to whether your project needs to be submitted for REB review; or
2. If you believe that it is QA/QI and you require an exemption letter (e.g., to provide at time of publication).

**6. How do I use the tool?**

Carefully read the questions, answer them accurately, and act in accordance with the instructions on the tool.

**7. Who is responsible for the decision?**

The Tri-Council Policy Statement (TCPS 2) states that the REB should be consulted “when in doubt”.[[4]](#footnote-4) You are responsible for the accuracy and completeness of the responses that will be used in the determination of whether a project requires REB review.

**8. What do I do if the tool suggests my project is research?**

Submit your project for institutional authorization and REB review via the [Nagano](https://nagano.muhc.mcgill.ca/login) platform.

**9. What do I do if the tool says my project is QA/QI?**

Regardless of whether the project is determined to be research or QA/QI, fundamental principles of respect for persons, welfare and justice apply and should be upheld. You are responsible for following any procedures regulating QA/QI initiatives in your department and at the MUHC. Ethical concerns related to QA/QI projects should be directed to the MUHC Centre for Applied Ethics rather than to the REB ([cae@muhc.mcgill.ca](mailto:cae@muhc.mcgill.ca)).

**10. What do I do if I use the tool and it is still unclear if my project is research or QA/QI?**

Submit the completed screening tool (including the project summary) via email to [reb@muhc.mcgill.ca](mailto:reb@muhc.mcgill.ca). The project will be reviewed and the REB will make a determination.

**11. What if my QA/QI project evolves into a research study?**

If you substantially change your project and you think it is moving towards research, you are responsible for obtaining REB review and the exemption letter will not apply to the new aspects of the project.

**12. How can I obtain an exemption letter?**

Only if you require an REB exemption letter, email the completed tool to [reb@muhc.mcgill.ca](mailto:reb@muhc.mcgill.ca) and write “Request for REB exemption letter” in the subject line. If you are confident that your project is QA/QI and you do not need an REB exemption letter, simply keep this form for your records. Note that the MUHC REB retains the right to make the ultimate determination regarding the need for REB review, regardless of the results implied by use of the screening tool.

**13. Are there special considerations for QA/QI projects I should keep in mind?**

**a) Access to health information:** QA/QI projects necessitating access to patients’ health information without consent require a privacy impact assessment (*évaluation des facteurs relatifs à la vie privée* (EFVP)). You must initiate this process directly, by contacting [efvp@muhc.mcgill.ca](mailto:efvp@muhc.mcgill.ca).

**b) Use of hospital resources:** QA/QI projects necessitating hospital resources must obtain authorization from the appropriate responsible authorities. You must initiate this process directly.

**c) Involvement of Indigenous populations:** QA/QI projects involving Eeyou/Eenou (Cree) populations must be declared to the Cree Board of Health and Social Services of James Bay (CBHSSJB).You must initiate this process directly, by contacting [18ctr.research.committee@ssss.gouv.qc.ca](mailto:18ctr.research.committee@ssss.gouv.qc.ca).

**14. Whom can I contact if I have questions or need help?**

Please contact the REB at extension 36077 or email [reb@muhc.mcgill.ca](mailto:reb@muhc.mcgill.ca).

**RESEARCH VERSUS QUALITY ASSURANCE/IMPROVEMENT (QA/QI) SCREENING TOOL**

**Instructions**:

Complete the information requested below, as well as the questionnaire found on the following page. Delete the pages preceding this one. Submit to [reb@muhc.mcgill.ca](mailto:reb@muhc.mcgill.ca) as needed.

1. **Project title:** Click here to enter text.
2. **Project leader[[5]](#footnote-5):** Click here to enter text.
3. **Project leader’s affiliation (Department):** Click here to enter text.
4. **Project leader’s email:** Click here to enter text.
5. **Collaborators (name and affiliation):** Click here to enter text.
6. **Target population, process, program, or system:** Click here to enter text.
7. **Project summary:**

|  |  |
| --- | --- |
| **Background:** | Click here to enter text. |
| **Objective:** | Click here to enter text. |
| **Methods:** | Click here to enter text. |
| **Risks:** | Click here to enter text. |
| **How will the results of the project be used at the MUHC:** | Click here to enter text. |

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| **Questions** | | **Y** | **N** |
| 1 | Does the project involve the use of an experimental medical device, drug, or natural health product that requires approval from Health Canada? |  |  |
| 2 | Does the project involve the off-label use of an existing drug? |  |  |
| 3 | Is the project funded by, or being submitted to, a funding agency, a research grant, or an award that requires ethics review? |  |  |
| 4 | Is the goal of the project to generate new generalizable knowledge by answering a question or testing a hypothesis using methods recognized by the scientific community? |  |  |
| **If YES to any of the questions 1–4 above, the project should be submitted to the REB** | | | |
| 5 | Does the project seek to control for variables or confounders to promote generalizability? |  |  |
| 6 | Will you determine the number of participants via formal statistical justifications, power calculations, or expected thematic saturation levels? |  |  |
| 7 | Is the project a pilot study or proof of concept designed to support a future, larger research project? |  |  |
| **“YES” answers to questions 5–7 above are suggestive of a research project** | | | |
| 8 | Is the project the result of a department-wide initiative at the MUHC (e.g., with concerted support from colleagues)? |  |  |
| 9 | Is the immediate goal of the project any of the following:   * To improve a process, program, or system at the MUHC? * To improve MUHC performance as judged by accepted practice standards? * To evaluate or implement a best practice at the MUHC? |  |  |
| 11 | Do you have reasons to expect that the results of your project will be quickly integrated into local practices at the MUHC? |  |  |
| 12 | Would the project still be done even if there were no opportunity to publish the results or if the results might not be applicable anywhere else? |  |  |
| **“YES” answers to questions 8–12 above are suggestive of a QA/QI project** | | | |

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 2022. (Thereafter, *TCPS2*.) [↑](#footnote-ref-1)
2. TCPS2, Article 2.1. [↑](#footnote-ref-2)
3. TCPS2, Article 2.1. [↑](#footnote-ref-3)
4. TCPS2, section “Activities Not Requiring Research Ethics Board Review”. [↑](#footnote-ref-4)
5. Please note that students and residents may not be listed as project leader. Only one person can be listed as project leader. [↑](#footnote-ref-5)