Guidelines for Differentiating among Quality Assurance, Quality Improvement, Program Evaluation and Research

Purpose:
This guideline is to assist researchers in differentiating between projects that are considered Quality Assurance/Quality Improvement/Program Evaluation (QA/QI/PE) versus those that are considered research and whether submission to a research ethics board is required. The following document is designed to help you determine if your project is considered research or QA/QI/PE.

What are QA/QI/PE projects?

QA/QI/PE studies are projects undertaken to assess the performance of a program, organization, group, faculty, or department. QA/QI/PE projects are conducted internally and for operational and/or administrative purposes. Per the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) QA/QI/PE are exempt from REB review per TCPS 2, Article 2.5:**

"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."

Conversely, **research is defined as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation**." **TCPS 2, Article 2.1**

Although QA/QI/PE 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/PE activities are designed solely for internal purposes, with no intention for external application or distribution. Examples of QA/QI/PE projects may include performance reviews, course evaluations, or data collection for internal organizational reports.

Regardless of whether the project is determined to be research or QA/QI/PE, fundamental principles of respect for persons, welfare and justice apply and should be upheld. QA/QI/PE projects, although not considered research as defined by the TCPS 2, are still expected to be conducted professionally and ethically, in accordance with the core principles of the TCPS 2. These core principles include: protecting the interests of the participants, respecting free and informed consent and voluntary participation, and respecting privacy and confidentiality.

In addition, please be cognizant that if your activities are deemed to be QA/QI/PE, the activites will still need to follow all other applicable institutional/departmental guidelines and policies (e.g., Privacy, Institutional Research and Planning).

A Detailed description of differentiating QA/QI/PE projects vs research can be found at:
Fraser Health, BC, Research and Evaluation. Differentiation of Research, Quality Improvement and Program Evaluation.
Website: https://www.fraserhealth.ca/-/media/Project/FraserHealth/FraserHealth/Health-Professionals/Research-and-Evaluation-services/20171010_research_QI_program_evaluation_differentiation.pdf?la=en&hash=1D8B4F96533B7196C56DA6AFC7E3B21CEEEA5E79

In order to help researchers, this process has been implemented to clarify if the project qualifies as research or if an exemption to seek REB review can be granted based on TCPS 2, Article 2.5:

1. Complete the **Quality Initiative Screening Tool** in TRAQ. The first step of the TRAQ application form will direct you to complete the ARECCI Ethics Screening Tool, which is available online for public use through a creative commons license.
2. Determining the risk category of the project: (figure 1)
   - **YELLOW**: A score of 0-7 represents minimal risk category. **If you do NOT require a formal exemption in TRAQ, simply delete the draft. If you do require an exemption, follow the process for ORANGE**.
   - **ORANGE**: A score of 8-46 indicates somewhat more than minimal risk and clarification from the REB is required. You will need to include your the ARECCI Ethics Screening Tool results along with a justification as to why this project would be exempt from ethics review based on the TCPS 2 Article 2.5. The Ethics Office will assess whether REB review is required and, if applicable, direct you to submit the appropriate ethics application form. 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. Exemptions will be sent via email communication that can later be viewed in TRAQ using the 'Shared Communications' - 'preview' icons. You can also find acknowledgment of this exemption in TRAQ via 'Event Info' in the 'Note(s)' communication box.
   - **RED**: A score result 47 or greater indicates the project is greater than minimal risk, where minimal risk is classified as the probability and magnitude of possible harms implied by participation are no greater than those encountered by participants in those aspects of their everyday life that relate to the research. For results in the RED range, an ethics application to the appropriate REB must be submitted. **Do not submit the Quality Initiative Screening Tool in TRAQ if your project does require REB review, simply delete the draft.**
3. Hospital-based researchers that may require access to medical records or use of hospital resources are not required to submit a TRAQ DSS if an exemption to seek REB review has been granted through the **Quality Initiative Screening Tool.**
   - If it is anticipated that hospital resources will be required such as chart pulls from off-site for QA/QI/PE projects, this should be discussed directly with the Director of Patient Flow, Registration and Health Information Services prior to initiating the project as further approvals might be required.
   - If there is an intention to include a student (i.e. medical student pre-clerkship or non-medical student) as a team member on the QA/QI/PE project, and if the student will have access to patient information or medical records, then completion of the appropriate hospital paperwork is required, and must be facilitated through the Department head and Director of Medical Affairs.
   - If access to Decision Support is required, an email along with REB exemption letter can be directly sent to the Decision Support team.

FAQs:

1. **If my project is determined to be QA/QI/PE, can I still publish or disseminate my findings?**
   Yes. Dissemination of QA/QI/PE findings through external channels is permitted, but it must be specified that the study was conducted for QA/QI/PE purposes and the results must not be generalized (i.e. applied outside of the organization for which the QA/QI/PE study was conducted). For example, QA/QI/PE 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/PE studies **in that manner** rather than presented as research. If you intend to publish the results of a QA/QI/PE project, you may require supporting evidence that the project was determined to be QA/QI/PE (note: this can 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/PE for that specific organization.The intent to publish results does not distinguish activity as research, as findings of QA/QI/PE are often published. Some projects may contain features of both research and QA/QI/PE that can make it difficult to clearly distinguish research from these initiatives. For further information on the publication of QA/QI/PE studies, refer to the SQUIRE (Standards for Quality Improvement Reporting Excellence) guidelines.

   If a journal requests ethics clearance, you would explain that these activities do not require institutional ethical

review under Article 2.5 of the TCPS and you can provide a copy of your exemption letter as applicable. Furthermore, in the event that you wish to publish, a notation that your project was determined to be QA/QI/PE by the completion of the ARECCI screening tool can be included in the methods section of your paper and submitted for review if the journal requests further documentation.

2. **Can I determine whether my project is QA/QI/PE or research after I have begun my project?**
   No. Ethics Clearance must be sought before a research project has begun and will **not be issued retroactively**.

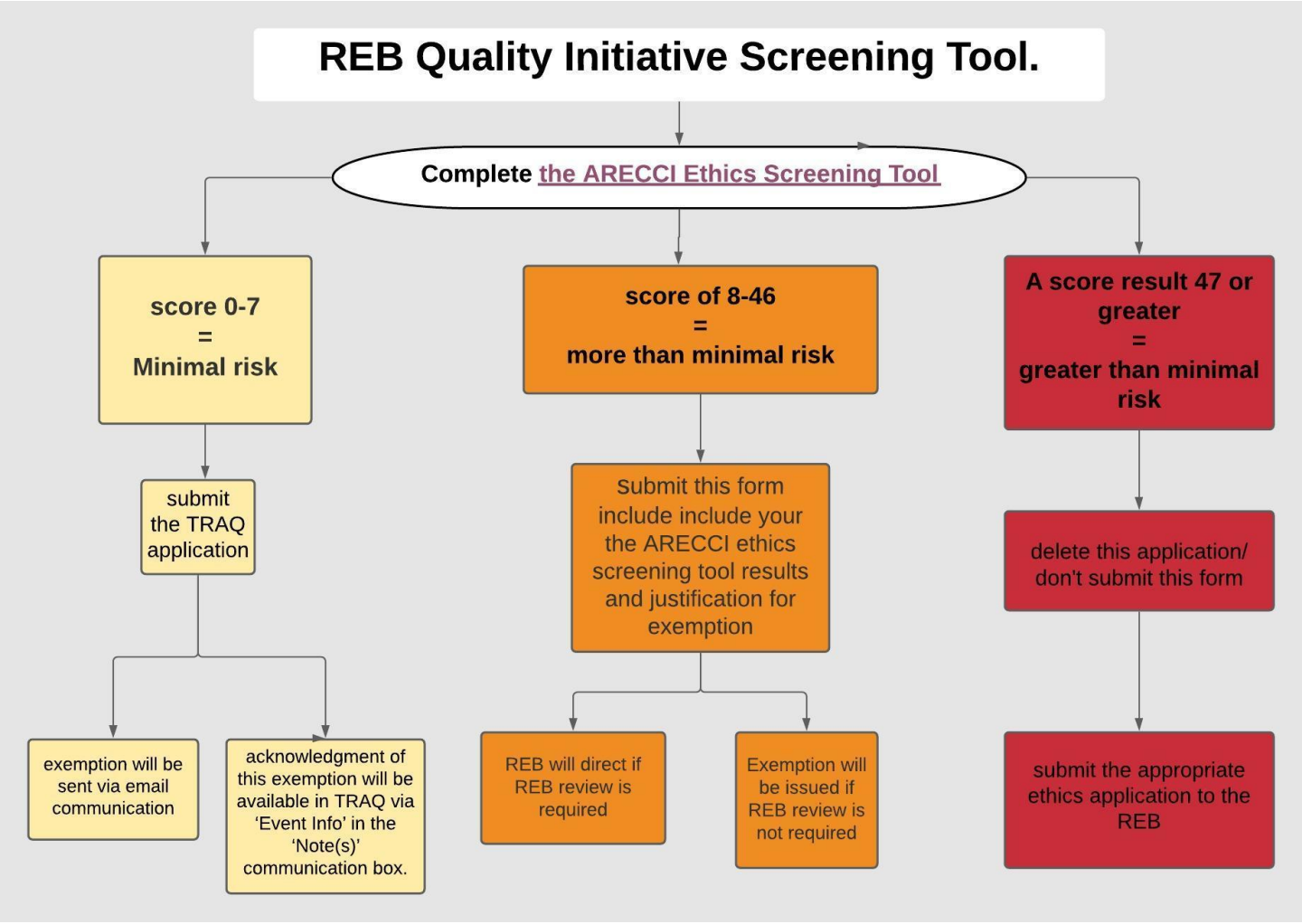
3. **I collected data for a QA/QI/PE project and would now like to use this information for research purposes. Is this permitted?**
   Yes, if data collection occurs as part of a QA/QI/PE project and that data is **later proposed for research purposes**, this would be considered secondary use of information not originally intended for research, and would require REB review (see TCPS 2, 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 Article 5.5A & 5.5B).

4. **What happens if I make changes to my project?**
   If there are any changes to your project that may now classify the project as research rather than QA/QI/PE, you may need to seek ethics clearance (e.g., change in risk status, publication plans, new funding requirements). You can make this assessment using the the ARECCI Ethics Screening Tool. If your ARECCI screening score has changed you can seek clarification if ethics is required through the submission of a **new Quality Initiative Screening Tool.**

5. **Can I access Personal Health Information for QA/QI/PE projects?**
   Yes, as long as anyone who accesses Personal Health Information (PHI) for QA/QI/PE 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.

6. **Can I access data from Shared Health Systems for QA/QI/PE projects?**
   No. Shared Health Systems (e.g., Connecting Ontario, OLIS, cCHN, HDIRS, IAR, etc.) are not to be accessed for use in QA/QI/PE studies.

Figure 1 Flow chart to determine risk category of the project



References

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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/PE) Tool, North York General Hospital, August 2016.