Toronto Academic Health Science Network

Research Ethics Board Working Group – *recommended guidelines*

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PURPOSE

In 2022, the TAHSN Research Committee (TAHSNr) established a Research Ethics Board Working Group to develop recommendations related to seven priority areas.

Over the 2022-23 academic year, the Research Ethics Board Working Group – composed of representatives from research ethics offices across TAHSN – prepared recommendations in consultation with the TAHSN REB Chairs group and the TAHSNr Committee. These recommendations are fully endorsed by TAHSNr.

This document provides recommendations for the priority area outlined below. Each institution is encouraged to consider and incorporate the recommendations into their processes and governance to the extent that they can.

PRIORITY: Review of Quality Improvement (QI) / Quality Assurance (QA) projects

Note: For the purpose of this document, the term Quality Improvement (QI) and Quality Assurance (QA) also includes program evaluation.

SITUATION: Understand institutional processes for reviewing ethics of QI/QA, and the process related to managing if research/QI review is needed and how to pursue it.

BACKGROUND

The Research Ethics Board (REB) Working Group was tasked with reviewing the current process across TAHSN institutions for performing an ethical review of QI/QA types of projects. The intention being to streamline the process for identifying these projects that do not fall under the definition of “research” (as per TCPS2’s definition) as well as proposing a review model.

ASSESSMENT

Information with respect to processes for reviewing QI/QA projects, including stakeholders, tools, and bridging mechanism, was obtained through self-report by each institution. The responses were reviewed for commonalities which form the basis of these recommendations.

RECOMMENDATIONS

Process for project type determination:

Recommendation: to use a tool/checklist/template for determining the project type in order to ensure consistency, and determine the type of review needed. For institutions who currently do not have any in-house tool/checklist/template, here are examples of a few tools/templates currently publicly available: ARECCI screening tool and Toronto Metropolitan University's guiding questions). Please note that this process should be in alignment with institutional policies.

Review process for QI/QA projects:

Recommendation: To have a review process that includes different stakeholders (e.g. legal, privacy, ethical, security, safety) to formalize institutional review and approval of such projects.

To ensure projects are always reviewed by the appropriate individuals, we recommend having a communication mechanism between the REB and the QI/QA review committee to ensure projects are being triage to the appropriate review type.

REFERENCES

TCPS2 (2022)

N2 SOP#102 - Research requiring REB Review

The following are case studies and/or tools used that demonstrate different models currently implemented at different institutions (Baycrest, North York and Sunnybrook).

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Case Study 1 - North York General Hospital

1. **Context:**

   North York General is a medium-sized community academic hospital serving a diverse population. The REB has been in place for 30+ years and members include 12 clinical, non-clinical, community and patient representatives. The scope of research includes clinical trials - oncology, paediatrics, plastics, genetics, intensive care as well as population health, maternal & newborn, COVID, observational and surveillance studies. Through our five Research Chairs, there is also a focus on investigations involving:

- Big Data/Artificial Intelligence to improve health outcomes
- Patient-centered outcomes
- Family & Community Medicine
- Knowledge translation & implementation
- Patient Safety & Quality Improvement

2. **Scenario(s) encountered that crosses research and QI:**

   Evaluation of an e-health self-management tool for seniors with multiple chronic conditions across primary care, hospital and community settings

3. **Example of pure QI that would <u>not</u> require REB review.**

   Improving neonatal outcomes by using simulation to test proof of concept of an obstetrics-specific emergency response team

4. **Process for review and decision making (list):**

   a. Information security
   b. Privacy
   c. Patient Experience
   d. Ethics

   NYGH's Quality Improvement Assessment Checklist is a tool designed to help determine whether it is quality improvement or research. To help reduce ambiguity, there are 18 questions about the details of the proposed project that require yes or no answers. The checklist is sent to the REB Co-ordinator, and then to the REB Chair to assess whether a determination could be made by delegated review or should go to the REB. If the study is determined to be solely QI, a letter to that effect is issued by the REB and may be used when submitting study results to the appropriate journal.

   Using the checklist and having the determination made by the REB avoids situations where the investigator believes the project is quality improvement and later finds that it is also research. In such cases, REB approval is required before the results can be published in a peer reviewed journal.

5. **Strengths and plans for change:**

   Strengths: ongoing educational materials for REB members to strengthen expertise.

   Change: evaluate other QI/research tools and adopt or amend our Quality Improvement Assessment Checklist as appropriate.

Case Study 2 - Baycrest

1. **Background:**

   The Rotman Research Institute (RRI) at Baycrest advances our understanding of human brain structure and function in critical areas of cognitive neuroscience, including perception, memory, language, attention, and decision-making.

   CORE RESEARCH THEMES

   - Sensory and Cognitive Neuroscience
   - Neuroinformatics and Computational Neuroscience
   - Aging and Brain Health
   - Alzheimer's and Related Dementias
     > Prevention
     > Early Detection
     > Intervention/Treatment
     > Care

2. **Projects encountered that crosses research and QI:**

   a. Understanding the needs of persons living with dementia, their caregivers, and family physicians in delivering care
   b. Gamifying training for frontline workers in long-term care

3. **Example of pure QI that would <u>not</u> require REB review.**

   Evaluated on a case-by-case basis.

4. **Process for review and decision making (list):**

   a. Data Sharing, Ownership, and Access
   b. Legal
   c. Privacy
   d. e-Health/IT Security
   e. Human Resources (Staff)
   f. Data Destruction
   g. Knowledge Dissemination Plan

   The program evaluation (attached) is used to help determine whether the proposed activity requires REB review or is exempt from REB review.

   Activities that are exempt from REB review are provided with an REB Clearance letter.

Baycrest REB: Program Evaluation Application

Date of Application: [Date]

Program: [Program name]

Institution: [Name of host institution running the program]

Evaluation Team:
[List all members of the evaluation team per site]

TCPS-2 Certificate Status: [Indicate whether TCPS-2 certificates have been obtained and logged with the Research Ethics Office for all team members]

To obtain TCPS-2 certification, please visit the following website: http://tcps2core.ca/welcome

Program Background: [Provide a brief description of the program to be evaluated. Include details regarding the target population; the problem the program is aiming to address; the nature of the program, including a description of the program and its associated activities; and note key team members involved in program implementation].

Project Goals/Objectives: [Describe the goals of the evaluation]

Evaluation Questions:

[List the key evaluation questions below]:

1. [Evaluation question 1]
2. [Evaluation question 2, if applicable, and so forth]

Evaluation Plan: [Provide the details of this evaluation. Describe whether the evaluation is a needs assessment, evaluability assessment, process evaluation, outcome evaluation, impact evaluation, cost-analysis, and so forth. Describe the associated data sources to be obtained for each population involved. Describe the quantitative (numerical) and qualitative (non-numerical) data sources. Describe general timelines – either of the data to be reviewed (e.g., data from the past 1 year of the program, from January 2019 to December 2019, will be examined), or the timelines in which the data will be collected (e.g., surveys and focus groups will be conducted over the course of the next year beginning in February 2020 and concluding in January 2021).]

Consenting Process
[Detail the consenting process to be used as part of this evaluation. Note whether and how informed consent will be sought. If receiving consent using a substitute decision maker (SDM),

note how the evaluation team will obtain client/participant assent, if applicable. If a consenting process is not in place, please indicate why.]

Analysis Plan

Quantitative Analysis

[Briefly describe the quantitative data analysis plan – this can include the descriptive statistics needed to characterize the target population of the evaluation, summaries/analyses of survey/questionnaire data, product usage data, usage statistics, scores on diagnostic measures, etc.]

Qualitative Analysis

[Briefly describe the qualitative data analysis plan – this can include summaries or thematic/narrative/other analysis of focus group/interview data, open-ended survey questions, (in)formal discussion questions related to client satisfaction/experience, etc.]

Potential Risks

- **Note:** Please consult the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2) website to help determine what might constitute a potential risk (https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html#9)
- [List the potential risks associated with this evaluation; note whether or not loss of confidentiality/privacy is a risk in this study]
- [List all additional risks as needed]
- [Note whether members of the evaluation team have active TCPS-2 certification]

Potential Benefits

- **Note:** Please consult the TCPS-2 website to determine what might constitute a potential benefit (https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html#9)
- [List the potential benefits associated with this evaluation]
- [List additional benefits as needed]

Data Sharing, Ownership, and Access

- [Describe who will own the various data sources – hard copies, electronic files, other data sources]
- [Describe who will be carrying out the evaluation – single-site, joint evaluation, etc.]
- [If this is a joint evaluation, list who will be responsible for which evaluation activities]
- [Describe where the data will be stored]
- [Describe how long the data will be retained for and by which site]
- [Describe the uses of each data type and by whom]

Legal

- [Note the legal documents/agreements (e.g., third-party user agreements) in place as part of this evaluation; if agreements require legal review; if this does not apply, indicate why]

Privacy

- [Describe what privacy provisions are in place to safeguard participant/client privacy – e.g., de-identification/anonymization of data; potentially identifiable data are only accessed by authorized members of the evaluation team, etc.; if Privacy Officer approval is required; if this does not apply, indicate why]

e-Health/IT Security

- [Detail the different e-Health/IT security provisions in place – e.g., document IT approval for use of a given app/service/technology; note whether data will be transferred over a secure server, how the data will be trafficked and to what jurisdictions; if e-Health/IT approval is required, etc.]

Human Resources (Staff)

- [Detail the human resources needed to implement the project and conduct this evaluation; document whether any team members will be involved/hired for this evaluation, what their role is, and how long they will be involved in the evaluation; if unions will need to be involved in the project; if this does not apply, indicate why]

Data Destruction

- [Describe whether/when the data will be deleted and by which site(s); if this does not apply, indicate why]

Knowledge Dissemination Plan

[Describe the knowledge dissemination plan – e.g., stakeholder reports, marketing materials, conferences, journals, presentations, etc.]

Next Steps

[Describe how the evaluation findings will be applied in the future – e.g., program refinement, to scale the program, solution commercialization, foundation for future evaluation or research activities, etc.]

Resources:

For more information about ethical conduct in research/evaluation practices, please consult the TCPS-2 website at: https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

Case Study 3 - Sunnybrook Health Sciences Centre

Overview of Quality Improvement vs. Research Assessment

It is Sunnybrook's standard operating procedure that Quality Improvement projects undergo a self-screening tool called the Ethics Review Self Assessment Tool (ER-SAT), and be registered with the institution. The QI registration process is accessible through Sunnybrook's intranet. This functions more as a registry rather than review process, and through a search query can link QI leads who may be interested in similar topics for collaboration.

The ER-SAT was developed in house and consists of several online questions which ultimately help to determine if the project is QI or research (requiring REB approval).

If, upon completion of the tool, the determination is not clear, it is recommended the project be submitted for REB review/approval. Submitters may also contact ethics or Quality & Patient Safety for assistance in answering the questions.

The QI Screening & Project Registration process is managed by the Quality & Patient Safety department, with engagement from the Clinical Ethics Centre and Practice Based Research & Innovation. Although submitters (QI Leads) must attest to a number of ethics, privacy and data security statements/requirements, there is no formal review process. However, any project can be reviewed based on the registration data. Each quarter, random projects are selected for review by a small oversight group to ensure appropriateness of the ER-SAT, compliance with the required registration information, and for ongoing improvement of the Screening & Registration process.

When there are questions, the Quality & Patient Safety team, Ethics or REB office refer the project lead to the ER-SAT tool. Submitters may also reach out to the Quality & Patient Safety team or ethics for additional guidance with the ER-SAT if unclear.

Following are links to:

Slide Deck – Screening & Registration Process

Project Registration Form

Screenshots of ER-SAT Screening Process