![Toronto Academic Health Science Network (TAHSN) logo]

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 multiple 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

Institutional Training

SITUATION

Understand and harmonize institutional investigator training requirements related to ethics, responsible conduct of research, privacy etc.

BACKGROUND

The Research Ethics Board Working Group was tasked with reviewing the current clinical research training requirements across TAHSN institutions toward making a recommendation. According to the Network of Networks' (N2)[1] publicly-posted membership list, all TAHSN institutions are members of N2, and therefore have access to the available Collaborative Institutional Training Initiative (CITI) Program training modules outlined below.

ASSESSMENT

Information was obtained through self-report by each institution and compiled into a comprehensive spreadsheet including training type, method, frequency and applicability. The details were reviewed for commonalities which form the basis of each recommendation.

OVERARCHING PRINCIPLES:

1. These are recommendations. Mechanisms to operationalize these recommendations may be required at individual TAHSN institutions.
2. It is the responsibility of the institution to determine training requirements and tracking processes.
3. It is the responsibility of the Research Ethics Board (REB) Chair and office to ensure REB members have completed the Tri-Council Policy Statement (TCPS2) or equivalent.
4. It is the responsibility of the Principal Investigator to ensure their team members - to which they have delegated responsibilities - have completed the applicable training.
5. Documented evidence of training completed in accordance with the recommendations below should be acceptable and transferrable across TAHSN institutions.

University researchers who submit to TAHSN hospitals must follow the training requirements of that hospital. While the University of Toronto is not mandating training requirements for its faculty members, it is strongly recommended that they follow the best practices outlined below

RECOMMENDATIONS*

<u>Ethical Conduct of Research Involving Humans</u>

- **Recommendation:** require completion by all persons involved in the ethical review and/or conduct of human participant research
- **Frequency:** once and with substantive changes to the policy, as determined by the institution
- **Methods available:** TCPS2 Core modules or CITI Basic Biomedical modules (these training methods are considered equivalent)

<u>Good Clinical Practice (GCP)</u>

- **Recommendation:** require completion by all persons involved in the conduct of interventional clinical trials (as applicable to their role)
- **Frequency:** every five (5) years or sooner with substantive changes to the GCP standard, as determined by the institution
- **Methods available:** CITI GCP modules

<u>Health Canada Division 5</u>

- **Recommendation:** require completion by all persons involved in the conduct of clinical trials subject to Division 5 regulations (as applicable to their role)
- **Frequency:** every five (5) years or sooner with substantive changes to the regulations, as determined by the institution
- **Methods available:** CITI Division 5 modules

Responsible Conduct of Research (RCR)

- **Recommendation:** recommend completion by persons involved in research (as applicable to their role)
  - o may also be required as a remedial action where deemed necessary
- **Frequency:** Once and with substantive changes to the Tri-Agency Framework on Responsible Conduct of Research, as determined by the institution
- **Methods available:** CITI RCR modules

Privacy

- **Recommendation:** defer to the TAHSN Privacy working group to make a recommendation on standardized privacy training for the research community, beyond that which is already covered in institutional and university privacy training requirements.
- **Frequency:** defer to Privacy working group for frequency
- **Methods available:** consider CITI Privacy modules (currently under review)

Network of Network SOPs and Training on Dangerous Goods

- **Recommendation:** defer to each institution to manage training requirements as these are very role specific.

University researchers who submit to TAHSN hospitals must follow the training requirements of that hospital. While the University of Toronto is not mandating training requirements for its faculty members, it is strongly recommended that they follow the best practices outlined.

REFERENCES

[1] Network of Networks (N2) Members: https://n2canada.ca/members/