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 specific 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

Use of Clinical Trials Ontario (CTO) for Multi-Centre Studies

SITUATION

Understand and harmonize the use of CTO for multi-centre studies (including clinical trials and minimal risk research) across TAHSN institutions.

BACKGROUND

The purpose of this working group was to review the current practices of TAHSN institutions with respect to how CTO is used for multi-centre studies, in order to put forward a recommendation for harmonization. Most TAHSN institutions are participating sites for CTO[1], while 9 institutions are also CTO-qualified REBs that conduct reviews through the CTO platform[2].

ASSESSMENT

A questionnaire was completed by all TAHSN institutions and the information was summarized in a spreadsheet to allow for comparison across sites. The commonalities observed form the basis of the three recommendations outlined below.

OVERARCHING PRINCIPLES

1. These recommendations are made in the spirit of harmonizing research ethics review of multi-centre research across TAHSN institutions. While CTO provides a mechanism for streamlining ethics review, it is recognized that institutions differ in their resources, capacity and local expertise. It is the responsibility of each institution to determine the level of participation that is appropriate for their site in the CTO model.

2. CTO Stream was originally conceived to streamline the ethics review of clinical trials, however the scope of eligible research has expanded to include minimal risk research. It is recognized that there is a general lack of awareness amongst researchers that CTO Stream may be used for review of all multi-centre studies in Ontario (including observational and other minimal risk research), and is not restricted to the review of clinical trials. It is the responsibility of individual institutions to inform their researchers around what research is eligible to use CTO Stream.

RECOMMENDATIONS

1. Participation in the CTO model as a qualified Board of Record

Recommendation: Institutions that have sufficient local resources, capacity and expertise are encouraged to undergo CTO REB qualification to enable their REBs to act as Boards of Record.

2. Participation in the CTO model as a participating site

Recommendation: Participation in the CTO model as a participating site is encouraged, as it provides a mechanism for streamlined review of multi-centre studies across institutions.

3. Use of the CTO model for multi-centre studies

Recommendation: Participating sites should encourage the use of CTO for all eligible multi-centre studies (including clinical trials and minimal risk research).

REFERENCES

[1]CTO Participating Sites: https://www.ctontario.ca/cto-programs/streamlined-research-ethics-review/participating-sites/

[2]CTO Qualified REBs: https://www.ctontario.ca/cto-programs/streamlined-research-ethics-review/qualified-rebs/