REPORT – Research Ethics Harmonization Working Group
December 1, 2016; Revised March 24, 2017, November 17, 2017, December 12, 2017

Co-Chairs:

- **Dr. Denise Figlewicz**, Vice Dean, Research & Innovation, Schulich School of Medicine & Dentistry, Western University
- **Dr. Jody Merritt**, Professor, School of Business, Human Resources and Management; Team Lead, Research and Innovation; Chair, Research Ethics Board, St. Clair College

Membership:

Ms. Erika Basile	Director, Research Ethics, Research Western	Western University
Dr. Pierre Boulos	Special Advisor Research Ethics Education And Internationalization; Centre for Teaching and Learning; Fellow, Centre for Research on Reasoning, Argumentation, and Rhetoric University of Windsor; President-Elect, International History, Philosophy, and Science Teaching; Vice-President, External Windsor University Faculty Association	University of Windsor
Dr. Mary Broga	Executive Director Lead Agency, Children & Youth Mental Health, Windsor-Essex	Hotel Dieu Grace Healthcare
Dr. Subrata Chakrabarti	Chair/Chief Department of Pathology	London Health Sciences Centre; St Joseph's Health Care; Schulich School of Medicine & Dentistry, Western University
Dr. Nicole Chabot	Research Coordinator, Faculty of Health Sciences	Western University
Dr. David Hill	Scientific Director	Lawson Health Research Institute
Ms. Marla Jackson	Manager, Research & Innovation	Hotel Dieu Grace Healthcare
Ms. Julie Joza	Senior Manager, Office of Research Ethics	University of Waterloo
Dr. Jo Kapalanga	Chief, Pediatrics; Medical Geneticist; Adjunct Professor	Grey Bruce Health Services / Schulich School of Medicine & Dentistry, Western University
Dr. Marlys Koschinsky	Scientific & Executive Director	Robarts Research Institute
Dr. Otte Rosenkrantz	Chair, Research Ethics Board	Fanshawe College

Working Group mandate:

Before the reorganization process was finalized in September 2017, SWAHN's Research Ethics Harmonization Working Group (REHWG) fell under the direction of the SWAHN Knowledge Generation and Translation Committee (KGTC). (NOTE: SWAHN's Standing Committees, like the KGTC, have been replaced with three new streams including Interprofessional Collaboration, Knowledge Generation & Translation, and Networking & Engagement in alignment to the Network's value proposition.)

The purpose of the REHWG was to explore potential frameworks with respect to developing a process for agreements involving organizations that contribute to SWAHN. In particular, the goal was to facilitate ethics approvals when working together on research initiatives that are in keeping with SWAHN's mission to improve the health of Southwestern Ontario's population. (NOTE: The Working Group's efforts focused on research that involves human subjects (only) and SWAHN-related projects.)

This mandate was reconfirmed at the SWAHN Retreat in April 2016 as research ethics harmonization was highlighted as a clear priority of SWAHN stakeholders. Erika Basile, Director, Research Ethics, Western University offered a presentation at the retreat on the state of research ethics harmonization in Ontario. In the post-presentation discussions, it was suggested that the Working Group should focus on a project to standardize submission forms across the region. A survey of existing research ethics approval practices across SWAHN stakeholders was also suggested.

Meetings:
The REHWG was assembled in 2016. At its September 2016 meeting, Susan Marlin, CEO, Clinical Trials Ontario (CTO) offered a slide presentation to the Working Group which included an overview of CTO and its efforts to develop a coordinated review process for clinical trials. (A process for health research studies which are not clinical trials was under development at that time.) It was noted that SWAHN's stakeholders could consider developing participation agreements with CTO to manage multi-site ethics approvals. While CTO has not engaged colleges to date, Susan indicated that they are willing to explore this opportunity.

Clinical Trials Ontario webinar:
The presentation offered by Susan Marlin at the REHWG's September meeting was the impetus to arranging a webinar on November 10, 2016 for the REHWG and other interested SWAHN stakeholders to discuss CTO's streamlined research ethics review system and processes in more depth. Over 160 individuals were invited to attend the webinar led by CTO Program Managers Erin Bell and Matthew D'Ascanio. In total there were 17 individuals who participated.

In addition to sending an electronic copy of each form, the CTO webinar hosts highlighted the following components of the CTO process:

- **Overview of CTO:**
  - Independent non-profit, established in June 2012 and funded by the Government of Ontario through the Ministry of Research & Innovation.
  - Established to address the decline in clinical trials in Ontario and leverage Ontario's clinical research capabilities to attract more investment.
  - A list of participating sites is posted on CTO website.

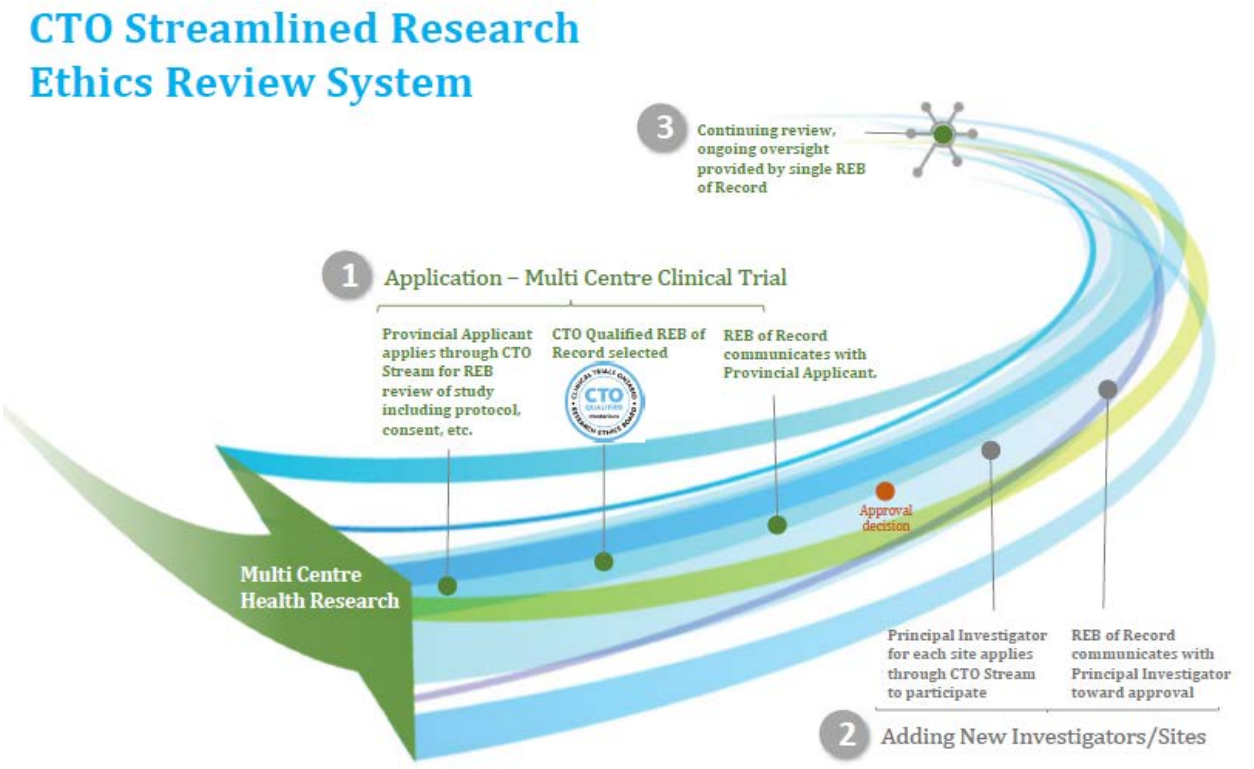
- **CTO's online system:**
  - The system can be used by any multi-centre clinical trial involving two or more academic institutions or public health care institutions (academic hospitals, community hospitals, universities) in Ontario. **(Private clinics and physician offices are not currently part of the CTO system.)**
  - Specialized application forms for multi-centre non-interventional (non-clinical) health research were launched in October 2017.

- **CTO streamlined research ethics review process:**
  - Study approval:
    - REB application submitted by lead investigator, i.e. "Provincial Applicant"
      Note: When an application is submitted in CTO Stream by the Provincial Applicant, other sites involved in the study will be notified of the submission.
    - CTO Qualified REB of Record selected, application advances to REB
    - REB of Record reviews application and resolves any issues with applicant
    - If/when issues are resolved REB of Record approves study

- Sites wishing to participate are notified and given access to REB approved study in CTO system

- Adding/recruiting sites:
  - Recruiting Institution signs REB of Record Agreement, delegating ethics review and oversight to REB of Record; Local PI adopts approved consent form and submits site application focused on site specific information
  - Site application advances to REB of Record
  - REB of Record Host Institution signs REB of Record Agreement and REB reviews application (usually expedited) and resolves any issues with site applicant
  - REB of Record issues approval for site to participate

- Continuing oversight/approval:
  - New overall (study-level) event, e.g. amendment, Data Safety Monitoring Board report, safety update
    - *Documentation submitted by "Provincial Applicant"*
    - *REB of Record reviews submission and resolves issues with provincial applicant*
    - *Approval/ acknowledgement issued by REB of Record; sent simultaneously to all approved participating sites*
  - New site level event, e.g. continuing review, local Serious Adverse Event, protocol deviation
    - *Documentation submitted by research site*
    - *REB of Record reviews submission and resolves issues with research site*
    - *Approval/acknowledgement issued by REB of Record*



CTO, c.2016

- **Approval/access to the system:**
  - Execute Participation Agreement with CTO
    - Developed by legal counsel and others from multiple institutions across the province

    - Outlines relationship and responsibilities between CTO and Participating Institutions
    - Consulted with major insurers in the province (HIROC, MARSH, CURIE) around insurance and liability language
    - Includes a template REB of Record Agreement, executed between the "Host Institution" of the REB of Record, and each recruiting site, for each study
  - CTO has indicated that it would welcome a discussion with any institution that has an interest in working through a participation agreement with the organization. (This invitation is extended to organizations beyond universities and hospitals.)
  - **To initiate a conversation with CTO, please contact Erin Bell, Program Manager, Streamlined Research Ethics Review: 416.673.6670, erin.bell@ctontario.ca**

- **Institutions engaging in a study:**
  - By acting as a Provincial Applicant
  - By acting as a recruiting site:
    - Institution must sign-off electronically on centre application in CTO Stream before it can go to REB of Record
    - REB of Record Study Agreement will be executed
  - By acting as the REB of Record (CTO Qualified REBs)

- **Technical facts:**
  - The web-based application for research ethics review is accessible from any location using multiple browsers.
  - The system is designed for any user regardless of technical knowledge or capabilities –no previous experience is required.
  - Every user has his/her own customizable dashboard which provides central point of access for all studies.
  - Email and in-software notifications are available.

- **Most pertinent to the mandate of this Working Group:**
  - All researchers will be using a standardized set of forms regardless of which REB is acting as the REB of Record.

Recommendation:
Based on the information shared by CTO, and the organization's openness to work with SWAHN-affiliated academic institutions and hospitals, the Research Ethics Harmonization Working Group and SWAHN's Secretariat proposes that institutions engaged with SWAHN adopt the CTO Stream as the solution to the challenge of research ethics approvals involving multi-site studies. (Application forms for multi-site observational health research (i.e., non-clinical studies) became available in October 2017.)

NOTES:

1. *There is only a financial cost to participate in CTO's streamlined process if the study is industry-sponsored. This cost is charged directly to the industry sponsor. (See the CTO fee schedule for industry-sponsored studies.) CTO does not charge fees if the study is investigator-initiated. This is based on the assumption that the CTO system will not be replacing a current system supported by SWAHN institutions (i.e., if an organization wanted to replace the system for ethics approvals that they are currently using with CTO's system, there would be a charge to do so).*

2. *Principal investigators or their sponsors will decide upon the sites they wish to include in a study before the ethics review is submitted, as part of the study planning process.*

3. *If an organization develops a participation agreement with CTO, they are not bound to the use of CTO for every single research study.*

4. *CTO will make every effort to ensure that a study initiated for a SWAHN project is sent to a Board of Record within the SWAHN region for review. When submitting a proposal for a SWAHN-specific*

study, investigators must clearly indicate "SWAHN" in the submission. NOTE: For organizations in the SWAHN region that have a CTO participation agreement in place, these organizations may submit their own multi-site studies through the CTO Stream (i.e., non-SWAHN studies). The CTO process for choosing the REB of Record is available at: http://www.ctontario.ca/cms/media/Schedule-B-CTO-Assignment-of-the-REB-of-Record1.pdf

5. *If the study is industry-sponsored, then the review may be assigned to a CTO-approved Board of Record in Ontario outside of the SWAHN region.*

6. *A list of qualified CTO Boards of Record can be found here. (As of December 5, 2017, Western University is the only CTO Qualified REB in the SWAHN region.)*

7. *CTO's REB of Record selection criteria can be found here.*

8. *A list of sites with CTO Participation Agreements can be found here.*