Clinical Trials Ontario

CTO Streamlined Research Ethics Review System

Making Ontario a preferred location for global clinical trials, while maintaining the highest ethical standards.

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About Clinical Trials Ontario

- Clinical Trials Ontario (CTO) is an independent, not-for-profit organization.
- Established in 2012 with seed funding from the Government of Ontario – $4.5 million over 4 years in response to:
- Significant decline in clinical research in Ontario
    - 2009: $550m | 2010: $500m | 2011: $438m (pharma investment)
- Stakeholder recommendations regarding what would help

- Mandate for CTO – provide a **streamlined approach to conducting multi-centre clinical trials** in Ontario while **maintaining the highest ethical standards for participant protection.**

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The Vision of Clinical Trials Ontario

The vision of CTO is being advanced upon 3 strategic pillars:

1. Improving speed and reducing costs of multi-centre clinical trials by streamlining the research ethics approval process and harmonizing other administrative processes and platforms.

2. Attracting clinical trial investments to Ontario based on CTO's success in streamlining activities and by leveraging strategic partnerships with investigators, industry and government to access global decision makers.

3. Improving participant recruitment and retention through education, and by engaging participants and the public in recognizing the benefits of clinical trials.

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The CTO Streamlined Research Ethics Review System

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The CTO Streamlined Research Ethics Review System

Supports any CTO 'Qualified' REB in Ontario in providing ethics review and oversight of a multi-centre clinical trial on behalf of multiple research sites across the province.

Two Primary Components

1. Research Ethics Board (REB) Qualification Program

- Offers external review and qualification of REBs against a standard (i.e. checklist) informed by regulations/guidelines applicable to ethics review of clinical/health research
- Required for any REBs participating in the CTO Streamlined Research Ethics Review System
- Qualification Reviews conducted by a team composed of an REB auditor and experienced members of the REB community (see College of Reviewers)
- Qualified Status remains in effect for 3 years (with brief annual reports)

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The CTO Streamlined Research Ethics Review System

2. Research Ethics Board (REB) Qualification Program

- Based on ‘delegated board of record model’; a Qualified REB is delegated by participating institutions the responsibility to provide ethical oversight for a study conducted across multiple institutions – “one study, one REB”

- Infrastructure includes web-based information technology system, policies and procedures, tools and education

To obtain the CTO REB Qualification Manual and other info about the Qualification Program, visit **ctontario.ca**

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Key Features of the CTO Research Ethics Review System

The CTO System is expected to provide significant benefits to sponsors, investigators, institutions and REBs conducting multi-centre clinical research by harmonizing processes and reducing time and effort required to initiate research across multiple sites in Ontario.

- Supports a single REB in providing research ethics review and oversight to multiple research sites
- Can be used for any multi-site clinical research, i.e. industry sponsored or investigator initiated
- Offers a web-based information technology system that will enable research ethics reviews, document management and communication across multiple REBs and institutions
- Ensures that all REB reviews done through the CTO system are conducted by high-quality REBS that have achieved Qualification status
- Investigators/applicants will use the same interface and REB application forms, irrespective of which REB is providing oversight
- Consistency in submission requirements
- Timely and reliable distribution of study events (e.g. safety updates, amendments) between the REB and multiple institutions
- Transparent and timely information to applicants regarding REB review status

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Delegated Board of Record Model

Initial Application Process

Step 1: Applying for a New Multi-Centre Clinical Trial

REB application submitted by any registered investigator/site, i.e. “Provincial Applicant”

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CTO assigns Board of Record (any Qualified REB in Ontario) and advances application

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Board of Record reviews application and resolves any issues with applicant

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Once issues are resolved Board of Record approves study

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Participating sites are notified and given access to REB materials in CTO system

Step 2: Adding New Investigators/ Research Sites

Site adopts approved Informed Consent Form. Submits site application focused on site specific information

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Site application advances to Board of Record

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Board of Record reviews application (usually expedited) and resolves any issues with site applicant

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Board of Record issues approval for site to participate

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Delegated Board of Record Model

Continuing Oversight and Approval

New overall (study-level) event, e.g. amendment, Data Safety Monitoring Board report, safety update

Documentation submitted by "Provincial Applicant"

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Board of Record reviews submission and resolves issues with prov. applicant

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Once issues are resolved, approval or acknowledgement is issued by Board of Record and sent **simultaneously** to all **approved** participating sites

New site level event, e.g. continuing (annual) review, local Serious Adverse Event, protocol deviation

Documentation submitted by research site

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Board of Record reviews submission and resolves issues with research site

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Approval or acknowledgement issued by Board of Record

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Supports for the CTO Streamlined Research Ethics Review System

College of Reviewers

- Members of the College will serve a minimum 2 year term, and participate in up to a maximum of 3 REB reviews/year.
- Members will require Tri-Council Policy Statement (TCPS 2) training, and at least one member of the Qualification Review team will have Good Clinical Practice (ICH-GCP) and Health Canada Food and Drugs Regulation (FDR) Division 5 training.

Common Application Forms

- Common set of application forms for research ethics review have been developed
- Based on the common elements identified through a national survey of forms (SPOR-SHRER), and advice from CTO Research Ethics Advisory Group and e-Forms Working Group, composed of REB operations experts from across Ontario

REB Standard Operating Procedures

- REBs must have Standard Operating Procedures (SOPs) in place in order to undergo a Qualification Review.
- CTO providing arms-length support for Networks of Networks (N2) / Canadian Association of Research Ethics Boards (CAREB) commitment to develop standard REB SOPs

Community Engagement in Building CTO

Our industry, hospital, university, research, and research ethics communities continue to collaborate with CTO in the development and implementation of our programming. Our community is building CTO with us.

Advisory Groups and Committees

- CTO Working Groups:
  - REB Streamlining
  - IT Harmonization and Performance Metrics
  - Legal and Liability
- Research Ethics Review Advisory Group
- Technical and REB Operational Group
- eREB RFP Evaluation Committee
- E-forms Working Group
- mCTA Ontario Team
- Patient Engagement Advisory Group
- Industry Advisory Committee

CTO Board of Directors and Member Representatives

Board of Directors

Arthur Slutsky (Chair)
Vice-President, Research, St. Michael's Hospital

Mark Lundie (Vice-Chair and Secretary)
Regional Director, R&D, Pfizer Canada

Michael Owen (Treasurer)
Vice-President, Research, Innovation & International, UOIT

Raphael Saginur
Chair, Ottawa Health Science Network Research Ethics Board

James Wilson
President, Brancorth Medical Inc.

Anne Ellis
Associate Professor and Chair, Department of Medicine, Queen's University

Clive Ward-Able
Executive Director, R&D, Amgen

Raphael Hofstein
Chief Executive Officer and President, MaRS Innovation

Michael Wood
Director, Office of Research & Innovation, North York General Hospital

Institutional Member Representatives

Council of Academic Hospitals of Ontario (CAHO)
Karen Michell, Executive Director

Canada's Medical Technology Companies (MEDEC)
James Wilson, President, Brancorth Medical Inc.

Canada's Research-based Pharmaceutical Companies (Rx&D)
Jared Rhines, Vice President, Scientific and Strategic Affairs

Industrial Biotechnology Association of Canada (BIOTECanada)
Alison Vanlerberghe, Director, Market Access, Celgene

Council of Ontario Faculties of Medicine (COFM)
Alison Buchan, Vice Dean Research and International Relations, Faculty of Medicine University of Toronto

Ontario Council on University Research (OCUR)
Michael Owen, Vice-President, Research, Innovation & International, University of Ontario Institute of Technology

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Building CTO

CTO Team

- **Susan Marlin**, President and CEO
- **Manal Siddiqui**, Manager
- **Jessa Gill**, eREB Project Manager
- **Suzanne McGovern**, Program Coordinator
- **Andrew Milroy**, Program Coordinator
- **Margaret Polanyi**, Senior Communications Specialist (part-time)
- **Sean Power**, Communications Specialist (part-time)
- **Anita Sengar**, Lead REB Qualification Program Auditor (part-time)
- **Delilah Ofosu-Barko**, REB Qualification Program Auditor (part-time)

Community Expertise

- **Janet Manzo**, Executive Director OCREB (Multi-centre ethics review expertise)
- **Lam Pho**, Director of IT, NCIC CTG (IT & Multi-centre clinical trials expertise)
- **Terry Liu**, Sr. Business Systems Analyst, OCREB (Multi-centre ethics review systems implementation expertise)
- **Teddy Brown** - Programming Support
- **Lorelei Nardi**, REB Program Manager at the Hospital for Sick Children (REB operations expertise)
- **Erika Basile**, Director, Research Ethics, Western University (REB operations expertise)
- **Linda Bennett**, Executive Director, Canadian Rheumatology Research Consortium (Participant Engagement/Asset Map)
- **Chris Riddle**, Governance/Board Support
- **Andy Scotter**, Procurement Specialist, Queen's University
- **Kevin Cheung**, Sunnybrook Health Sciences Centre (IT/RFP expertise)

For More Information

Go to ctontario.ca

To find out more about the CTO Streamlined System, contact us at info@ctontario.ca

To request Qualification status or learn more about the Qualification Program, write to us at: qualification@ctontario.ca

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@clinicaltrialON

linkedin.com/company/clinical-trials-ontario

Clinical Trials Ontario
661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
Canada M5G 1M1
Tel / 416.276.1381

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