CLINICAL
TRIALS
ONTARIO

655 Bay Street, Suite 600
Toronto, Ontario
M5G 2K4 Canada
ctontario.ca

Clinical Trials Ontario Call for Nominations for Working Groups

August 8, 2012

Clinical Trials Ontario held its inaugural meeting in late July to provide attendees with its operational priorities in year one (Presentations are available at http://www.ctontario.ca/resources). As a result of input at this meeting, Clinical Trials Ontario is establishing three expert Working Groups from a broad cross-section of stakeholders to provide experienced advice on some key aspects of the organization's five core projects:

1. Develop Ontario Standards to support the Delegated Board of Record Review Model (harmonized with national and international standards);
2. Define a framework for streamlining research ethics review to support a Delegated Board of Record Review Model;
3. Develop a Standard Operating Procedure to support the implementation of the Delegated Board of Record review system for Ontario;
4. Propose a technological solution for online administrative and application systems in support of the Delegated Board of Record Review Model; and
5. Develop appropriate performance metrics and targets to demonstrate the impact of Clinical Trials Ontario's streamlining activities.

The three Working Groups will be comprised of 6 to 8 Members with each Member serving for a period of 4 to 5 months, depending on the Working Group (please refer to the applicable draft Terms of Reference below). Clinical Trials Ontario will provide administrative and contractor support for all the Working Groups to draft documents arising from the discussions. Clinical Trials Ontario will also provide external experts for support of the Working Group as required.

Expressions of interest (name and organizational affiliation) and relevant professional experience should be forwarded to the contact information below by **Friday, August 17, 2012** (appointments expected to be made by August 27, 2012). We encourage participation from the broad Ontario clinical trials stakeholder community. Please circulate this Call for Nominations as widely as possible to appropriate individuals or organizations, including those that were not in attendance at the inaugural meeting.

For further information, please contact:

Ronald Heslegrave, Ph.D.
Executive Director, Clinical Trials Ontario
655 Bay Street, Suite 600, Toronto, ON M5G 2K4
Phone: (647) 847-3129
Email: Ron.Heslegrave@ctontario.ca

CLINICAL
TRIALS
ONTARIO

655 Bay Street, Suite 600
Toronto, Ontario
M5G 2K4 Canada
ctontario.ca

About Clinical Trials Ontario

Clinical Trials Ontario is an independent not-for-profit organization that has been established through the Ministry of Economic Development and Innovation as part of Ontario's Life Sciences Commercialization Strategy. Our mandate is to make Ontario a preferred location for global clinical trials in the life sciences industry by initially streamlining the ethical and administrative processes for multi-centre clinical trials while ensuring the highest ethical standards for patient safety. For more information, please visit http://www.ctontario.ca/.

Draft Terms of Reference

Working Group One:
Research Ethics Board Review Streamlining

PURPOSE	To provide expert advice to help guide the implementation of the following aspects of Clinical Trials Ontario's activities: 1. Develop Ontario Standards to support the Delegated Board of Record Review Model (harmonized with national and international standards); 2. Define a framework for streamlining research ethics review to support a Delegated Board of Record Review Model; and 3. Develop a Standard Operating Procedure to support the implementation of the Delegated Board of Record review system for Ontario.
RESPONSIBILITIES	■ Evaluate the current parallel initiatives related to REB standards and put forward recommendations for implementation of a province-wide mechanism for Ontario REB standards; ■ Provide feedback on options for an REB credentialing process; ■ Develop Standard Operating Procedures to support the Delegated Review process, including the criteria that will be used for the selection of a Delegated Board of Record; and ■ Develop recommendations for the pilot study roll-out of the new streamlined REB review system.
MEMBERSHIP	Membership should represent a wide range of perspectives from across the broad Ontario clinical trials stakeholder community. Considerations for nominations will include, but are not limited to, standards, accreditation and operational experience, geographical location, and leaders in healthcare (academic and community hospitals), academic institution research ethics boards, and private industry (including CROs and private ethics review services). The position of Chair will be determined by Clinical Trials Ontario. Clinical Trial Ontario will be represented as an ex-officio member of the Working Group.
LENGTH OF TERM	August 29 – December 21, 2012
KEY DELIVERABLES	1. Recommendations for an Ontario REB Standard and credentialing process — **October 26, 2012** 2. A Standard Operating Procedure for implementation of the Delegated Board of Record Review model — **November 20, 2012** 3. Recommendations for rolling-out the pilot study — **December 14, 2012**
FREQUENCY OF MEETINGS	4 monthly in-person meetings with additional meetings by teleconference or alternative means as required.

Draft Terms of Reference

Working Group Two:
Information Technology Harmonization

PURPOSE	To provide experienced advice on the following aspects of Clinical Trials Ontario's activities: 1. Evaluate the current online and administrative application systems utilized by REBs; 2. Develop recommendations for a technological solution for online administrative and application systems in support of the Delegated Board of Record Review Model; and 3. Develop appropriate performance metrics and targets to demonstrate the impact of Clinical Trials Ontario's streamlining activities.
RESPONSIBILITIES	■ Provide recommendations and/or options for a technological solution to support institutional requirements for REB communications with investigators, sponsors and REBs; ■ Develop recommendations for the implementation of a technological solution and provide input into the development of an RFP; ■ Suggest key performance metrics to demonstrate the impact of the Delegated Board of Record Review Model; and ■ Provide advice on performance targets that need to be achieved to ensure that the streamlining initiatives are effective.
MEMBERSHIP	Membership should represent a wide range of perspectives from across the broad Ontario clinical trials stakeholder community. Considerations for nominations will include, but are not limited to, technological, regulatory and operational expertise in electronic REB application and communication systems, geographical location, and leaders in healthcare (academic and community hospitals), institutional research ethics boards, and private industry (including pharmaceutical, medical device, biotechnology industries, CROs and private REB companies). The position of Chair will be determined by Clinical Trials Ontario. Clinical Trial Ontario will be represented as an ex-officio member of the Working Group.
LENGTH OF TERM	August 29, 2012 – January 31, 2013
KEY DELIVERABLES	1. Recommendations on options for a technological solution — **November 2, 2012** 2. Provide provisional performance metrics to assess the impact of Clinical Trials Ontario activities and propose the most effective manner to collect and analyze these metrics. — **December 2, 2012** 3. Recommendations for implementing the preferred technological solution in support of the Delegated Review Model — **January 14, 2013**
FREQUENCY OF MEETINGS	4-5 monthly in-person meetings with additional meetings by teleconference or alternative means as required.

Draft Terms of Reference

Working Group Three:
Institutional Legal Agreements

PURPOSE

To provide experienced advice on the following aspects of Clinical Trials Ontario's activities:

1. Establish the most suitable mechanism for an Institutional Agreement between Clinical Trials Ontario and participating institutions to support the Delegated Board of Record Review model;
2. Develop draft Institutional Agreements that best support the Delegated Board of Record Review Model at the institutional level; and
3. Provide advice on how to implement such agreements.

RESPONSIBILITIES

- Evaluate existing inter-institutional agreements;
- Determine the most appropriate inter-institutional agreement approach;
- Provide recommendations on the legal implications of institutional agreements through Clinical Trials Ontario to support the Delegated Board of Record Review Model;
- Provide a draft of a proposed Institutional Agreement between Clinical Trials Ontario and participating Institutions;
- Provide recommendations on additional documents necessary to support such an agreement; and
- Evaluate enhanced institutional liability issues and implications for the insurer (HIROC) associated with the implementation of the Delegated Board of Record Review Model.

MEMBERSHIP

Membership should represent a wide range of perspectives from across the broad Ontario clinical trials stakeholder community. Considerations for nominations will include, but are not limited to, legal, insurance, and operational experience, geographical location, and leaders in healthcare (academic and community hospitals), academic institution legal representatives, and private industry (including CROs and private ethics review services).

The position of Chair will be determined by Clinical Trials Ontario.

Clinical Trial Ontario will be represented as an ex-officio member of the Working Group.

LENGTH OF TERM

August 29 – December 21, 2012

KEY DELIVERABLES

1. Recommendations on the most appropriate mechanism and legal implications arising out of agreements between Clinical Trials Ontario and participating Institutions	**October 12, 2012**
2. Evaluation of Insurance and Liability Implications	**November 9, 2012**
3. Draft Institutional Agreement to support the Delegated Board of Record Review model	**December 7, 2012**

FREQUENCY OF MEETINGS

3-4 monthly in-person meetings with additional meetings by teleconference or alternative means as required.