CLINICAL TRIALS ONTARIO

661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
M5G 1M1 Canada
www.ctontario.ca

Preliminary Questionnaire

The purpose of the Preliminary Questionnaire is to assist the REB and the CTO Qualification Team in preparing for the on-site review process. Please complete and sign the Preliminary Questionnaire and email it to CTO along with the documents requested.

Please complete form by either checking the appropriate box and/or providing responses as applicable. Attach additional sheets as necessary.	
SECTION 1 - General Information	
a) Name of Institution Click to enter institution name.	(b) Name of Research Ethics Board (REB) **A separate questionnaire should be completed for each REB** Click to enter REB name.
c) Does the REB have any subcommittees or panels? Yes ☐ No ☐ If yes, please provide the purpose and focus of review for each subcommittee or panel: Click to enter purpose and focus of review.	
d) Please describe any affiliated institutions or external sites for which the REB is a Board of Record: Click to enter description of affiliated institutions/external sites.	
e) Are there formal agreements covering the Board of Record arrangements with each of the affiliated institutions or external sites? Yes ☐ No ☐	
f) Is there an Annual Report available either electronically or in hard copy? Yes ☐ No ☐ If yes, please provide a hard copy or the link to an online version: Click to enter link to online version if applicable.	

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SECTION 2 - REB Standard Operating Procedures

a) Please select one of the following options to submit your REB Standard Operating Procedures (SOPs) to CTO:

☐ Option 1: Copy of REB SOPs enclosed

☐ Option 2: REB SOPs are publicly available. Please provide website link:

Click to enter link to online version if applicable.

b) Are any SOPs under revision or currently being developed and have not been submitted?

Yes ☐ No ☐

If yes, please list the titles of these SOPs and the expected completion date:

Click to enter title and completion date of SOPs being revised/developed.

SECTION 3 - REB Governance

a) Please describe the formal reporting relationship of the REB to the home institution:

Click to enter description of formal reporting relationship of the REB.

b) Please describe the formal reporting relationship of the REB Office, and personnel within the office, to the REB/institution:

Click to enter description of formal reporting relationship of REB Office.

c) If available, please provide an organizational chart(s) depicting the reporting relationships of the REB and the REB office.

Enclosed ☐ Not Available ☐

SECTION 4 - REB Membership

a) Please select one of the following options to submit your REB membership list (including name, qualifications, gender, citizenship and areas of expertise and role(s) each member serves on the REB) to CTO. If the REB has subcommittees or panels please provide the membership for these as well.

☐ Option 1: Copy of REB membership enclosed

☐ Option 2: REB membership is publicly available. Please provide website link:

Click to enter website link if applicable.

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b) Are any changes expected to the REB membership in the near future?

Yes ☐ No ☐

If yes, please describe:

Click to enter description of REB membership changes if applicable.

SECTION 5 - REB Office/Administrative Support

a) Please provide a list of individuals working with the REB (e.g., REB Operations Personnel), their roles and responsibilities:

Click to enter name, role and responsibilities of individuals working with the REB.

SECTION 6 - Research Reviewed by the REB

a) Please estimate how many reviews the REB conducts annually in each of the categories:

Click to enter # Initial Reviews

Click to enter # Continuing Reviews/ Renewals

Click to enter # Amendments

Click to enter # Reportable Events (unanticipated problems, deviations, etc.)

b) Please provide a brief description of the types of studies reviewed by the REB (e.g. clinical trials, epidemiologic studies, etc.):

Click to enter brief description of types of studies reviewed.

c) Please indicate how often your REB meets:

Click to enter how often your REB meets.

d) Are the meeting dates and deadline dates for REB submissions publicly posted?

Yes ☐ No ☐

If yes, please provide website link:

Click to enter website link to REB meeting/submissions dates if applicable.

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e) Please provide a brief description of any metrics collected by the REB (e.g., time from meeting to letter issuance, etc.):

Click to enter description of metrics.

SECTION 7 - REB Records

a) Are REB records (minutes, correspondence, etc.) available for inspection?

Yes ☐ No ☐

b) Please indicate where and how REB records are stored. If records are stored electronically, please provide website link:

Click to enter where and how REB records are stored, and provide link if applicable.

c) Please describe measures to protect the privacy and confidentiality of the records:

Click to enter description of measures to protect privacy and confidentiality.

d) Please provide the following documents as part of the Qualification package:

1. REB Application forms (Initial submission, Amendments, Continuing Review, Unanticipated Problems):

☐ Option 1: Enclosed

☐ Option 2: Publicly available. Please provide website link:

Click to enter link to online version if applicable.

2. Guidance documents, terms of reference, policies, templates:

☐ Option 1: Enclosed

☐ Option 2: Publicly available. Please provide website link:

SECTION 8 – Institutional Contacts

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a) Please provide the name of the institutional contact(s) for the REB (such as the Vice-President, Research), for the institution hosting the REB and institution(s) the REB serves:

Contact Name	Contact Role	Contact Email	Institution Name
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.	Click here to enter text.	Click here to enter text.

SECTION 9 - Review Focus

b) If you have any areas of compliance you would like the reviewers to pay particular attention to, please describe:

Click to enter areas of compliance for special attention.

This form has been completed by:

Print Name: Click to enter name.	**Signature:**
Title: Click to enter title.	**Date:** Click here to enter a date.