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Preliminary Questionnaire

The purpose of the Preliminary Questionnaire is to assist the REB and the Qualification Team in preparing for the on-site review process. Please complete and sign the Preliminary Questionnaire and email it to CTO at **qualification@ctontario.ca** 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	(b) Name of Research Ethics Board (REB) **A separate questionnaire should be completed for each REB**
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:	
d) Please describe any affiliated institutions or external sites for which the REB is a Board of Record:	
e) Are there formal agreements covering the Board of Record arrangements with each of the affiliated institutions or external sites? ☐ Yes ☐ No	

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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:

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:

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:

SECTION 3 - REB Governance

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

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

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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:

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

☐ Yes ☐ No

If yes, please describe:

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:

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SECTION 6 - Research Reviewed by the REB

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

Initial Reviews	Continuing Reviews/ Renewals
Amendments	Reportable Events (unanticipated problems, deviations, etc.)

b) How many studies (total) are currently approved and require ongoing review by the REB?

(i) How many of these are clinical trials?

(ii) How many of these are multi-centre clinical trials?

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

d) Please indicate how often your REB meets:

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

☐ Yes ☐ No

If yes, please provide website link:

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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.):

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:

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

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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:

2. Informed Consent form templates

☐ Option 1: Enclosed

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

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SECTION 8 - REB Compliance Inspections

a) Has the REB been inspected by a regulatory agency such as the Food and Drug Administration within the last 5 years?

☐ Yes ☐ No

If Yes:

	When was the inspection? (YYYY/MM/DD)	Type of inspection		Is the report available for review?	
		Routine	For Cause		
1	s	☐	☐	☐ Yes	☐ No
2		☐	☐	☐ Yes	☐ No
3		☐	☐	☐ Yes	☐ No

b) Does the REB hold an accreditation?

☐ Yes ☐ No

If Yes:

(i) Name of the accreditation:

(ii) Accreditation Expiration Date:

SECTION 9 - Regulatory Compliance

a) Please indicate what regulations, policies, etc. your REB is either required to comply with or complies with on a voluntary basis.

	Compliance?	
Canadian Food and Drugs Act and applicable Regulations	☐ Yes	☐ No
US Code of Federal Regulations	☐ Yes	☐ No
ICH GCP	☐ Yes	☐ No
PHIPA and Ontario Regulation 329/04	☐ Yes	☐ No
Tri-Council Policy Statement (TCPS 2)	☐ Yes	☐ No
Other (Please specify):		

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SECTION 10 – Institutional Contacts

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

SECTION 11 - Review Focus

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

This form has been completed by:

Print Name:	**Signature:**
Title:	**Date:**