

Annual Report for CTO Qualified REBs

This report is intended to collect information about any changes occurring over the last year (e.g., since the Qualification review or previous annual report). Please complete and sign this report and email it to CTO at qualification@ctontario.ca along with the documents requested.

Please complete this form by either checking the appropriate box and/or providing responses as applicable.	
Annual Report Due Date (YYYY/MM/DD):	
SECTION 1 - General Information	
a) Name of Qualified Research Ethics Board (REB)	(b) CTO Qualification Date
<p>c) Is there an Annual Report available either electronically or in hard copy?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide a hard copy or the link to an online version:</p>	
SECTION 2 – REB Governance, Mandate, Authority, Membership	
<p>a) Have there been any changes to the REB governance, mandate or authority in the past year?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide details of the changes, and any supporting documents as applicable:</p>	
<p>b) Have there been any changes to the REB membership in the past year?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide details of the membership changes:</p> <p><input type="checkbox"/> Option 1: Copy of current REB membership list enclosed</p> <p><input type="checkbox"/> Option 2: Current REB membership list is publicly available. Please provide website link:</p>	

Making Ontario a preferred location for Global Clinical Trials, while maintaining the highest ethical standards.

SECTION 3 - REB Standard Operating Procedures

a) Have there been any changes to the REB Standard Operating Procedures (SOPs) in the last year?

Yes No

If yes, please provide details of the changes:

- Option 1:** Copy of REB SOPs enclosed
- Option 2:** REB SOPs are publicly available. Please provide website link:

SECTION 4 - REB Templates and Application Forms

a) Have there been any changes to the REB's template Informed Consent Form, Consent form guidance documents or checklists (as applicable) in the last year?

Yes No

If yes, please provide details of the changes:

- Option 1:** Copy of updated materials enclosed
- Option 2:** Materials are publicly available. Please provide website link:

b) Have there been any changes to the REB application form(s) in the last year?

Yes No

If yes, please provide details of the changes:

- Option 1:** Copy of updated materials enclosed
- Option 2:** Materials are publicly available. Please provide website link:

Making Ontario a preferred location for Global Clinical Trials,
while maintaining the highest ethical standards.

SECTION 5 - REB Compliance Inspections				
<p>a) Has the REB been inspected by a regulatory agency such as the Food and Drug Administration within the last year?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If Yes:</p>				
	When was the inspection? (YYYY/MM/DD)	Type of inspection		Is the report available for review?
		Routine	For Cause	
1		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No
2		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No
SECTION 6 – Other Material Changes				
<p>a) Have any other material changes (e.g., related to the CTO REB Qualification Checklist) been made in the last year?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please provide details of the changes:</p> <p>Please provide copies of associated material as applicable</p>				
This form has been completed by:				
Print Name:		Signature:		
Title:		Date:		

Making Ontario a preferred location for Global Clinical Trials, while maintaining the highest ethical standards.