

Questionnaire - Scope of REB Review

This questionnaire is intended to identify areas of expertise and the scope of reviews conducted by REBs participating in the REB Qualification program. Please complete this questionnaire and submit to CTO as part of the Qualification/Re-Qualification package.

It is important that REBs serving as an REB of Record have the experience and expertise necessary to provide a high quality review. Additionally, where there is opportunity to do so, CTO would like to match REBs with specific expertise to reviews requiring such expertise.

The information you provide below will help CTO in determining which REB is appropriate to act as an REB of Record. The information you provide will be discussed during the Qualification review and may be modified prior to finalization.

Please complete this form by either checking the appropriate box and/or providing responses as applicable.

Name of REB:

SECTION 1 – Study Types

1. Which of the following study types does the REB currently oversee:

Clinical Trials (interventional studies)

Approximate number of new CT in the last 12 months:

- None
- 1-10
- 11-20
- 21+

Non-interventional health outcome studies

Number of new non-interventional health outcome studies in the last 12 months:

- None
- 1-10
- 11-20
- 21+

FDA/OHRP (US) regulated studies

Number of new FDA/OHRP regulated studies in the last 12 months:

- None
- 1-10
- 11-20
- 21+

Health Canada regulated studies

Number of new Health Canada regulated studies in the last 12 months:

- None

<input type="checkbox"/> 1-10 <input type="checkbox"/> 11-20 <input type="checkbox"/> 21+
<p>2. Any additional information you wish to provide on study types reviewed by the REB:</p>
<p>SECTION 2 – Intervention Type</p>
<p>3. Does the REB provide oversight for the following types of interventions?</p>
<input type="checkbox"/> Drugs, biologics (including vaccines), genetic therapies or radiopharmaceuticals Estimated number of new studies in the last 12 months:
<input type="checkbox"/> Natural health products or non-prescription or disinfectant drugs <input type="checkbox"/> Estimated number of new studies in the last 12 months:
<input type="checkbox"/> Medical devices Estimated number of new studies in the last 12 months:
<input type="checkbox"/> Research in emergency situations Estimated number of new studies in the last 12 months:
<p>4. Any Additional information you wish to provide on study interventions reviewed by the REB: Click here to enter text.</p>
<p>SECTION 3 – Participant Population</p>
<p>5. For the studies you will review, please indicate any restrictions to the participant populations (if any):</p>
<input type="checkbox"/> Children only (under age 18)
<input type="checkbox"/> Adults only (over age 18)
<input type="checkbox"/> Specific disease (e.g., cancer, HIV/Aids) Please specify:
<input type="checkbox"/> Capacity to consent (e.g., illiteracy, unconscious patients) Please specify:
<input type="checkbox"/> Language, cultural, geographic or socioeconomic Please specify:
<input type="checkbox"/> Other Please specify:
<p>6. Any additional information you wish to provide on participant populations for which the REB currently provides oversight:</p>

SECTION 4: Specialized/Specific Expertise

7. Are there any areas where the REB has specialized or specific expertise which differentiates the REB's capacity from other medical/health science REBs?

- Yes
- No

If yes, please provide details:

This form has been completed by:

Name:

Title:

Date: