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

CTO Qualification Review Process

Preparation for Qualification

1. To undergo a Qualification review, the REB must have Standard Operating Procedures (SOPs). CTO recommends that the REB SOPs and operations be reviewed against the **CTO REB Qualification Checklist** prior to requesting a Qualification review. The **Quality Management** component is optional.
2. A two-day Qualification visit will be arranged by CTO with the REB contact person. Interviews with the REB Chair(s) and/or Vice-Chair(s), facility tour, and entrance and exit meetings will be scheduled. In addition, the REB contact person is asked to arrange a meeting room with internet access for the CTO Qualification Team for the duration of the visit.
3. The REB Office will be asked to complete the **Preliminary Questionnaire** and provide the requested materials (or links if the material is/are publically accessible) for review at least two weeks prior to the Qualification visit.

On-site Review

1. The REB contact person should be available to assist the CTO Qualification Team as needed during the Qualification Review period.
2. The CTO Qualification Team will hold an entrance meeting with the REB operations personnel. During this meeting the CTO Qualification Team will provide an overview of the CTO REB Qualification process and answer any questions. The REB operations personnel will be asked to provide the CTO Qualification Team with an overview of the operations and structure of the REB and the REB Office and access to the requested documents.
3. The CTO Qualification Team will review the requested documents (as outlined in the **CTO REB Qualification Manual**) during the on-site visit and follow-up with the REB operations personnel as necessary for clarification. This material may be provided in paper format or electronically. If electronic, it must be accessible by the CTO Qualification Team during the on-site review period.
4. The REB operations personnel will lead a brief facility tour, showing the Qualification Team where and how paper records are stored (if applicable), outlining record security measures, and giving an overview of the office space.
5. The CTO Qualification Team will interview(s) the Chair(s) and/or Vice-Chair(s) at the arranged time.
6. An exit meeting will be held with the REB operations personnel at the end of the visit. During this meeting, the Qualification Team will discuss the preliminary comments and provide the REB operations personnel with an opportunity to clarify any findings (as applicable).

CLINICAL TRIALS ONTARIO

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

Qualification Report and REB Qualification

1. Following the Qualification visit, CTO will provide the REB with a Qualification Report.

2. If the Qualification Report does not contain any findings, the REB will be designated as a *CTO Qualified REB*.

3. If findings are identified, the REB will have the opportunity to submit a Corrective Action Plan (CAP). The CAP must be submitted to CTO within 3 months of the Qualification Report. Once the CAP has been reviewed by CTO and all findings have been resolved, the REB will be designated as a *CTO Qualified REB*.

4. *CTO Qualified REBs* will be provided with the CTO Qualification Seal and guidance on the Seal's use. The Seal signifies that the REB has achieved CTO Qualification status following a CTO Qualification review.

5. A list of *CTO Qualified REB*s will be posted publically on the CTO website.

***Items in bold can be found in the CTO REB Qualification Manual**

CLINICAL TRIALS ONTARIO • RESEARCH ETHICS BOARD • CTO QUALIFIED ctontario.ca