Clinical Trials Ontario

CTO REB Re-Qualification Visits - Remote Options

Due to the ongoing COVID-19 pandemic, travel limitations and visitor restrictions at CTO Participating institutions, REB Re-Qualification visits are on hold. These visits are normally conducted on-site at the REB by the Qualification Team. In order to continue the critical work of Re-Qualifying existing boards, CTO is exploring ways to adapt the format and structure of these visits. This document proposes various tools and options to facilitate remote REB Qualification visits.

Visit Elements	Tools and Options
Pre-Visit	

1. Scope of Review and Re-Qualification Questionnaires are emailed to the REB once the visit is booked
    a. CTO collects and organizes questionnaires and all electronic documents received from the REB.
    b. Documents are shared with the Qualification Team at least 2 weeks in advance of the visit via a password protected link to the CTO drive (Datto Workplace)
    c. Qualification Team reviews all documentation and identifies any questions, concerns and items for discussion at the qualification visit. Documents reviewed include: SOPs, membership lists, templates, Terms of Reference, org chart, previous qualification reports, Corrective Action Plan, etc.
	No change to current procedures; documents will continue to be collected and shared with the Qualification Team electronically.

Re-Qualification Visit	
2. Remote Re-Qualification Visit – 2-day visit may need to be extended over a few days to accommodate scheduling requirements and remote review of documents.	
a. Entrance and Exit meetings - Prescheduled	Conducted via videoconference (Zoom, Microsoft Teams, WebEx)

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Visit Elements	Tools and Options
b. Interviews with REB Chair, REB Operations Lead - Prescheduled	Conducted via videoconference (Zoom, Microsoft Teams, WebEx)
c. "Ad hoc" discussions with REB Operations Lead/Staff	Conducted via teleconference or videoconference (Zoom, Microsoft Teams, WebEx) and coordinated based on availability of REB Staff and Qualification Team members REB Staff can be available to respond to questions by phone or email throughout the visit or during specified blocks of time. Qualification Team (QT) can compile questions and book time to meet with the REB staff via videoconference as needed.
d. Qualification Team (QT) member discussions	Conducted via teleconference or videoconference (Zoom, Microsoft Teams, WebEx) and coordinated based on availability of Qualification Team members. QT can schedule time to discuss their comments, questions, and findings at timepoints throughout the visit. CTO staff available throughout the visit.

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e. QT review of **unredacted** REB study files, REB training and membership files meeting minutes, meeting agendas, correspondence and any other files not provided for pre-review. The study files to be reviewed will be primarily focused on studies located within CTO Stream. If the REB does not have an appropriate study(s) within CTO Stream local study files will be used. *Note: QT will provide the REB with a list of critical documents that would typically be requested at the on-site visit. The REB staff can provide these documents electronically as part of the pre-review package in advance of the visit (i.e. with the questionnaires) to facilitate the review process.* Depending on the format of the REB files and where they are stored (paper based, electronic documents or within an electronic platform), the REB may be able to provide access in a variety of ways, in advance of or during the visit on an as-needed basis.	**Access to CTO Stream Files:** i. The CTO Program Manager will have access to the necessary files. No actions will be required by the REB. **Access to Paper Based Files can be provided as follows:** i. Scan and email or upload to an electronic file sharing system ii. In cases where transmission of scanned documents is restricted, REB staff can do a live screen-share during a videoconference with the QT (ie REB staff scans the document and uses the screen-share feature to show the document to the QT members on the call. **Access to Electronic Documents can be provided as follows:** i. Email or upload to an electronic file sharing system **Access to an Electronic Platform** i. REB staff can provide QT with access and training and/or instructions on how to navigate the REB's electronic system. REB staff will need to be available throughout the visit in order to assist QT members in locating documents within the system as needed.
Post-Visit	
3. All post-visit activities would continue as normal. The QT will provide Re-Qualification Report to the REB following the visit as usual. REB will submit a Corrective Action Plan response addressing any findings. Once Corrective Action Plan is accepted, the Re-qualification letter will be issued.	

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