What you need to know to submit a new study in CTO Stream

Tips

- CTO Stream can be accessed via <u>apply.ctostream.ca</u> (do not add "www" in front of the address);
- CTO Stream works with current versions of all browsers. However, Internet Explorer (IE) is not as highly recommended;
- All OCREB policies, procedures and templates remain in effect (just as before);
- Continue submitting to OCREB based on the submission deadlines posted on the OCREB website;
- CTO Stream will generate a project ID number (a four digit number e.g., 0917) instead of the OCREB numbering system. This number and the "Project Short Title", which is entered by the applicant when creating the provincial initial application (PIA), will be included in system notifications and in correspondence from the REB;
- In O2, individuals were selected from a drop-down list. In CTO Stream, each user keeps his/her own personal address book within CTO Stream under "Contacts" (found in the black navigation bar). Once a contact is entered the first time in an application and saved to address book, it can be imported into future application forms;
- When re-submitting an application, applicants must answer "Yes" to question 1.0 "*Is this a resubmission in response to a request from the Research Ethics Board to make changes to your application?*" If there is a Co-Investigator listed in the application, you will also need to update question 11.0 on the signature page;
- Signatures can be obtained in parallel from all required signatories. The requester will receive an email notification when each signature is applied, and the application will submit automatically once the last signature is applied;

Need assistance? Both CTO and OCREB are here to help! CTO provides training and access to CTO Stream along with technical support, while OCREB will continue to provide the feedback, assistance with REB review or application form questions, and help with other inquiries just like you are used to.

Accounts

All OCREB users will require a CTO Stream account to submit applications to OCREB. If you are involved in an OCREB study and do not have a CTO Stream account, please contact CTO (<u>streamline@ctontario.ca</u>).

Provincial Initial Application (PIA) Form

The applications in CTO Stream are used for all multi-centre clinical trials across the province and were developed with the involvement of a number of Research Ethics Boards (REBs) and with the consideration of a wide variety of REB application forms. The process requirements (such as signatures and institutional notifications/authorizations) were developed with an Advisory Group that included members of REBs and institutions in Ontario.

Signatures

- The Provincial Applicant (PA) must sign off on the initial submission of the PIA, as well as on each re-submission of the PIA (e.g., in response to a request for modifications from OCREB). The signature requirements were determined by a Working Group, who felt it was important for the PA to take responsibility and assure oversight for the materials submitted to the REB on behalf of all participating sites in the province. The PA is not required to sign the REB response letter uploaded into the application, as she/he will be applying an e-signature to the application form;
- The PA is also required to sign the initial submission of all post-approval applications (e.g., provincial amendments, provincial reportable events). However, signatures on post-approval re-submissions may be delegated to the main study contact.
- To sign, the PA/PI must re-enter his/her username (i.e., email address) and password;
- If a Provincial Co-Applicant is listed in the PIA, he/she will need to sign off on the initial submission; however it is not mandatory to include a Provincial Co-Applicant.

Form Content

- The PIA includes the Institutional Representative (IR) relevant to the lead (Provincial Applicant) site. Each institution identifies and provides CTO with the IR information. This information can be found in the "SRERS Administration" form maintained by CTO. The IR does not sign the PIA but is added for informational/notification purposes to satisfy institutional requirements;
- In the PIA, question 1.4 should usually be answered "Yes" and the main research coordinator should list themselves as the "Main Study Contact" in question 1.5;
- Sponsor billing information is not collected in the PIA. CTO will manage the fees and invoicing according to the schedule on the CTO website;
- The consent forms with tracked changes are uploaded in the resubmission section at the end of the application form that appears when "Yes" is selected in question 1, section 1 "Is this a resubmission in response to a request for changes from the Research Ethics Board?"

Collaboration

- The collaboration features for Sponsors/CROs allow for improved coordination between sponsors/CROs and the research team. For example, the sponsor/CRO can be the project owner (e.g., create the study), and sponsors/CROs can work on the application at the same time as the research team (a yellow "!" will appear in the top right of the screen anytime two users are working on the same page note that work may not be saved if this occurs).
- A member of the provincial research team (which may include the sponsor) will normally create the CIA for each participating site, and then add a member of that site's study team to the application by giving them a 'role' on the study (this is managed via a user email address). This user can add other site users as needed. Participating sites also may contact a member of the provincial team or CTO to gain access to a study and their centre application. Centres are selected by centre name and not by PI name;
- Entering a user into an application form does not automatically grant that user access/permissions to the study. The user must be given access/permissions via the Roles feature (i.e., by assigning them a role).

Navigation

- The consent form with OCREB recommendations is located under the "correspondence" tab (a live link to the consent form(s) will not appear in the review letter);
- REB review letters can be found in the 'History' tab, which is sortable/searchable.

Note: CTO Stream does not display the name of the REB Coordinator assigned to the submission.

What's next?

- CTO will continue to set up site-specific training opportunities for sites that need access;
- CTO offers general WebEx sessions on a regular basis for new users;
- Additional guidance documents are available on the OCREB website

Whom to contact with questions

- For study-related questions, please contact the responsible OCREB Research Ethics Coordinator or the OCREB Research Ethics Officer see https://oicr.on.ca/research-portfolio/ocreb/contact-ocreb/ for contact details.
- For technical assistance with the online system, please contact the CTO Helpdesk at streamline@ctontario.ca or 1-877-715-2700.



