What you need to know to submit a Centre Initial Application (CIA) in CTO Stream

Tips

- CTO Stream can be accessed via apply.ctostream.ca (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), Go to www.ocreb.ca to access the OCREB policies, procedures, guidelines and templates;
- 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 the 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. This reduces the signatures required on the re-submission;
- 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;
- Centres can begin working on their CIA any time after the Provincial Initial Application (PIA) has been created, but will not be able to submit their CIA until the PIA is approved;

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 assistance with the REB review process or with application form questions, and any other inquiries just like you are used to.

Accounts

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

Centre Initial Application (CIA) Form Differences

The applications in CTO Stream are used for multi-centre clinical trials conducted 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 by an Advisory Group that included REBs and institutions across the province.

Signature Requirements

The Advisory Group established the signature requirements as a measure of accountability and oversight of the submissions to the REB;

- Initial submission of the CIA:
  - The signature of the Principal Investigator (PI) as well as the appropriate department head/departmental approver (DA) is required on the initial submission of the CIA;
  - The signature of the primary Institutional Representative (IR) is required. CTO works with each institution to identify the appropriate IR(s) and will provide this information to each site;
  - If a Co-Investigator is listed in the CIA, a signature will be required; however, it is not mandatory to list a Co-Investigator.
- Re-submissions of the CIA:
  - The signature of the PI is required whenever the CIA is re-submitted (e.g., in response to a request for modifications from OCREB);

- The IR must sign off again only when the PI, or the Co-I (if included), changes during the study.

- Post-approval centre submissions:
  - The signature of the PI is required on the initial submission of each post-approval application (e.g., centre amendments, centre reportable events, centre continuing reviews);
  - Signatures on any subsequent re-submissions may be delegated to the main study contact.

PI Qualifications

- The IR and DA attest to the qualifications of the PI when signing the CIA;
- The PI's CV and information about his/her training documentation will be housed in a registry that will be available to OCREB. More details on the CTO Registry to follow!

CIA Form Content

- If you have any questions about how to complete the application form, please contact OCREB;
- Contact information for the PI, the DA, the main study contact and the IR information must be entered into the CIA. If the information already is saved in the user's address book, it can be imported easily into the CIA;
- In question 1.10, the main research team member tasked with completing and coordinating the REB submissions should be listed as the "Main Centre Study Contact";
- Centre consent forms:
  - OCREB will continue with its controlled honour system for the approval and use of consent forms at the centre level. However, in order for CTO to meet its institutional obligations, centres will upload their centre-specific consent/assent forms into the CIA (see CTO Screening below). This requirement includes uploading a tracked version in question 4.7 showing the changes to the provincial approved consent form(s), and a clean version (with the changes accepted) in question 4.8;
  - As per current OCREB practices and policies, the centre-specific consent forms <u>will not be reviewed</u> by OCREB and will not be listed in the centre approval letter;
  - The process for creating the centre consent forms remains the same – i.e., apply OCREB approved administrative changes to provincially approved materials (as described in the Guidance document), and any pre-approved, centre-specific changes (if applicable) to the approved provincial consent documents;
  - Be sure to answer "yes" to question 4.6 "*Does this centre require any changes (other than inclusion of centre letterhead and local contact information) to the approved provincial consent form(s)?*" One or both of the following statements (as applicable) may be used to "Explain" the changes:
    - <u>For all centres</u>: include the statement "See OCREB Guidance for approved 'administrative changes'";
    - <u>For those centres with OCREB pre-approved changes</u>: also include the statement "See OCREB approved centre-specific changes document";
  - If possible, upload the current version of your centre's OCREB pre-approved, centre-specific changes document in 4.8 along with the consent forms. Contact the OCREB Research Ethics Officer if you need a copy of your centre-specific pre-approved changes;
  - If additional study-specific centre-specific changes to the approved provincial consent form are being requested please contact <u>OCREB</u> prior to completing the CIA.

CIA Screening Process by CTO

- Institutions have been providing CTO with institution-wide policy (e.g., that relates to the application/consent/assent form(s)) and administrative requirements (e.g., identification of institution representatives and instructions for completion of the REB of Record Study Agreement, etc.) for inclusion in the CIA and in the centre consent forms, as applicable. These are identified for research teams in the "Documented Institutional Ethics Requirements" (DIER) and "Streamlined Research Ethics Review System (SRERS) Administration" forms. Although each institution has an SRERS Administration form, only some have a DIER form. CTO sends the DIER and SRERS forms to users along with their CTO Stream account information, and to OCREB through CTO Stream when the CIA is submitted. The DIER must be included in the OCREB pre-approved, centre-specific changes.

- Once the CIA is submitted, CTO will conduct an administrative review of the CIA prior to sending it to OCREB for review. CTO ensures that:
    - The correct IR(s) is/are listed in the application form and have been given access;
    - The required signatures have been obtained;
    - The DIER have been addressed in the application and in the centre-specific consent/assent form(s) (as applicable).
- CTO will send the application back to the centre research team if changes are required.

REB of Record Study Agreement

- The CTO REB of Record Study Agreement is used for studies submitted through CTO Stream. Each site's SRERS Administration form includes details on the process for administering these Agreements;
- CTO will obtain the final signature from OICR/OCREB. Fully executed Agreements are distributed through correspondence in CTO Stream (they are not uploaded into the CIA);
- The Agreement must be signed before study activities at the site commence.

Access

- A member of the Provincial Applicant research team may create the CIA for each participating centre and immediately give access to the CIA to a member of that centre's study team if the participating centre notifies them of their participation and provides them with the email address of a contact at the participating centre. This user can then add other centre specific users as needed;
- Note: Entering a user's contact information into an application form does not automatically grant the user access to the study. Each user must be given access/permissions using the collaboration feature of assigning a role (e.g., "Principal Investigator" role, "centre study staff" role). This includes the PI, the Department Approver and all relevant Study Staff. Assigning a role grants each user access to both the centre and the provincial REB materials. Read/write/edit permissions are dependent on the assigned role. More information can be found in the CTO Stream Collaboration manual;
- Participating centres may contact a member of the Provincial Applicant team or CTO to gain access to a study.

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.