CTO Stream Application Forms

CTO Stream is a web-based ethics application system for multi-site research in Ontario.

In this guide you will find:

- Descriptions of the application forms found within CTO Stream and information on when to use them
- Information on who is responsible for submitting the various types of forms
- Other helpful tips and reminders

Need Help?

- Click here for general information and an overview of the CTO Streamlined Research Ethics Review System.
- Access CTO Stream User Manuals, Quick Guides and Tip Sheets for instructions on everything from navigating CTO Stream and creating application forms to finding REB approval letters and managing access to projects.
- Visit our Tools and Resources page to download the CTO Informed Consent/Assent form templates and Word versions of the CTO Stream application forms.
- Looking for REB submission deadlines and meeting dates? Each CTO Qualified REB posts this information on their local website. Links to each REB's website are posted here.
- Connect with the CTO Helpdesk by submitting a ticket at https://support.ctontario.ca/.

PROVINCIAL (STUDY-WIDE) APPLICATION FORMS
The Provincial Applicant / Provincial Applicant team is responsible for submitting these forms. *Note: A Sponsor/CRO may choose to assist the Provincial Applicant team in completing these forms but they cannot sign-off or be listed as the Provincial Applicant in the forms.*

Form Type	When to use it	Additional Notes and Tips
Provincial Initial Application (PIA)	Use this form to submit a new multi-site research project for ethics review through CTO Stream	➢ Provincially approved documents are approved for use at all sites who join through CTO Stream. All sites have the ability to view and download the PIA, relevant documents and any REB review and approval letters. ➢ Non-consent, participant materials approved at the Provincial level can be used by sites approved in CTO Stream. This includes materials such as diaries, recruitment posters, wallet cards etc. Sites can make administrative changes to these Provincially approved documents. Administrative changes include the addition of site logos/letterhead, insertion of local PI and study team contact information. No additional REB submission is required when administrative changes are being made to these Provincially approved documents.
Provincial Amendment Form (PAM)	Use this form when you need to submit an amendment or when you need to report changes in study-wide (provincial) information to the REB of Record (REB). Examples: ☐ Changes to the protocol/research plan, study design or methodology ☐ Changes to biological specimen collection/use	➢ When a Provincial Amendment Form is approved or acknowledged by the REB, the approval/acknowledgement applies to all sites participating in the study through CTO Stream. There is no need for individual sites to submit anything further to the REB EXCEPT in the following cases: a) when the amendment involves a change to the Provincial Consent template(s). See REMINDER below. **OR**

Form Type	When to use it	Additional Notes and Tips
Provincial Amendment Form (PAM) *continued*	☐ Changes to the consent form(s), assent form(s), debriefing material(s) ☐ Changes to participant materials or data collection forms provided to participants (such as study instruments/questionnaires, participant diaries, wallet cards, etc.) ☐ Changes to the recruitment plan or materials ☐ Updated/new Investigator Brochure (IB) or Product Monograph (PM) ☐ Translation of approved materials ☐ Change to the data collected (including Personal Information/Personal Health Information) and/or how data is accessed, collected, used or stored ☐ Changes in study funding or material support providers ☐ Changes to participant compensation/reimbursement, provision or access to product(s)/device(s), and/or financial pressure(s)/incentive(s) ☐ Change/updates relating to the communication of results ☐ Change in clinical trial registry information ☐ Change in US regulatory information ☐ Change(s) to Provincial Applicant or Provincial Co-Applicant; and/or change in study information (i.e., study title, study acronym/nickname/short name, sponsor's study ID) New information about a rejection/refusal to approve the study by another REB ☐ Change to informed consent/assent/debriefing process ☐ Change(s) to contact details for the Provincial Applicant/Provincial Co-Applicant; and/or the name/contact details for the provincial administrative study contact/institution representative(s)/Main Sponsor Contact/Main CRO Contact ☐ Other changes not described in the examples above	b) if the site needs to opt out of the Amendment because they are not implementing the Provincial Amendment as approved by the REB. ➢ The PA can submit a single PAM form to report multiple changes at once, if applicable. For example, if you have a new Product Monograph to submit and also wish to report a change in the Provincial administrative study contact, you can report them both on a single PAM form. ➢ Each site will receive a notification whenever the PA submits a PAM form and when the PAM form has been approved or acknowledged by the REB. These notifications are sent to study staff who have full access (read/write) Roles in CTO Stream. ➢ Each site has access to the PAM and is responsible for reviewing and implementing any changes, new documents etc., that are approved by the REB *REMINDER* **If the PAM involves a change to the Provincial consent/assent template(s)**, each site **must complete the following:** 1. Download the newly approved Provincial consent/assent form(s) from the approved PAM 2. Apply your site-specific changes (such as adding your site letterhead, local PI info, inserting your Documented Institutional Ethics Requirements (DIERs - if applicable) 3. Submit your revised consent/assent document(s) to the REB using the Centre Amendment Form to obtain REB approval

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Provincial Reportable Event (PRE)	Use this form when you need to notify the REB of a study-wide reportable event. Examples: ☐ DSMB/C report ☐ Interim Analysis Results ☐ Unanticipated Problem ☐ Safety Notice/Update (e.g., Action Letter) ☐ Periodic External (non-local) AE/SUSAR Summary Report ☐ Single External (non-local) Adverse Event ☐ Other reportable event not described in these examples	➢ All sites will receive a notification whenever the PA submits a PRE form and when the PRE form has been approved or acknowledged by the REB. ➢ Each site has access to the PRE and is responsible for reviewing the form, documents and REB letters
Provincial Continuing Review (PCR)	Submit this form to maintain ongoing Provincial ethics approval for the study. ***IMPORTANT *** **If the PCR is not approved by the REB prior to the expiry date, ethics approval for the entire study will lapse.**	➢ The PCR form must be submitted by the deadline for the full-board REB meeting that occurs prior to the ethics expiry date. Check the REB of Record's website for submission deadlines and meeting dates. ➢ Each centre (including the PA's own site) must also submit their own Centre Continuing Review form in order maintain ethics approval for their site.
Provincial Study Closure (PSC)	Submit this form to close out the ethics file in CTO Stream when the study is complete and Provincial ethics approval is no longer required.	➢ Before the PA can submit the PSC form, all centres in CTO Stream must have submitted their individual Centre Study Closure (CSC) forms. Only after each site file has been closed in CTO Stream can the PSC form be submitted to close out the study in CTO Stream. **Transferring the PA Role** In some instances, the PA may have completed the study at their own site and submitted their CCR (i.e., closed their REB file) before the other sites have completed the study. When this happens, the PA may wish to transfer the PA responsibility to another site PI so they can take over the responsibilities for

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Provincial Study Closure (PSC) *continued*		maintaining ongoing ethics approval in CTO Stream. The PA will need to identify a PI from one of the other sites who can take on the role. The change in Provincial Applicant can be reported by submitting a Provincial Amendment Form. The PA will also need to ensure study staff are assigned/re-assigned the correct Role to ensure appropriate access. Refer to CTO's Roles and Sharing Guide for instructions on how to do this.

CENTRE (SITE-SPECIFIC) APPLICATION FORMS
The individual site PI/site PI's research team is responsible for submitting these forms. *Note: A Provincial Applicant or Sponsor/CRO may choose to assist the sites in completing these forms but they <u>cannot</u> sign-off or be listed as the Centre PI in the forms.*

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Centre Initial Application (CIA)	Use this form to join a study which has received Provincial ethics approval through CTO Stream.	➢ The CIA form is used to obtain ethics approval to conduct a study at the site. Each site joining through CTO Stream must submit a CIA form (including the Provincial Applicant site). Note: The PA must submit a CIA for their own site if they wish to obtain ethics approval to conduct the research at their own site. **Reminder** Provincially approved, non-consent, participant materials are approved for use by all sites who join through CTO Stream. This includes diaries, recruitment posters, wallet cards etc. Sites can make administrative changes to these Provincially approved documents and use them without re-submitting them for REB approval. Administrative changes include the addition of site logos/letterhead, insertion of local PI and study team contact information.
Centre Amendment Form (CAM)	Use this form when you need to submit an amendment or when you need to report changes in **local** (site-specific) information or study conduct to the REB. Examples:	**Reminder** Sites do not have to seek REB approval to use Provincially approved, non-consent. participant materials when only administrative changes are being made to these documents.

Form Type	When to use it	Additional Notes and Tips
Centre Amendment Form (CAM) *continued*	☐ Site-specific changes to the consent/assent form(s) or debriefing material(s) used at this site ☐ Changes in the informed consent/assent/debriefing process at this site ☐ Site -specific translation of approved material(s) ☐ Changes in recruitment methods and/or recruitment material(s) (e.g., telephone, web or email scripts, flyers, brochures, etc.) used at this site ☐ Changes to other site -specific material(s) that will be given to study participants (including surveys/questionnaires/scripts, diaries and wallet cards) ☐ Changes to how personal information or personal health information is being accessed, collected, used, stored or transferred at this site ☐ Changes in the conflict of interest information previously provided to the REB for any of the investigators, study staff or members of their immediate families ☐ Changes in participant reimbursement and/or communication of study results ☐ Changes in site -specific study conduct (including location of visits/procedures, standard of care, and protocol implementation) ☐ Change in Principal Investigator or Co-Investigator ☐ Change(s) to contact details for the PI/Co-Investigator or the name/contact details for the centre administrative study contact/institution representative(s) ☐ Other changes not described in these examples	Sites should ensure they are using the most current, Provincially approved materials as indicated on the relevant Provincial approval letters.
Centre Reportable Event (CRE)	Use this form when you need to notify the REB of a <u>local</u> (site-specific) reportable event. Examples: ☐ Local (internal) serious adverse event (SAE) ☐ Protocol deviation/violation	

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Centre Reportable Event (CRE) *continued*	☐ Privacy breach ☐ Audit/Inspection report ☐ Study participant compliant ☐ Other reportable events not	
Centre Continuing Review (CCR)	Submit this form to maintain ongoing ethics approval for your site.	➢ The CCR form must be submitted by the deadline for the full-board REB meeting which occurs prior to the ethics expiry date. Check the REB of Record's website for submission deadlines and meeting dates.
Centre Study Closure (CSC)	Submit this form to close out the ethics file in CTO Stream when you have completed the study and no longer need ethics approval at your local site.	