QuickGuide: Submitting a New Observational Study in CTO Stream

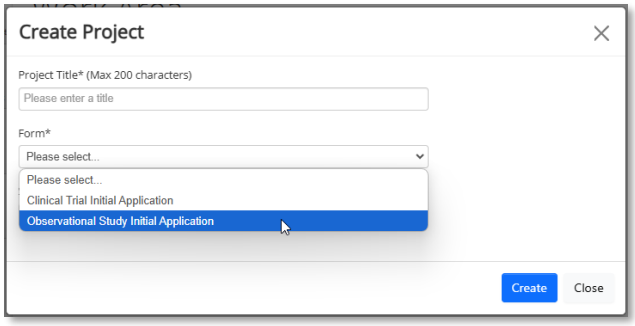
Before creating your new study in CTO Stream, you must consider whether your study is a clinical trial (an interventional study) or an observational (non-interventional) study. This key step will help determine which set of forms you should use when creating the new project in the system; you will not be able to switch part way through the review process.

The Observational Research Informed Consent Form Template should be used when creating the study-wide consent form template for observational studies. The template can be downloaded from the Tools and Resources page of the CTO website.

All other aspects of CTO Stream remain the same – only the forms are different, to ensure that research teams are provided with customized questions that relate to the nature of their study.

To create a new observational study application:

1. Login to CTO Stream at apply.ctostream.ca.
2. Click the 'Create Project' button in the Actions Menu on the left-hand side of the page.
3. Enter the study short title or nickname (this will be used throughout the system).
4. Select Observational Study Initial Application (OSIA) as the type of form in the drop-down menu.



5. Tick off the checkbox to indicate you are happy with giving CTO Support personnel access to the study, then click 'Create'. You will automatically be directed into the new project where the OSIA form is ready for you to begin working on.
6. Once all mandatory questions of the form have been completed, navigate to the last section of the form called, "Agreement & Approval" and request signatures from the Lead Applicant (and Lead Co-Applicant, if applicable). The form will automatically submit once the signature has been applied (or once the final signature has been applied if the form requires multiple signatures).

Tips:

1. Share access to the new project with other members of the study team at your site using the 'Roles' button. See the Adding new study team members using Roles QuickGuide for guidance on assigning roles to other users.
2. Download the **DIER** and/or **SRERS Administration form** for your site from the Participating Sites page. The **DIER (Documented Institutional Ethics Requirements)** lists any institutional policies which may impact research ethics review and must be addressed within the Participating Site Initial Application and site-specific consent form. The **SRERS (Streamlined Research Ethics Review) Administration form** contains details about a site's research administration processes and identifies the contact details of the institution representative(s) which you will need when completing the OSIA and Participating Site Initial Application (PSIA) forms.
3. PSIAs can be created at any point (i.e., you do not need to wait until the OSIA has been approved). Guidance on creating a PSIA can be found in the Creating a PSIA Quick Guide.
4. View the list of CTO Participating Sites on the CTO website to ensure there are at least two or more sites that will be participating on your study. If you don't see a site on the list contact CTO by submitting a support ticket at support.ctontario.ca and we can give you an update.

5. Make sure to use the mandatory CTO Informed Consent Form template when drafting the study-wide consent form template (for oncology studies, please use the OCREB consent templates). This template has been accepted by the CTO Qualified REBs and contains language and elements required by CTO participating institutions. You can find the consent form template on the Tools and Resources page of the CTO website.

Questions? Submit a support ticket at support.ctontario.ca