

# Quick Guide: Creating a New Observational Study

Research teams conducting multi-site observational (non-interventional) health studies in Ontario can now access customized application forms and apply for a streamlined research ethics review in <a href="CTO Stream">CTO Stream</a>.

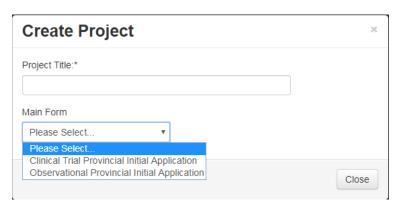
Before you create your new study in CTO Stream, you'll need to know whether your study is a clinical trial (an interventional study) or an observational (non-interventional) study. These different types of studies use different forms; you won't be able to switch part way through the review process.

Please use the <u>Observational Research Informed Consent Form Template</u> when creating the study-wide consent form template.

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. Log in to CTO Stream (apply.ctostream.ca)
- 2. Click the "Create Project" button
- 3. Enter your short study title (a shortened version of the study title that will appear to all users and be used to identify the project in informal communications)
- 4. Select the "Observational Provincial Initial Application" form



- 5. Check that you are happy to continue with the addition of the CTO Support team
- 6. Click "Create"

<u>TIP:</u> Don't forget to <u>add other members of the research team</u> to the study. Additional user manuals and Quick Guides can be found on the CTO <u>website</u>.

## Questions? Contact us at streamline@ctontario.ca or 1-877-715-2700.

## **TERMS AT A GLANCE**

#### **Observational Study**

In an observational study, researchers assess health outcomes in groups of participants according to a research plan or protocol. Participants are not prospectively assigned to receive specific interventions by the researcher (as in a clinical trial). For example, in an observational study, researchers may observe a group of adults to learn more about the effects of different lifestyles on cardiac health.

#### **Clinical Trial**

In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the researchers.

Making Ontario a preferred location for Global Clinical Trials, while maintaining the highest ethical standards.