

# Instructions for Investigator's submitting in the Clinical Trials Ontario (CTO) Stream

## Clinical Trials Ontario – Streamlined Research Ethics Review System

Clinical Trials Ontario (CTO) is an independent not-for-profit organization established with support from the Government of Ontario. CTO works collaboratively with the clinical trials stakeholders (researchers, community, and strategic partners) to improve the environment of clinical trials in Ontario and to attract clinical trial investment to the province, while supporting the highest standards of ethics and quality.

CTO supports applications for both Industry Sponsored and Investigator-Initiated trials by providing a process for harmonized REB review in Ontario.

One REB is chosen as the 'Board of Record' to conduct a review on behalf of all participating centres/sites located in Ontario. Please note centres outside the province are not supported in this process and must apply through their usual REB process.

The Ottawa Health Sciences Network Research Ethics Board (OHSN-REB) is a 'CTO Qualified REB' and may be assigned as the Board of Record for any project submitted through CTO Stream.



Also, there are agreements in place for TOH and/or UOHI Investigators to submit through CTO Stream as either a **Provincial** (lead in Ontario) or **Centre** (participating site) applicant.

- If you are conducting an Industry Sponsored or Investigator-Initiated multi-centre clinical trial or minimal risk research study with a minimum of 2 sites in Ontario, you may choose to submit your REB application through the CTO Stream.
- If you are conducting any type of OCREB (Ontario Cancer Research Ethics Board) study, you are required to submit through the CTO Stream.

## A single review system eases the burden on investigators and REBs and SAVES TIME!

Instead of numerous REB reviews for the same trial/study at different sites, the review only needs to be done by one REB. Once the bulk of information is reviewed and approved through the Provincial Initial Application (PIA) submitted by the provincial lead, each participating centre completes a simple 'Centre Initial Application' (CIA) which links to the provincial application.

## General Overview for CTO Submission

- While CTO Stream provides a streamlined approach to research ethics review, researchers at TOH and UOHI must also register their projects via the Clinical Research Registration Form (CRRF) to ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research. Institutional approval is only granted once the Ethics registration tab, Contracts tab and Notification tab are complete.

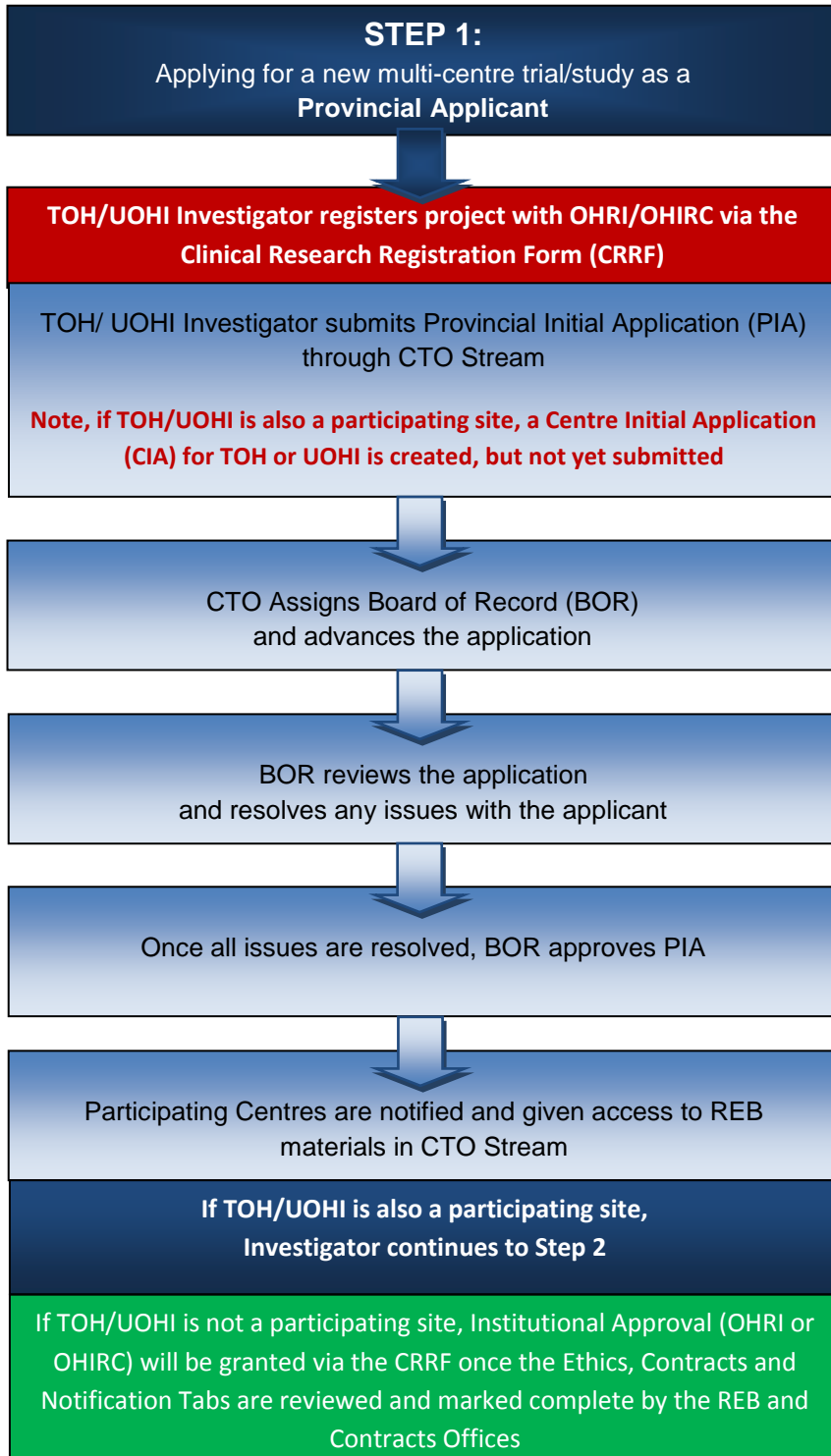
- The CRRF must be completed and submitted simultaneously with the ethics submission via the CTO Stream. Immediately upon receipt of final CTO Stream approval(s) (PIA and/or CIA), the approval letter(s) must be uploaded into the CRRF. Please see the [Guidance Document for CRRF/CTO Stream Submissions \(coming soon\)](#) for more information.
- All CTO Stream applicants must use the CTO Consent Form templates found on the CTO website. The Provincial Consent Form must be created without institution specific information (a customizable template of sorts). Then, each participating site must add their institutional specific information into the provincially approved Consent Form, for centre approval and local use.
  - Ensure you review the [Streamlined Research Ethics Review document \(SRERS\)](#) for The Ottawa Hospital and University of Ottawa Heart Institute to ensure your study has been assigned to the appropriate personnel for signing.
- If you have any questions, please contact the OHSN-REB Manager, Ms. Amy Geertsma, at [ageertsma@ohri.ca](mailto:ageertsma@ohri.ca) or 613-798-5555, ext. 15072.
- If you have technical issues or need help with your submission in CTO Stream, contact CTO Help Desk, [streamline@ctontario.ca](mailto:streamline@ctontario.ca) or 1-877-715-2700 (9AM-5PM).
- CTO's template for completing CTO applications can be found on the [CTO website](#). The following are other CTO supporting documents that can be found on our website.
  - [QuickGuide: Submitting a new Study in CTO Stream \(Applicant\)](#)
  - [QuickGuide: Creating Centre Initial Applications \(Applicant\)](#)
  - [QuickGuide: Participating Sites – Getting Started \(Applicant\)](#)
  - [QuickGuide: Creating a new Observational Study \(CTO term for minimal risk study\)](#)

## Clinical Trials Ontario Institutional Representatives (IR)

- For TOH, OHRI and OCREB contact Amy Geertsma, REB Manager
- For UOHI, OHIRC contact Sharon Finlay, Manager, Clinical Research Compliance and Support Office

## Process Map for CTO TOH and/or UOHI Provincial Applicants

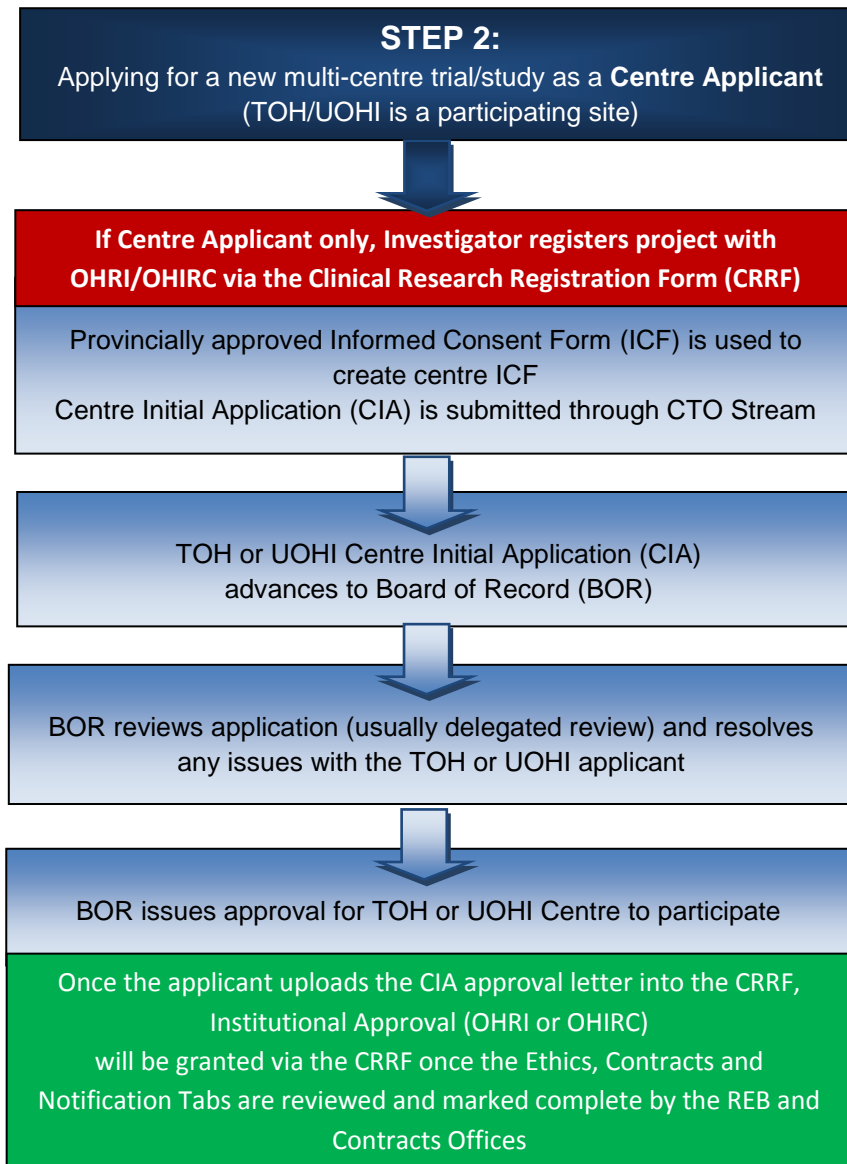
**Note:** The Ottawa Hospital (TOH) or University of Ottawa Heart Institute (UOHI) Applicants are required to register their CTO Stream projects in the CRRF to obtain **Institutional approval - a mandatory requirement prior to starting the study**. Investigator's must follow the Translation Process policy, if applicable to the study.



**Note:** when TOH or UOHI is the Provincial Applicant, and participants from the institution are involved in the study, the research team must immediately create (but not submit) the Centre Initial Application for TOH or UOHI. Creating the CIA will enable the contracts team and Research Administration team viewing access to your application to help with simultaneous facilitation of the project.

If the investigator is only leading the project and no participants from the institution are involved in the study, the research team must immediately contact the Institutional Representative to inform them that only a Provincial Application will be submitted.

## Process Map for CTO TOH and/or UOHI Centre Applicants



**Note:** a Centre Initial Application is required when the TOH or UOHI Applicant is participating in the study. Although the CIA must be created at the time of PIA submission, applicants can only submit the CIA if the Provincial Initial Application has already been approved by a CTO qualified Board of Record.

## CTO Stream Amendments and When to Contact the Contracts Office

If an amendment is submitted in CTO Stream for any of the following reasons, the Investigator and/or Research Study Team must contact their applicable Contracts Officer, as an amendment may be required to the contract agreement.

- Change to the Principal Investigator, Co-Investigator, Sponsor or CRO or Multi-Centre Investigator
- Change to study conduct (e.g., coordinating centre/sponsor role)
- Change to study participant location of visits/procedures, standard of care, and protocol implementation
- Change to biological specimen collection/use or access, collection, use, storage or transfer of biological specimen data
- Change to how personal identifying information (PII), personal health information (PHI), or data is being accessed, collected, used, protected, stored and/or transferred
- Change to study funding
- Change to the conflict of interest (e.g., for any of the Investigators, study staff or members of their immediate families)
- Addition of sub-studies/correlative studies
- Changes to the protocol requiring a notification or amendment to Health Canada related to the current CTA/NOL/NOA/ITA
- Addition of new product (e.g., drug, biologic (including vaccines), genetic therapy or radiopharmaceutical/health product (natural or non-prescription)/device) to the study

## Clinical Research Registration Form (CRRF) Annual Administrative Form *(Coming Soon)*

Once a year, Investigators and/or research staff will be required to update their CTO study in the CRRF. The Annual Administrative Form will need to be completed **no later than 10 days** after the CTO Provincial expiry date.