USING CTO at UHN for Multi-Site Research

How to get ethics approval through CTO for multi-site studies and how to obtain and maintain IA at UHN

CLINICAL TRIALS ONTARIO

CTO STREAM

UHN Toronto General Toronto Western Princess Margaret Toronto Rehab

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CAPCR

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Today's Agenda

1. What is a Research Ethics Board (REB) of Record?

2. Clinical Trials Ontario:
   - What is CTO?
   - How to get ethics approval via CTO Stream?

3. University Health Network (UHN):
   - How to ***obtain*** Institutional Authorization (IA) for your study through CAPCR?
   - How to ***maintain*** Institutional Authorization (IA) for your study through CAPCR?

1. What is a Research Ethics Board of Record?

A Research Ethics Board of Record, also known as an REB of Record or Board of Record, provides research ethics review and oversight for a study with multiple participating sites.

This means, only one Research Ethics Board (REB) reviews and approves the ethics of a study for more than one site.

2. CTO: How to Get Ethics Approval via CTO Stream

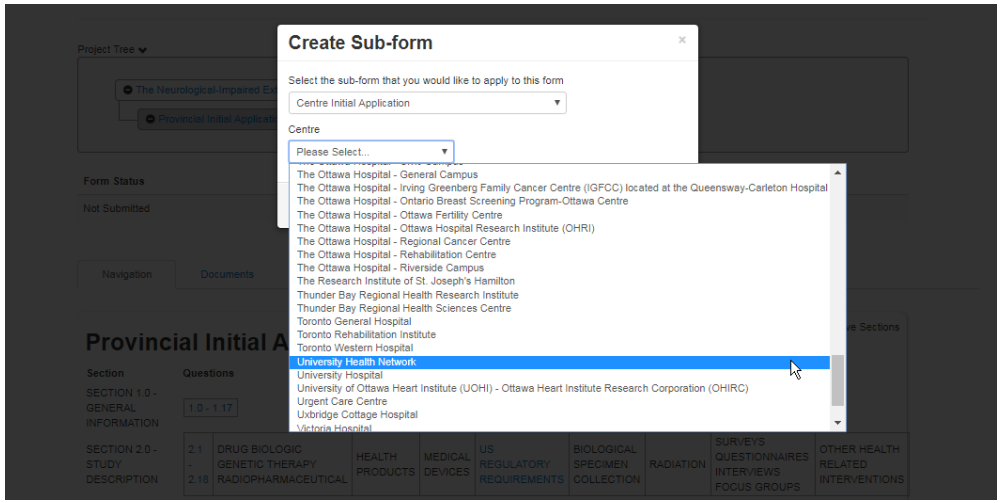
Things to Consider When You are the Provincial Applicant:

1. A Centre Initial Application (CIA) must be created and submitted for each site (including the Provincial Applicant site).

2. When the Provincial Application is created, research teams should immediately create the CIAs for any known Centre (right after creating the PIA). When the CIA is created for UHN, two things happen:

    i. The UHN Institution Reps and Admins will automatically be tagged to the study.

    ii. One of the UHN Institution Reps will reach out to the UHN Centre PI to guide them through the process of obtaining Institutional Authorization (IA) at UHN.



CTO STREAM

2. CTO: How to Get Ethics Approval via CTO Stream

Things to Consider When You are the Centre Applicant:

1. As Institution Rep for UHN, Paul MacPherson will be signing off on the CIA in CTO Stream before it is submitted for review by the REB of Record. Before the Institution Rep will sign, the following has to be completed:

    - ✓ UHN Centre PI credentials confirmed
    - ✓ CAPCR application submitted
    - ✓ Department Head in CIA and CAPCR must match
    - ✓ Centre Applicant must sign in CTO Stream

    Note: This list might change as we fine-tune our internal processes. If you are waiting for a signature for the UHN Institution Rep, please contact boardofrecord@uhn.ca.

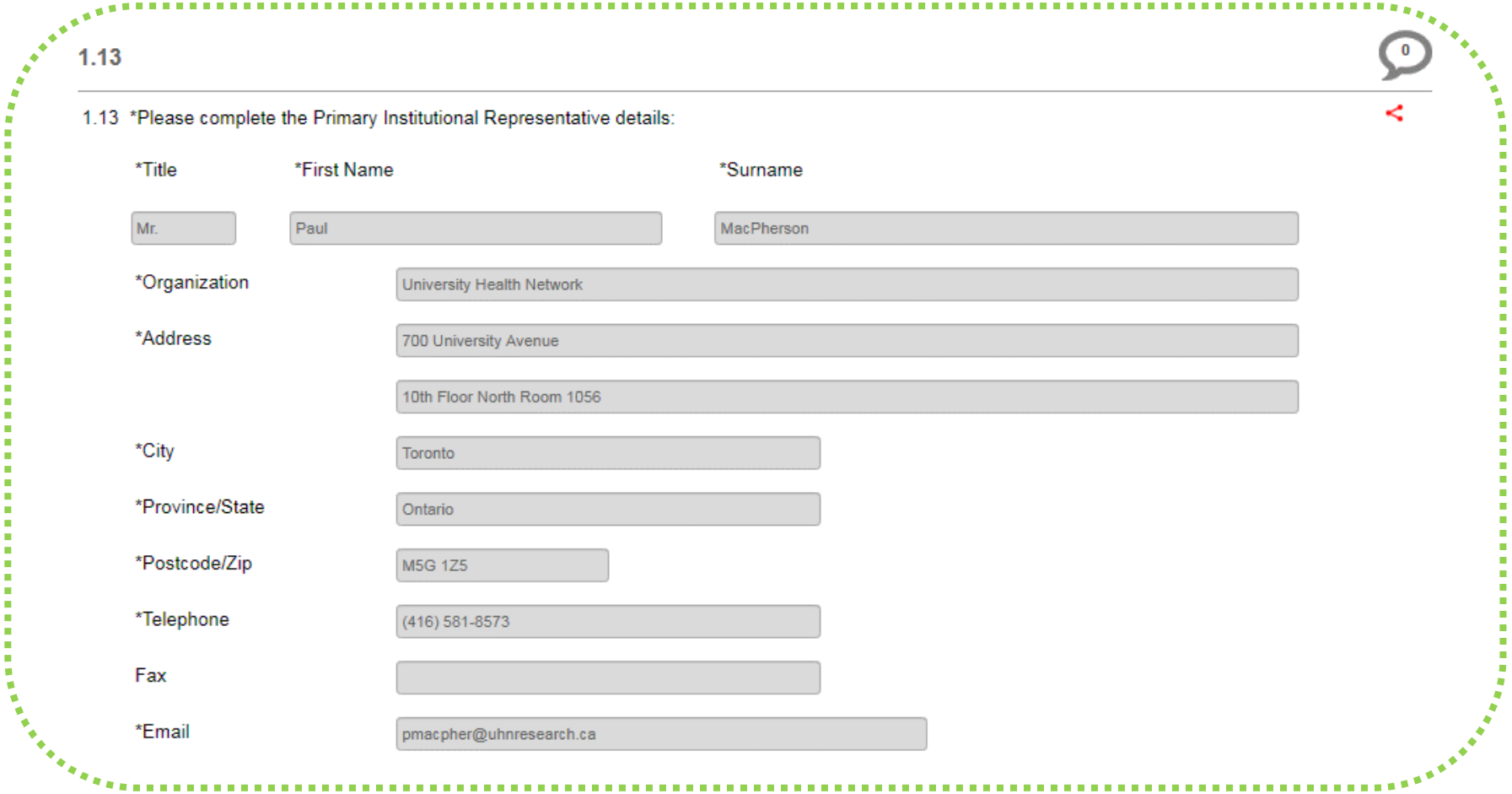
2. Fully executed CTO REB of Record Study Agreements are required to start study activities at the site. These are the steps for obtaining the necessarily signatures for the CTO REB of Record Study Agreement:

    i. CTO will send the REB of Record Study Agreement to the PI for signature.
    ii. The PI/delegate will send a scanned copy of the Agreement (signed by the PI and witness) to boardofrecord@uhnresearch.ca who will obtain the necessary signature from the UHN signing authority.
    iii. The scanned copy of the Agreement will be sent back to CTO (streamline@ctontario.ca), who will obtain the necessary signatures from the REB Host Institution.
    iv. Fully executed Agreements will be circulated via the correspondence feature in CTO Stream and by email after the CIA is submitted.

2. CTO: How to Get Ethics Approval via CTO Stream

Things to Consider When You are the Provincial Applicant and/or Centre Applicant:

1. The Primary Institution Rep must be indicated as follows in the applications within CTO Stream:



1.13

1.13 *Please complete the Primary Institutional Representative details:

*Title	*First Name	*Surname
Mr.	Paul	MacPherson

*Organization	University Health Network
*Address	700 University Avenue
	10th Floor North Room 1056
*City	Toronto
*Province/State	Ontario
*Postcode/Zip	M5G 1Z5
*Telephone	(416) 581-8573
Fax	
*Email	pmacpher@uhnresearch.ca

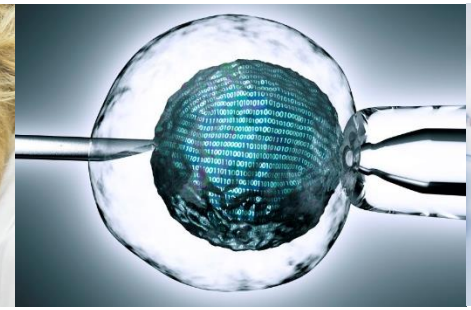
Q. 1.16 in the PIA
Q. 1.13 in the CIA

This information can be found on the SRERS Administration Form provided by CTO at the time of account creation or upon request.

3. CAPCR: How to obtain Institutional Authorization (IA) at UHN?

When using an REB of Record model like CTO, it is important to note that each institution will have requirements, in addition to ethics approval, **for an initial submission**, before study activities can begin at that centre.

These institutional requirements will change based on the nature of the study and structure of the organization.



3. CAPCR: How to obtain Institutional Authorization (IA) at UHN?

If there is a Centre Initial Application (CIA) for UHN in CTO Stream, the UHN Centre PI is responsible for completing and submitting an application through CAPCR.

CTO STREAM

1 Study Approval

- REB application submitted by lead investigator, i.e. "Provincial Applicant"
- CTO Qualified REB of Record selected, application advances to REB
- REB of Record reviews application and resolves any issues with applicant
- If/when issues are resolved REB of Record approves study
- Sites wishing to participate are notified and given access to REB approved study in CTO system

2 Adding/ Recruiting Sites

- Recruiting Institution signs REB of Record Agreement, delegating ethics review and oversight to REB of Record; Local PI adopts approved consent form and submits site application focused on site specific information
- Site application advances to REB of Record
- REB of Record Host Institution signs REB of Record Agreement and REB reviews application (**usually expedited**) and resolves any issues with site applicant
- REB of Record issues approval for site to participate

3 Continuing Oversight/ Approval

New overall (study-level) event, e.g. amendment, Data Safety Monitoring Board report, safety update

Documentation submitted by "Provincial Applicant"

REB of Record reviews submission and resolves issues with provincial applicant

Approval/ acknowledgement issued by REB of Record; sent simultaneously to all approved participating sites

- New site level event, e.g. continuing review, local Serious Adverse Event, protocol deviation

Documentation submitted by research site

REB of Record reviews submission and resolves issues with research site

Approval/acknowledgement issued by REB of Record

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3. CAPCR: How to obtain Institutional Authorization (IA) at UHN?

You can create and submit the initial application in CAPCR at anytime so long as you understand study activities cannot begin at UHN until your receive Institutional Authorization (IA) in CAPCR.

Considerations for the *Current Version of CAPCR*:

1. Applications *are not* recognized as CTO studies
2. Full CAPCR application must be completed and submitted, including REB-only sections
3. Protocol and Consents are required for submission
4. REB will be triggered as a reviewer but won't actually complete the review
   IMPORTANT → send Institution Admin the CAPCR number upon creation so the UHN REB will flag it

Considerations for the *New CAPCR Release*:

1. Applications *are* recognized as CTO studies
2. Only non-REB sections must be completed and submitted
3. Protocols and Consents are not required for submission but required for IA
4. REB of Record Approval Letter is a document required for IA
5. REB of Record Study Agreement is a document required for IA

Required for IA means the document doesn't have to be attached before submission, but *will* have to be attached in CAPCR to be granted Institutional Authorization (IA).

3. CAPCR: How to obtain Institutional Authorization (IA) at UHN?

So, when should you submit the CAPCR Application?

ASAP.

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Summary – When You Can Start Study Activities at UHN

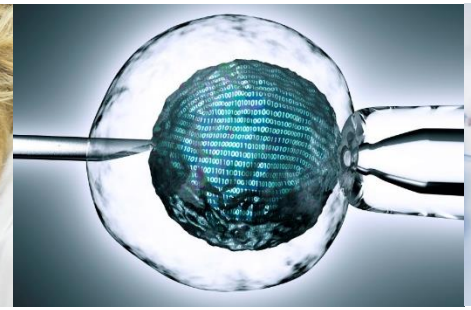
There are 3 things required before you may begin study activities at UHN if you are the Provincial or Centre Applicant:

- ✓ CTO REB of Record (ethics) Approval for the UHN Centre
- ✓ Fully Executed (signed) CTO REB of Record Agreement
  Note: this is only required if the REB of Record is not the UHN REB
- ✓ Study Granted Institutional Authorization (IA) in CAPCR

3. CAPCR: How to maintain Institutional Authorization (IA) at UHN?

When using an REB of Record like CTO, it is important to note that each institution will have requirements, in addition to ethics approval, **for ongoing submissions**, before study activities can begin at that centre.

These institutional requirements will change based on the nature of the study and structure of the organization.



3. CAPCR: How to maintain Institutional Authorization (IA) at UHN?

If there is an ongoing submission in CTO Stream (Amendment, Continuing Review, Reportable Events, Study Closures, etc.) the Centre PI will need to consider if a submission is required in CAPCR.

CTO STREAM

1 Study Approval

- REB application submitted by lead investigator, i.e. "Provincial Applicant"
- CTO Qualified REB of Record selected, application advances to REB
- REB of Record reviews application and resolves any issues with applicant
- If/when issues are resolved REB of Record approves study
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3 Continuing Oversight/ Approval

New overall (study-level) event, e.g. amendment, Data Safety Monitoring Board report, safety update

Documentation submitted by "Provincial Applicant"

REB of Record reviews submission and resolves issues with provincial applicant

Approval/ acknowledgement issued by REB of Record; sent simultaneously to all approved participating sites

- New site level event, e.g. continuing review, local Serious Adverse Event, protocol deviation

Documentation submitted by research site

REB of Record reviews submission and resolves issues with research site

Approval/acknowledgement issued by REB of Record

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Summary – When to Submit to CAPCR After the Initial Submission?

Amendments – if an amendment in CTO Stream impacts a service provider or impact assessment reviewer triggered to the study

Continuing Reviews – submission to confirm REB of Record Continuing Review Approval

Centre Closure – submission to confirm REB of Record approval of closure/completion

Contact Information

For more information, assistance or if you have questions, please contact:

Clinical Trials Ontario
streamline@ctontario.ca

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CTO STREAM

University Health Network (UHN)
boardofrecord@uhnresearch.ca

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