CLINICAL TRIALS ONTARIO

661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
M5G 1M1 Canada
www.ctontario.ca

Documented Institutional Ethics Requirements
Children's Hospital of Eastern Ontario (CHEO)

Informed Consent Form Requirements (Not applicable for studies reviewed by OCREB)

1. Ensure the first page of the consent/assent form is on CHEO-OCTC and CHEO RI institutional letter head.

2. Replace the statement (or variations of this statement) "Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care" with the following:
"Deciding not to take part or deciding to leave the study later will not affect the care you receive at CHEO."

3. In the section 'How many people will take part in this study?'
Insert an additional sentence specifying the number of participants expected to participate at CHEO.

4. In the 'Reproductive Risks' section: if there is a risk of sperm mutation or a teratogenic risk, then (as applicable) the Principal Investigator is responsible for ensuring the following sentences are included after the description of those risks:
Patients on the study should discuss these risks with sexual partners of the opposite sex. Adolescents will be given appropriate information about methods of birth control.

5. If the study is an oncology study that includes medication
Section: What is the cost to participants? Insert the following language, IF applicable
'You can ask to speak with the CHEO oncology pharmacist about added costs. No patient will be excluded from this study based on their ability to pay for additional drug costs. Everything possible will be done to help you access reimbursement from your insurance company or other third party payer. '

6. In the 'How will participant information be kept confidential?' section, the list of authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, for quality assurance (to check that the information collected for the study is correct and follows proper laws and guidelines); include the following bullet point:
    - The Children's Hospital of Eastern Ontario – Ottawa Children's Treatment Centre and the Research Institute, to oversee the ethical conduct of the research at this location;

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SRERS Administration
Children's Hospital of Eastern Ontario (CHEO)

Reminder: Institutional Research Administration Requirements

The CTO Streamlined System provides a streamlined approach to research ethics review. Each participating site must ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research.

The research team will complete an administrative application in ROMEO; which will include a CHEO external board of record signature page. The administrative form will capture metrics, ongoing research at the Institution, the departmental impacts as well as the assurance of adherence6 to the privacy and confidentiality requirements at CHEO.

Upon completion of the administrative application; the reviewer will notify the Institutional Representative and the research team that the administrative requirements have been completed. The institutional representative and departmental reviewer will then sign off on the centre application.

The Board of Record agreement should be sent to the attention of the CHEO REB office, who will obtain the signature of Mr. Bruce Squires.

It is the responsibility of the research team to ensure that the contracts/agreements are in place prior to beginning the research, if applicable.

CTO Stream

Collaborators:

The following collaborators must be given a role on all Provincial Initial Application (PIA) forms and Centre Initial Application (CIA) forms.

Email: bsquires@cheo.on.ca
Role: Institutional Representative

Email: VBourada@cheo.on.ca
Role: Institutional Representative

Email: jpepper@cheo.on.ca
Role: Institution Admin

Email: sledoux@cheo.on.ca
Role: Institution Admin

Email: shamer@cheo.on.ca
Role: Institution Admin

Email: schamaa@cheo.on.ca
Role: Institution Admin

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This access is automatically granted when the Centre Initial Application is created. **When CHEO is the Provincial Applicant site the research team should immediately create the CIA for CHEO (right after creating the PIA)**. This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the PIA prior to submission.

Institution Representative in application forms

The Primary Institution Representative must be indicated as follows in the applications within CTO Stream:

Title:	Mr.
First Name:	Bruce
Surname:	Squires
Organization:	Children's Hospital of Eastern Ontario
Address:	401 Smyth Road
City:	Ottawa
Province/State:	Ontario
Postcode/Zip:	K1H 8L1
Telephone:	613-737-7600 x 2533
Fax:	
Email:	bsquires@cheo.on.ca

The Secondary Institution Representative should be indicated as follows:

First Name:	Valerie
Surname:	Bourada
Organization:	Children's Hospital of Eastern Ontario
Address:	401 Smyth Road
City:	Ottawa
Province/State:	Ontario
Postcode/Zip:	K1H 8L1
Telephone:	613-737-7700 x 2128
Fax:	613-798-4875
Email:	vbourada@cheo.on.ca

Institution Representative signature

Research teams are encouraged to notify Ms. Valerie Bourada (VBourada@cheo.on.ca) by email when the Centre Initial Application and the CHEO administrative application is complete, prior to requesting signatures, to facilitate the institutional sign-off process.

Departmental approver in application forms

OCREB Studies - Dr. Donna Johnston should be listed as the departmental approver.
Non-OCREB Studies – Ms. Valerie Bourada should be listed as the departmental approver.

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REB of Record Study Agreement (OCREB)

The study team will complete the PDF fillable Agreement template (provided by CTO) with the information from CTO Stream and send the Agreement to the PI for signature. The study team will send a scanned copy of the Agreement (singed by the PI and witness) back to the CHEO REB office, who will obtain the necessary signatures from the CHEO signing authorities. The PI/delegate will send a scanned copy of the Agreement back to CTO who will obtain signature from the REB Host Institution. Fully executed Agreements will be circulated via the correspondence feature in CTO Stream and by email.

REB of Record Study Agreements (all other studies)

CTO will send the REB of Record Study Agreement to the PI for signature. The PI/delegate will send a scanned copy of the Agreement back to CTO. The study team will send a scanned copy of the Agreement (singed by the PI and witness) back to the CHEO REB office, who will obtain the necessary signatures from the CHEO signing authorities. The PI/delegate will send a scanned copy of the Agreement back to CTO who will obtain signature from the REB Host Institution. Fully executed Agreements will be circulated via the correspondence feature in CTO Stream and by email.