CLINICAL TRIALS ONTARIO

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

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

Scope

Multi-centred, pediatric oncology Clinical trials. In accordance with the existing letter of intent between CHEO and the Ontario Cancer Research Ethics Board (OCREB), OCREB is an external ethics board of record that may act as the research ethics BOR for pediatric oncology trials for CHEO.

CHEO has specific requirements about the membership of external REBs that provide ethics oversight for studies involving pediatric participants and/or outcomes in pediatric population being conducted under the auspices of CHEO. These requirements will be considered before agreeing to the external Board of Record acting as the BOR.

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, add the following bullet to the list of organizations with direct access to participant records:
   - The Children's Hospital of Eastern Ontario – Ottawa Children's Treatment Centre and the Research Institute, to oversee the conduct of the research at this location;

   Note: if the consent template includes the statement "This institution and affiliated sites, to oversee the conduct of research at this location", the above bullet point language is not required.

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7. If the study team is using the study association function in EPIC, the following language should be place in the confidentiality section:

> *Information that is collected as part of a patient's clinical care is stored in an electronic medical record/health record. Participation in this research study will be indicated in your medical record*. *(insert as applicable: This includes your research visits and the results of study procedures).* *This information can be seen by both the research team and the clinical care staff at the hospital.*

Note: CTO will not screen for the following elements however they must be addressed in the Centre Initial Application and post-approval events, if and as applicable

Consent Process Requirements

Capacity assessments cannot be based on age. The ability to consent must be based strictly on the individual's capacity to consent.

Recruitment strategies and Future Contact

Due to the complexities regarding capacity in the pediatric population, the use of a 'permission to contact' program (i.e., contacting a person whose contact information is in a database that's purpose is the recruitment into future yet to be identified or approved research studies) is not permitted at this time at CHEO. The only use permitted is research team approach in the clinic (i.e., the person/family is in a hospital clinic and has agreed to the permission to contact program, therefore the study team can approach the family in the clinic about study participation).

These same complexities apply for the collection of personal identifiers (contact information) for the purposes of contact for future yet to be identified or approved studies, therefore CHEO does not allow for this method of recruitment/future contact. This should not be approved as part of CHEO participation in a study.

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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 adherence to the privacy and confidentiality requirements at CHEO. The research team will receive a letter of institutional approval, once the requirements of this application are met. This must be obtained prior to beginning the research project.

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: WGale@cheo.on.ca
Role: Institutional Representative

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

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

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

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

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: Watson
Surname: Gale

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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 3899
Fax:
Email: WGale@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

Note: For applications where signatures were requested prior to June 14, 2019, Mr. Bruce Squires may be identified as the Primary Institution Representative within the application form.

Institution Representative signature
Research teams are encouraged to notify Ms. Valerie Bourada (VBourada@cheo.on.ca) by email when the Centre Initial Application 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. The CHEO external board of record signature page may be required prior to sign off in the CTO system. This form is found on the CHEO REB website.