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.

Safety plans:

Studies administering assessments that ask questions relating to suicidality/self-harm/acute psychopathology must include a safety plan for appropriate follow up (including following the child and family until appropriate follow-up is arranged). The limits of confidentiality must also be specified in the confidentiality section (refer to ICF changes #4d).

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

1. Insert the CHEO and CHEO RI institutional letterhead on the first and signature page of the consent/assent form.

2. Consider adding gender-neutral pronouns to allow for gender diversity (she/he/they).

3. For studies with participants under the age of 16 where there is pregnancy testing, the limits for confidentiality should be indicated in the consent form. Suggested language:

   For a positive pregnancy test, the study doctor will contact you and, if appropriate, your family to discuss test results, so that you are aware of the result and a proper decision can be made about any follow up that may be needed. If you become pregnant, the study doctor may contact the appropriate authorities or clinics at this institution to discuss this with them to ensure you receive appropriate care

4. In the section "How will participant information be kept confidential?":

   a) Revise sentence "Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records to check that the information collected for the study is correct and follows proper laws and guidelines at the site where these records are held."
      - *Remove "at the site where these records are held".*

   b) Add 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: Not required if the consent template states: "This institution and affiliated sites, to oversee the conduct of research at this location."

   c) Indicate length of time study data will be retained.

   d) If applicable, add the following to state the limits of confidentiality:

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Any information that may indicate that a child is being harmed or at risk of harm would not be kept confidential and instead be disclosed to appropriate authorities.

e) If applicable regarding data transfer outside Canada, revise sentence "By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside Canada."
- *Replace disclosure with transfer ("you are consenting to the transfer of your coded information").*

f) If applicable regarding the use of a virtual platform (e.g., zoom, Microsoft teams), add the following:

The use of virtual platforms, like any internet communication or storage and retention of information, involve privacy risks around access and disclosure of information, however, there are safeguards in place to reduce these risks, (e.g., account registration, meeting passwords, disposal of records or devices on which information is stored).

Add bullet point in the signature section
- I understand that the [*activity, e.g., interviews*] will be conducted using Zoom, which has privacy risks associated with its use.

If recorded
- I agree that my participation in the *[insert procedure (e.g., focus group, training session, assessment)]* will be recorded for research purposes.

5. If the study includes future uses of data add the following bullet point in the signature section:
- I agree that my data collected for this research may be used in future research within or beyond the general area of research of the current study.

Assent Form Requirements (Not applicable for studies reviewed by OCREB)

1. Insert the CHEO and CHEO RI institutional letterhead on the first and signature page of the assent form.

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

Consent/Assent Requirements

The ability to consent is based on the participant's capacity to consent to research, not age. Assent is based on the ability of a child to assent to research, not on age. Pediatric participants should be consented or assented using a consent or assent process appropriate to their capacity or ability.

Interventional studies for pregnant participants during their pregnancy and after birth *and* the infant participates in study procedures after birth, the study requires *two* consent forms: 1) for the mother as a participant and 2) for the infant as their substitute decision maker after birth – to account for the fact that the infant becomes a participant upon birth.

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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.

As of January 5th, 2021, **all** studies at CHEO, will be required to go through the CHEO RI Start Smart program https://is.gd/StartSmart.

The program consists of three steps:

Step 1: Intake

The intake form is a step by step guide on how to get your project up and running at CHEO. All the forms and resources you need are provided in this intake form.
Note: Step 2 link will be provided upon completion of the intake form.

Step 2 A & B: Pre-Institutional Approval & Administrative Application

A: This step requires that you submit your Interdepartmental impact and CHEO authorization signature pages and confirm mandatory training is complete.

Pre-Institutional Approval should be obtained via the link provided at the end of step 1.
Note: Step 3 link will be provided at the end of the Pre-Institutional Approval.

B: Complete an administrative application in ROMEO.
The administrative form captures key metrics, and adherence to the privacy and confidentiality requirements at CHEO.
The research team will receive a letter of acknowledgement, once the requirements of this application are met.
Note: the application must include a copy of the pre-institutional approval PDF.

Step 3: Institutional Approval

This step requires that the PI of the project attests to having all the applicable approvals and tasks in place. This must be obtained prior to beginning the research project and kept on file by the team.

CTO Stream Collaborators:

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

Name: Dr. Jason Berman
Email: CTOIR@cheo.on.ca
Role: Institutional Representative

Name: Natalie Anderson
Email: nanderson@cheo.on.ca
Role: Institutional Representative

Name: Sarah Tagliapietra
Email: stagliapietra@cheo.on.ca
Role: Institution Admin

Name: Sabrina Hamer
Email: shamer@cheo.on.ca
Role: Institution Admin

Name: Samira Chamaa
Email: schamaa@cheo.on.ca
Role: Institution Admin

Name: Yulia Rosenstein Levin
Email: YRosensteinLevin@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:	Dr.
First Name:	Jason
Surname:	Berman
Organization:	Children's Hospital of Eastern Ontario/Children's Hospital of Eastern Ontario Research Institute
Address:	401 Smyth Road
City:	Ottawa
Province/State:	Ontario
Postcode/Zip:	K1H 8L1
Telephone:	613-737-7600 x2957
Fax:	N/A
Email:	CTOIR@cheo.on.ca

The Secondary Institution Representative should be indicated as follows:

Title:	Ms.
First Name:	Natalie
Surname:	Anderson
Organization:	Children's Hospital of Eastern Ontario
Address:	401 Smyth Road
City:	Ottawa
Province/State:	Ontario
Postcode/Zip:	K1H 8L1
Telephone:	613-737-7600 x3350
Fax:	N/A
Email:	nanderson@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.
- For application where signatures were requested prior to March 19, 2021, Mr. Watson Gale may be identified as the Primary Institution Representative within the application form.
- For applications where signatures were requested prior to June 10th, 2022, have Valerie Bourada may be identified as the Secondary Institutional Representative.

Departmental approver in application forms

OCREB Studies - Dr. Donna Johnston should be listed as the departmental approver.