

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

Scope

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. Specifically, the review should include 2 reviewers with pediatric, biomedical expertise. 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. Insert the CHEO and CHEO RI institutional letterhead on the first and signature page of the consent/assent form.
2. For studies where there is pregnancy testing, the results management plan must be stated in the section "What if researchers discover something about a research participant?":

During the study, the researchers may learn something about you that they didn't expect. For example, the researchers may identify that you are pregnant.

If any new clinically important information about your health is obtained as a result of your participation in this study, you will be informed. Referral for medical care related to the pregnancy will be facilitated by the researchers.

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

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

Any information that may indicate that a child is being harmed or at risk of harm would not be kept confidential as required under the law.

- b) unspecified future research, include the following:

Other future research

Your coded **study data and/or coded samples** may be used or shared with other researchers (inside and outside of Canada) for future studies. "Coded" means that directly identifying information (such as your name and date of birth) will be replaced by a randomly generated number, which will be applied to the **study data and/or samples**. The goal of sharing is to make more research possible. However, the code matching your **study data and samples** with your name and other directly identifying study data will not be shared.

[If applicable, also include: This may include storing the **coded study data and/or samples** in controlled-access **databases/biobanks**, for which access is limited to researcher(s) who submit a study plan and who sign an agreement to use the coded study data and/or coded samples only for that research. Very limited coded study data may also be placed in an open access, publicly accessible database.]

You will not be asked if you agree to take part in future research studies using your **study data and/or samples**. You or your study doctor will not be told what type of research will be done. You will not be given reports or other information about any research that is done with your **study data and/or samples**.

4. 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.
2. If de-identified data or samples may be used or shared for unspecified future research, include the following:
Who will see information about me?
Other people doing studies in the future would have to ask special permission to look at your information.
These researchers would not know your name either.

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

1. 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.
2. 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.

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 #3a).

Privacy/Confidentiality

1. For participants consented/assented at CHEO/CHEO RI the consent/assent forms must be stored locally (i.e., on-site, local institutional servers). The use of external e-consent platforms is not permissible unless authorized by CHEO Privacy.
2. Studies that will register a participant in a research study in EPIC (medical record), this must be described in the application form and confidentiality section of the consent form.

How will participant information be kept confidential?

If you decide to join this study, information about your participation will be included in your health record/hospital chart, and those with access to your medical records (for your care, or for research) will be able to see this information.

Recruitment

1. Permission to Contact (PTC): Effective February 1, 2025, CHEO researchers may use CHEO's PTC program ('Research Connection') for minimal risk research. Researchers must comply with the institutional policy on use of the program. Research protocols must include clear information on the method of contact (in-person, phone, MyChart) and initial contact must use predefined scripts (that are not provided with the REB application). Study specific scripts or recruitment material that supplement the predefined scripts must be reviewed and approved by the REB of Record.
2. CHEO Recruitment Posters: Posters that will be posted on the walls of CHEO or satellite sites must be bilingual.

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

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: K1H8L1
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: K1H8L1
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.