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)

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 Participating Site Initial Application (PSIA) 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 intuitional 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.