**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

1. In the section “How will participant information be kept confidential?”:
2. 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”.*

1. 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.”*

1. Indicate length of time study data will be retained.
2. 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 and instead be disclosed to appropriate authorities.

1. 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”).*

1. 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.

1. 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.