**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. Insert the CHEO and CHEO RI institutional letterhead on the first and signature page of the consent/assent form.
2. In the section “How will participant information be kept confidential?”:
3. 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 and not otherwise described regarding secondary uses of data, add the following:

Data collected for this research may be used in future related research projects that are either an extension of the original project or in the same general area of research (secondary use of data). Any personal identifying information will be removed from the data and cannot be linked back to you. Researchers outside of this specific study may request access to the data for new research purposes. You will not be asked to provide additional informed consent for the use of your de-identified data for future research.

1. If applicable and not otherwise described, regarding future uses of data (broad use), add the following:

Data collected for this research may be used in future research within or beyond the general area of research of the current study (futures uses of data). Any personal identifying information will be removed from the data and cannot be linked back to you. Researchers outside of this specific study may request access to the data for new research purposes. You will not be asked to provide additional informed consent for the use of your de-identified data for future research.

Note: This requires a separate, optional consent 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.

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.

**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 thus be consented or assented using a consent or assent process appropriate to their capacity or ability.