**Children’s Hospital of Eastern Ontario (CHEO)**

**Changes to the CTO consent form template for use in submission to CHEO REB via ROMEO for Full Board Initial Applications**

1. Ensure the first page of the consent/assent form is on CHEO-OCTC and CHEO RI institutional letter head.
2. Replace the statement (or variations of this statement) “Deciding not to take part or deciding to leave the study later will not result in any penalty or affect current or future health care” with the following:

“Deciding not to take part or deciding to leave the study later will not affect the care you receive at CHEO.”

1. In the section ‘How many people will take part in this study?’

Insert an additional sentence specifying the number of participants expected to participate at CHEO.

1. In the ‘Reproductive Risks’ section: if there is a risk of sperm mutation or a teratogenic risk, then (as applicable) the Principal Investigator is responsible for ensuring the following sentences are included after the description of those risks:

Participants on the study should discuss these risks with sexual partners of the opposite sex. Adolescents will be given appropriate information about methods of birth control.

1. In the ‘How will participant information be kept confidential?’ section, the list of authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, for quality assurance (to check that the information collected for the study is correct and follows proper laws and guidelines); include the following bullet point:

* 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;

1. In the ‘How will participant information be kept confidential?’ section, the investigator should remove the following language: *~~Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study.~~*
2. In the ‘How will participant information be kept confidential?’ section, the investigator should indicate the length of time the study data will be retained.
3. In the ‘How will participant information be kept confidential?’ section , should there be secondary use of data the following should completed and inserted into this section:

The de-identified research data will be used to answer future related research questions about {*insert*}. Any researcher wishing to use the de-identified data will need research ethics board approval, as well as approval from the {*insert who – study research team, principal investigator, etc.*}. You will not be re-contacted for this use.

1. If the study team is using the study association function in EPIC, the following language should be place in the confidentiality section:

Information that is collected as part of a patient’s clinical care is stored in an electronic medical record/health record. Participation in this research study will be indicated in your medical record.  *(insert as applicable: This includes your  research visits and the results of study procedures)*. This information can be seen by both the research team and the clinical care staff at the hospital.

1. In the ‘Whom do participant contact for question?” section, the following should be inserted:

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

The CHEO Research Ethics Board 613-737-7600 x 3272