**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. Insert the CHEO and CHEO RI institutional letterhead on the first and signature page of the consent/assent form.
2. The CHEO REB strongly recommends that throughout the consent form, gender-neutral pronouns and gender-diverse appropriate language is used to allow for gender diversity. For example, ‘themselves’ or ‘them’ for ‘him/herself’ or ‘he/she’ respectively.
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 ‘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?’
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. 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. indicate the length of time the study data will be retained.
3. 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. 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 or email: [reb@cheo.on.ca](mailto:reb@cheo.on.ca)

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.

**Contact for future studies, CHEO REB has the following criteria:**

1. *Purpose limitation:* CHEO RI researchers may seek consent to contact participants for studies that are either an extension of the original project or in the same general area of research of the original protocol.
2. *Time limitation:* 5-yr ceiling with justification in original protocol; allowance for longer retention with appropriate justification.
3. *Frequency and method of future contact:* Ask participants how (method) and how often (frequency) they want to be contacted both in the original ICF and upon re-contact; upon re-contact, ask participants if they want to remain on the contact list. All contact attempts must be documented by the study team.
4. *Ownership and storage of contact list:* PI(s) of original study has the authority to decide when to use it; anyone on the research team can contact participants; contact list must be stored separately from research data with the same privacy protections as the Master List and must be kept at CHEO if the PI leaves the CHEO RI.
5. **Proposed ICF language:**

**Consent to contact for future studies**

You are being asked for permission to be contacted in the future for participation in research projects. The research team may contact you within the next 5 years regarding projects that are in that [insert general area of research related to original protocol].

I agree to be contacted about future research projects:

* Yes
* No

Preferred contact information:

* Phone
* Email

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

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