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

**Changes to the CTO consent form template for use in submission to CHEO REB via ROMEO for all 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 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. 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 length of time study data will be retained.
3. 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. 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

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.
4. *Record of contact*: Keep a record of re-contact, including number of attempts at re-contact.
5. *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.
6. ***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. If you agree to be contacted in the future for research purposes, the research team may contact you within the next 5 years.

Your decision to allow your information to be retained for research purposes is completely voluntary. While there may be no benefit to you, your information will help researchers to quickly identify individuals who may be suitable to participate in a research project.

*I agree to be contacted in the future for participation in research projects that are in the [nsert general area of research related to original protocol] where the research team will explain the project and ask if I am willing to participate at that time.*

Yes

No

Not sure – I have some questions I would like to discuss with someone

*I agree to be contacted*

As often as the research team wants to contact me within the next 5 years

Not more than once a month

Not more than once every 6 months

Not more than once a year

*I want to be contacted by*

Phone \_\_\_\_\_\_\_\_\_\_\_\_

Email \_\_\_\_\_\_\_\_\_\_\_\_

\*Please provide your contact information of your choice

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