

# Memo

To: Pediatric Clinical Trial Sites  
 From: Ontario Cancer Research Ethics Board (OCREB)  
 Date: June 10, 2026

**RE: Implementation of Team-based Consenting for Paediatric Studies Approved by OCREB**

## Background:

After consultation with paediatric oncology centres on the implementation of team-based consenting for paediatric trials, OCREB is ready to move forward with the change.

Recognizing the operational issues that must be addressed and the need for staff training and education, OCREB proposes this change take effect by July 31, 2026. Sites requiring additional time should consult Natascha Kozlowski at [nkozlowski@oicr.on.ca](mailto:nkozlowski@oicr.on.ca).

## What we heard from sites:

Five sites provided feedback to OCREB. The following table summarizes the feedback.

There were no ethical concerns with this change and most expressed agreement with the change.	
Concern	Response
The major concern was meeting the consenting requirements by the Children’s Oncology Group that specifies a physician or Advanced Practice Provider must explain the study and obtain consent from study participants.	Under the team-based consenting model, the physician remains responsible for explaining the study and will sign the consent form to document that role as one of the two individuals obtaining consent. OCREB will add two signature sections at the end of the consent form template. One for the treating physician / Study Investigator who explained the study to the potential participant and one for the neutral person who confirmed consent / assent.
The majority of the feedback reflected operational challenges such as:	OCREB will work with sites to implement the change.

<p>a) Needing to train the neutral person in consenting process</p> <p>b) Research staff do not have access to the EMR so cannot make notes about consenting or participation in trial. This will need to be requested and the timeline for getting access is unknown.</p> <p>c) Some study staff are unionized and consenting is not part of their job description.</p>	<p>Study staff consent adult patients as OCREB does not allow the treating physician or study PI to consent adults and perhaps exploring how this is handled in the adult population could be helpful in the paediatric context.</p>
<p>Many (if not most) of the CRAs on COG studies work remotely and are not on site every day</p>	<p>The memo has an extenuating circumstance clause where physician can obtain consent and start the trial and at the next feasible time, the neutral person can obtain ongoing consent.</p>
<p>Concern about providing consistent information and flow of the consent process.</p>	<p>OCREB acknowledges the need for staff education on the consenting process and the protocols.</p> <p>Sites may also look to non-OCREB approved paediatric studies or adult studies that use a neutral person during consent as examples for education and process strategies.</p>
<p>Will consent updates also require a neutral person?</p>	<p>In following the process used with adult participants, consent updates are also obtained by a neutral person</p>
<p>Will electronic consenting be changed?</p>	<p>The only change will be the inclusion of the neutral person in this virtual process.</p>
<p>Updating submissions with updated consenting procedures</p>	<p>OCREB will work with sites to identify active studies that that will implement team-based consenting. The added consent signature line will be treated as a pre-approved administrative change.</p>