Ontario Cancer Research Ethics Board
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Ontario Cancer Research Ethics Board N2/CAREB REB SOP Addendum

OCREB has adopted the N2/CAREB REB SOPs. However, in order to reflect specific OCREB requirements, this addendum must be used in tandem with the SOP noted below*.

N2/CAREB SOP 701 – Informed Consent Form Requirements and Documentation

SOP Section	OCREB Addendum
5.1.8 N/A	**5.1.8 added** To facilitate compliance with OCREB's long-standing controlled honour-system for the implementation of consent forms at the centre, and to present consistent information to all study participants in Ontario, each centre must adopt the OCREB approved provincial consent forms with the addition of the authorized pre-approved administrative changes only. Centres are not required to submit their centre consent forms to OCREB. OCREB does not review centre consent forms. Refer to the "*Guidance for pre-approved administrative changes*" on the OCREB website for details.
5.2.2 Oral consent: If applicable/acceptable, a qualified interpreter fluent in both English and the research participant's native language orally interprets the REB approved English consent form to the research participant. The interpreter should be an impartial person. When the person obtaining consent is assisted by an interpreter, the interpreter must sign and date the consent form;	**5.2.2** Oral Consent**:** If applicable/acceptable, a qualified interpreter fluent in both English and the research participant's native language orally interprets the REB approved English consent form to the research participant. The interpreter should be an impartial person. When the person obtaining consent is assisted by an interpreter, the interpreter must sign and date the consent form; **Additionally**: Oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary [i.e., the consent document] of what is presented orally can be implemented for COG (Children's Oncology Group) paediatric trials when applicable. A witness to the oral presentation is required, and the participant is given copies of the short form document and the consent. When this procedure is used with participants who do not speak English, (i) the oral presentation and the short form written document should be in a language understandable to the participant; (ii) the REB-approved English language informed consent document also will be provided (iii) the witness should be fluent in both English and the language of the participant. At the time of consent, (i) the short form document is signed by the participant (or the participant's guardian); (ii) the English language informed consent document is signed

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	by the participant (or the participant's guardian) and the person obtaining consent; and (iii) the short form document and the consent are signed by the witness. When the person obtaining consent is assisted by an interpreter, the interpreter may serve as the witness. The REB must approve all language versions of the short form documents. The translated short form documents will be available to participating centres and can be implemented as appropriate to the study/study participants. It is the responsibility of the REB to determine which of the consenting procedures is appropriate for documenting informed consent in protocols that it reviews. A**dditionally:** The interpreter may be in person or remote. If the interpretation is conducted remotely the name of the interpreter and the date of the interpretation must be documented in the consent form by the study staff and information of the interpreter will be included in the study file including contact information.

Revision History	
Date/Version	**Summary of Changes**
August 28, 2018/001	Original version.
October 2, 2022/002	5.2.2 added to address the use of remote interpretation
March 23, 2023/003	5.2.2 added to address the use of short form consents for COG paediatric studies https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.html
March 21, 2025/004	No revisions needed