Ontario Cancer Research Ethics Board
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Memo

To: Paediatric Centres

From: OCREB

Date: March 18, 2025

RE: Short Form Consents for COG trials

OCREB has approved the implementation of the NIH CIRB-reviewed and approved English language Short Form, and translated Short Forms for applicable COG trials conducted at OCREB participating centres.

The 45 languages are:
Albanian, Amharic, Arabic, Armenian, Bengali, Bulgarian, Burmese, Chinese (Simplified), Chinese (Traditional), Czech, Farsi, Filipino, French, German, Greek, Gujarati, Haitian Creole, Hebrew, Hindi, Indonesian, Italian, Japanese, Khmer, Korean, Lithuanian, Mongolian, Polish, Portuguese-Brazil, Portuguese-European, Punjabi, Romanian, Russian, Serbian, Sinhalese, Spanish, Swahili, Tagalog, Tetum, Thai, Tigrinya, Turkish, Ukrainian, Urdu, Vietnamese, and Yoruba

Implementation of the short form and main consent is reflected in [SOP701 Addendum]:
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 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.

Additionally:
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.

The Ontario Cancer Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: TCPS 2 - 2nd edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations. OCREB is registered with the U.S. Department of Health & Human Service under the IRB registration number IRB00003960.

Jacqueline Limoges PhD RN
Chair, Ontario Cancer Research Ethics Board