CLINICAL TRIALS ONTARIO

661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
M5G 1M1 Canada
www.ctontario.ca

Documented Institutional Ethics Requirements
The Hospital for Sick Children (SickKids)

Scope

Non-Phase 1, multi-centred, pediatric Children's Oncology Group (COG) clinical trials.
In accordance with the existing Letter of Intent (LOI) between The Hospital for Sick Children (SickKids) and Ontario Cancer Research Ethics Board OCREB, OCREB is the only ethics board that can act as the Board of Record (BOR) for these studies until August 31, 2017, at which point an extension may be granted.

SickKids has specific requirements about the membership of other Research Ethics Boards (REBs) that provide ethics oversight. These requirements will be considered before agreeing to participate in a study with CTO.

Informed Consent Form Requirements

1. For studies that include pregnancy testing: the following paragraph should be included:
   The results of the pregnancy test will be told to you (the participant) by one of the study team members in private. Every effort will be made to keep positive pregnancy test results private. These results will not be shared with your parents/guardian unless you request it.

2. In the Confidentiality Section, add the following bullet to the list of organizations with direct access to (e.g., who can look at) participant records:
   - Representatives of the Hospital for Sick Children (SickKids), to oversee ethical conduct of research at this location

Consent Process Requirements

Capacity assessments cannot be based on age. The ability to consent must be based strictly on the individual's capacity to consent. In addition, capacity assessments must be conducted by a registered healthcare professional.

When consenting participants at SickKids, separate consent forms must be used for participants who have the capacity to consent for themselves, and participants who cannot consent for themselves and have a substitute decision maker (SDM) provide consent (i.e., parent or guardian).

For example: If the study involves participants that MAY have the ability to consent for themselves, study teams should submit:

- Consent Form for the participants that have capacity to consent;
- Consent Form for the SDM (i.e., Parent or Guardian) of the participants who do not have capacity to consent and an Assent Form for the participant.

If the study involves only participants who will NOT have the ability to consent for themselves, study teams should submit:

- Consent Form for the SDM (i.e., Parent or Guardian) and an Assent Form for the participant.

The Researcher is responsible for ensuring that this requirement is followed.

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SRERS Administration
The Hospital for Sick Children (SickKids)

Reminder: Institutional Research Administration Requirements

The CTO Streamlined System provides a streamlined approach to research ethics review. Each participating site must ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research.

CTO Stream

Collaborators:

The following collaborators must be given a role on all Provincial Initial Application (PIA) forms and Centre Initial Application (CIA) forms.

Email: david.kenney@sickkids.ca
Role: Institutional Representative

This access is automatically granted when the Centre Initial Application is created. **When The Hospital for Sick Children is the Provincial Applicant site the research team should immediately create the CIA for The Hospital fo Sick Children (right after creating the PIA)**. This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the PIA prior to submission.

Institution Representative in application forms

The Primary Institution Representative must be indicated as follows in the applications within CTO Stream:

Title:	Mr.
First Name:	David
Surname:	Kenney
Organization:	The Hospital for Sick Children
Address:	555 University Avenue, Rm 5506 Hill Wing
City:	Toronto
Province/State:	Ontario
Postcode/Zip:	M5G1X8
Telephone:	416-813-5718
Fax:	N/A
Email:	david.kenney@sickkids.ca

The Secondary Institution Representative field should be left blank.

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REB of Record Study Agreement

CTO will send the REB of Record Study Agreement to the PI for signature. The PI/delegate will send a scanned copy of the Agreement back to CTO. CTO will then disseminate to the Institutional Representative who will send to the Institutional Signing Authority for signature once all institutional impacts have been approved. Institutional Representative will then send the fully signed Agreement to CTO.

REB of Record Study Agreements (OCREB)

The study team will complete the PDF fillable Agreement template (provided by CTO) with the information from CTO Stream and obtain signatures from the PI/witness. The study team will send a scanned copy of the Agreement to CTO (streamline@ctontario.ca). CTO will then disseminate to the Institutional Representative who will send to the Institutional Signing Authority for signature once all institutional impacts have been approved. Institutional Representative will then send the fully signed Agreement to CTO.