Ontario Cancer Research Ethics Board

OCREB Team

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Ontario Cancer Research Ethics Board…
safeguarding the rights and well-being of cancer research participants

Objectives

- Overview of OCREB as an REB and how we work
- Definitions of Lead Applicant vs Participating Site Applicant
- OCREB Review types and Review of some of the CTO application forms
- Q & A

What is OCREB?

- Centralized oncology-specific REB for Ontario; started in 2003
- Board Members are from across Ontario
- OCREB provides a single review of a study that can be conducted at multiples sites
- Studies are submitted to OCREB through an online system - CTO Streamline

Lead Applicant

Who can be Lead Applicant?

- A site is identified as a lead applicant after an agreement between PI & Sponsor
- First Ontario site ready to activate the study

Lead Applicant Responsibilities

- Lead Applicant will submit:
  - The initial study
  - Any changes to the study and study documents (i.e., study protocol, IB, consents, etc)
  - Study reportable events
  - Study ethics approval renewal

Study Wide Applications

- Clinical Trial Initial Application (CTIA)
  - Application with study specific information/questions (e.g. objectives, eligibility criteria, statistical analysis details, study procedures, etc.)
  - all study documents (protocol, provincial consent form, participant materials, IBs, Questionnaires, etc.)
  - CTIA **must** be signed by the PI at the initial submission; Delegated study staff can sign resubmissions

Study Wide Applications

- Study Wide Amendment (SWAM)
  - Updates to questions that are study-specific (e.g. objectives; eligibility criteria; statistical analysis details; study procedures; etc.)
  - Changes to study documents (consents; participant materials; IBs; Questionnaires; etc.)

Study Wide Applications

- Study Wide Reportable Events (SWRE)
  - Reportable events such as DSMB/C and IA results
  - Any new information that would impacting the overall conduct of the study or cause the sponsor to modify study documents Safety Notice/Report)
- Study Wide Continuing Review (SWCR)
  - SWCR must be submitted once per year to ensure continuous ethics approval of the study

Participating Site Applicants

- Any Centre or site in Ontario that would like to conduct the study (including the Provincial applicant site)
- 1st step > Centres must submit a Participating Site Initial Application (PSIA) any time after CTIA is approved
- Once the PSIA is approved, an approval letter will list all provincially-approved documents (consents, protocol, IBs, participant materials, etc.)
- Same version dates for all study documents (including consents) are used at all sites

Participating Site Initial application

- To submit Site-specific information:
  - Confirm standard of care at the centre
  - Describes conduct of the study at the site: consenting process; recruitment processes, etc.
  - Privacy policies/identifiers
  - Conflict of interest declarations
  - Reimbursements
  - Plan to disseminate of study results

Participating Site responsibilities

- Submission of **participating site-specific applications**:
  - Participating Site Initial Application (PSIA): Initial application to join a provincially approved study
  - Reportable Events (PSRE): Local SAEs, privacy breaches, protocol deviations
  - Participating Site-Specific Amendments (PSAM): Change in centre PI; centre-specific recruitment materials;
  - Participating Site Continuing Review (PSCR): Annual centre renewals

Study Wide vs Participating Site

Activities/Responsibilities	Study Wide	Participating Site
Approval	Study is ethically sound; study is REB-approved in Ontario	Study can now be conducted at the site
Initial application	YES	YES
Amendment application:		
Protocol changes	YES	-
Consent changes	YES	-
Translated materials	YES	-
Updated IB	YES	-
Change in PI	YES	YES
Change in reimbursement		YES
Change in consenting process		YES

OCREB study reviews

- Full Board vs Delegated review
- Examples of applications reviewed by OCREB

Full Board Review

- Clinical Trial Initial Applications (CTIAs) OR;
- Any changes to a study that increases the risk for participants
- OCREB FB meetings > held on the 2nd Friday of each month
- Board members are from across Ontario
  - Scientific members including oncologists and statisticians
  - Clinical trial staff
  - Bioethicists and lawyers
  - Community

Full Board Review - CTIA

Submission Deadline *(12pm on the following days)*	Meeting Date	Meeting Capacity for Initial Applications (CTIAs)	Continuing Reviews for Studies Expiring
Tuesday, February 25, 2025	Friday, March 14, 2025		March 14 to April 10
Tuesday, March 25, 2025	Friday, April 11, 2025		April 11 to May 8
Tuesday, April 22, 2025	Friday, May 9, 2025		May 9 to June 12
Tuesday, May 27, 2025	Friday, June 13, 2025		June 13 to July 10
Tuesday, June 24, 2025	Friday, July 11, 2025		July 11 to August 7
Tuesday, July 22, 2025	Friday, August 8, 2025		August 8 to September 11
Tuesday, August 26, 2025	Friday, September 12, 2025		September 12 to October 9
Tuesday, September 23, 2025	Friday, October 10, 2025		October 10 to November 13
Tuesday, October 28, 2025	Friday, November 14, 2025		November 14 to December 11
Tuesday, November 25, 2025	Friday, December 12, 2025		December 12 to January 8
Tuesday, December 9, 2025*	Friday, January 9, 2026		January 9 to February 12

 *Accepting applications*  *Nearing capacity*  *At full capacity, no longer accepting applications* * *Modified to accommodate the holiday schedule*

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Full Board Review - CTIA

- Goes to a Full Board Meeting
- Review letter and consent revisions sent back to the lead applicant
- OCREB review letter notification from system - access under ‘History’ tab
- Response re-submitted by lead applicant
- OCREB final review and APPROVAL

Full Board Review – PI Response to OCREB

- To create PI response, copy and paste the questions and provide a response to each question
- For application questions, letter should confirm changes were made & application form should be revised as requested

Example of PI Response Letter

This letter serves as a response to the OCREB review letter sent on XXXXX, for the CTO Project ID:XXX sponsor study ID XXXX

Required Modifications:

1) Section 2.12 - Please confirm if GMALL is offered in Ontario as standard of care for this participant population. If GMALL is not considered SOC in Ontario, please remove all reference to this regimen from the ICF, and revise response in this Section accordingly.

Response: I confirm that both HyperCVAD and GMALL regimens are offered in Ontario as standard of care for this patient population. As discussed during the call with Sponsor and OCREB, several participating sites located in Ontario have chosen to offer GMALL as their SOC for this study.

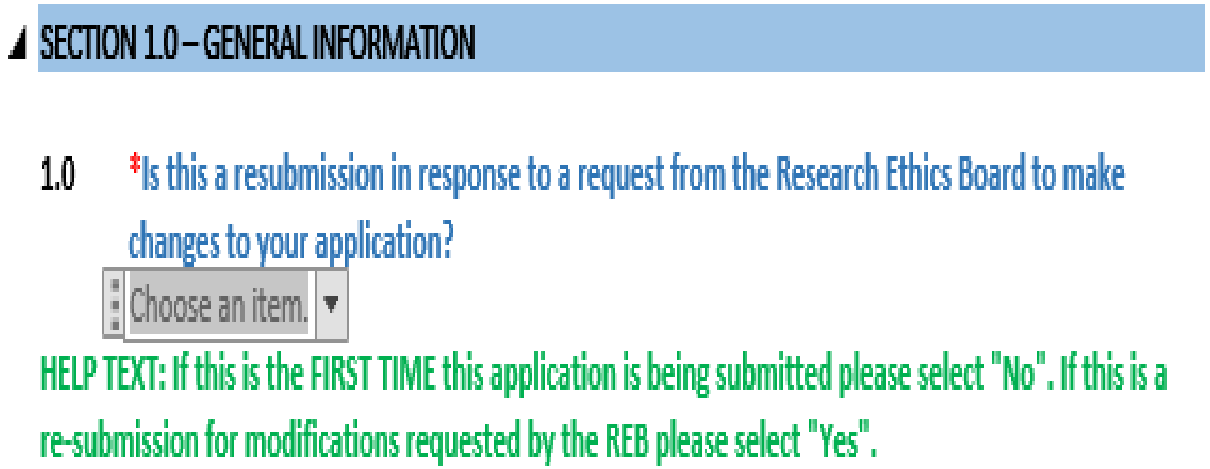
2) Section 2.18 - As tumor imaging may be done as per Schedule of Activities, please also select "Radiation"

Response: Provincial initial application has been revised. The imaging performed in this study is as follows: 1) ECHO or MUGA; 2) Ultrasound, CT scan, or MRI of liver (to identify hepatic stenosis); 3) Imaging assessments to be conducted per SOC (i.e.: PET, CT) in case of suspicion for extramedullary disease. Therefor, while the imaging being performed is not necessarily of the tumor itself, radiation may be applicable given the imaging assessments described (ECHO, MUGA, Ultrasound, CT, MRI, PET).

8) Section 7.9 - Please select NO, this is referring to secondary database aside from those that have been listed in Section 7.9.1

Response: Provincial initial application has been revised

CTIA Re-Submission and PI Response Letter



CTIA Re-Submission and PI Response Letter

SECTION 10.0 - RE-SUBMISSION INFORMATION

10.1 Upload Provincial Applicant Response to REB request for modification letter (if applicable):
Upload Document - Document Type: Response to REB letter

10.2 If changes have been made to a previously submitted consent/assent form at the request of the REB, please upload track-changes versions of all proposed consent and/or assent form(e.g. screening, main, optional), if applicable:
Upload Document - Document Type: Track Changes Version Document

10.3 Upload any additional materials requested by the REB (if applicable):
Upload Document - Document Type: Other materials

10.4 Please provide any additional comments for the REB to consider (if applicable): Click here to enter text.

CTIA - Approval

- Study is ethically sound and approval criteria have been met (i.e. *risks to participants are minimized; risk-benefit ratio is acceptable; participant selection is equitable; free and informed consent is sought; research plan is adequate as far as data monitoring, data protection and confidentiality, etc*.)

- Study CANNOT be conducted at any site yet

- A site or Centre in Ontario who would like to conduct the study needs to submit a Participating Site initial application (PSIA) and obtain PSIA approval

Full Board Review – Study Wide Amendment

- SWAMs receive either Full Board or Delegated Review

- FB SWAMs: Amendments that increase the risk to study participants (i.e., addition of a new cohort, new significant tissue samples are being collected, IB has significant change in risks, or moving from dose escalation to dose expansion for Phase 1 trials)

SWAMs - When a study has active participants and consent changes are made:

- Consent Update Form is required if amendments include changes to the ICF and there are currently enrolled participants
  - *A Consent Update Form outlines any relevant changes made to the Main ICF that would affect currently enrolled participants*
- Should follow OCREB template
- Should only include relevant new information

Consent Update Form

- How to communicate this new information in the consent update is Sponsor/PI driven
- OCREB may ask for changes/clarification
- Several options:
  - **Q# 5.11 : Describe how this information will be communicated to participants who are currently enrolled in the study and receiving study treatment or intervention: choose one of the following options:**

    •Contact participant (via phone) to provide new information orally (using the approved consent update form). Document in health record. At next visit, provide consent update form and obtain signature

    •At next visit, provide consent update form and obtain signature

    •At next visit, provide consent update form. Document in health record.

Consent Update Form

- **Q# 5.12: Describe how this information will be communicated to participants who are currently being followed for the purposes of the study but are no longer receiving study treatment or intervention: choose one of the following options:**

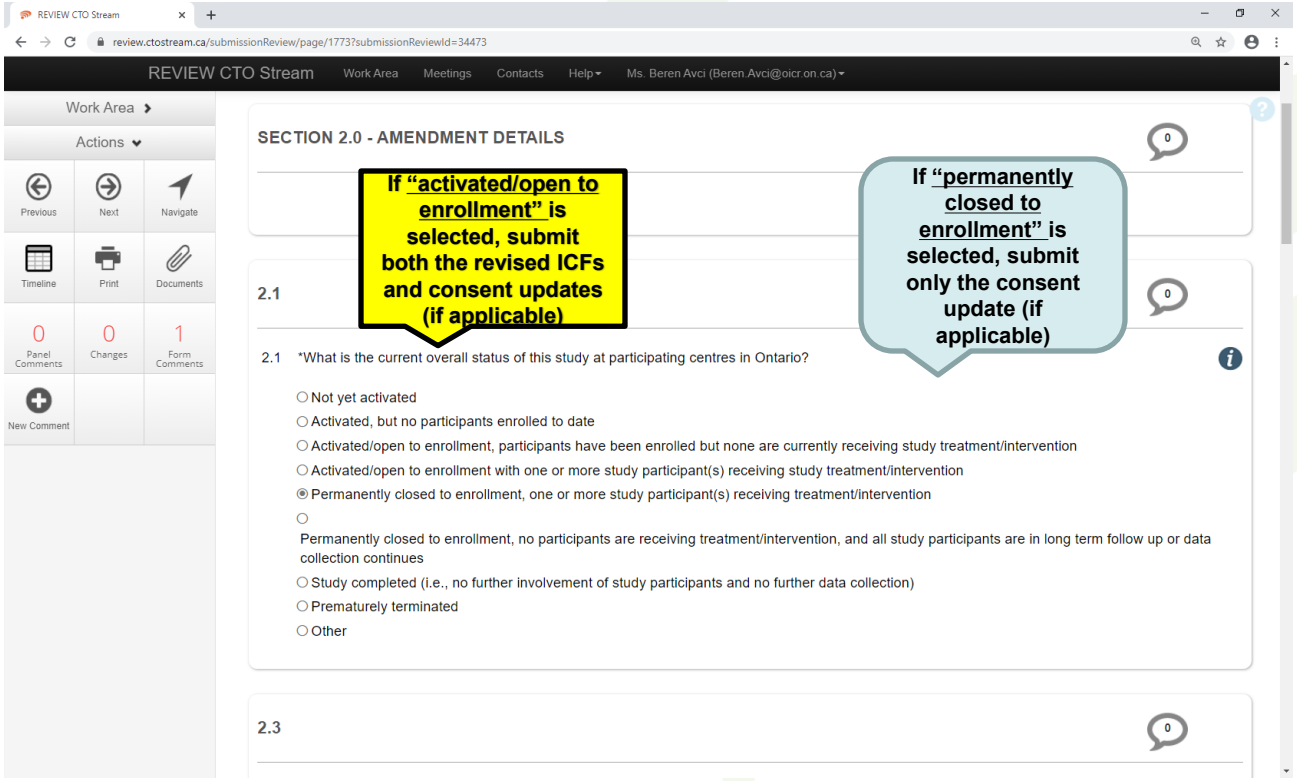
  •Contact participant (via phone) to provide new information orally (using the approved consent update form). Provide consent update form at next visit.

  •Contact participant (via phone) to provide new information orally (using the approved consent update form). Document in health record. Mail the consent update form (if no further visits are scheduled) and confirm receipt.

  •At the next visit, provide consent update form. Document in health record.

  •Mail consent update form. Document in health record. Confirm receipt at next visit.

Study Wide Amendment Form: Study Status



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Study Wide Amendment Approval

- Applies to all participating sites
- Participating site amendments are NOT required
- For consents: same process as with initial approval sites ‘adopt’ the Study wide approved template

Delegated Reviews

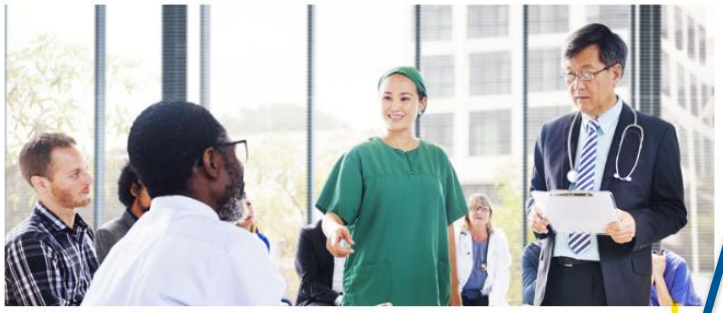
- Delegated review:
  - Research projects that involve no more than minimal risk
  - Minor or minimal risk changes to approved research
  - Continuing review of approved minimal risk research
  - Changes to consent documents that do not affect the rights and welfare of research participants or involve increased risk, or affect data integrity, or require significant changes in research procedures
  - Reportable events, including adverse events and safety updates such as reports from Data and Safety Monitoring Boards

Delegated Reviews

- Application types
  - Participating site initial application
  - Study wide and Participating site Amendments
  - Study wide and Participating site Reportable Events
  - Participating site Continuing Reviews

Participating Site Initial Applications

Investigators & Research Teams



List of Studies and Participating Study-Centres

- For a list of active studies, please contact one of the OCREB office personnel.

Annotated Versions of the CTO Stream Application Forms

To assist Applicants with the interpretation of the questions in the CTO Stream Application Forms, OCREB has prepared application forms with notes or comments added to explain many of the questions:

- CTO Provincial Initial Application (PIA) Annotated Application 20-Apr-2021
- CTO Centre Initial Application (CIA) Annotated Application Form 14-Dec-2023 ***REVISED***
- CTO Provincial Amendment (PAM) Annotated Application Form 22-Apr-2021
- CTO Centre Amendment (CAM) Annotated Application Form 10-Mar-2021
- CTO Provincial Reportable Event (PRE) Annotated Application 20-Apr-2021
- CTO Centre Reportable Event (CRE) Annotated Application Form 10-Mar-2021
- CTO Provincial Continuing Review (PCR) Annotated Application 20-Apr-2021
- CTO Centre Continuing Review (CCR) Annotated Application Form 10-Mar-2021
- CTO Provincial Study Closure (PSC) Annotated Form 20-Apr-2021
- CTO Centre Study Closure (CSC) Annotated Application Form 10-Mar-2021

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Participating Site Initial Applications
Remote Consent

SECTION 4.0 – INFORMED CONSENT INFORMATION

Provincial/CHEER (study-wide) information: Questions 4.1.1 – 4.1.2 below reflect information that has previously been provided to the REB and is here for reference purposes only.

4.1.1 ***Is a waiver of the requirement to obtain informed consent being requested for this study?**
☐ Yes ☐ No

4.1.2 ***A waiver of the requirement to obtain informed consent is being requested for:**
☐ All participants
☐ Some participants

If 'Some participants':

4.1.2.1 ***Describe the participant population for whom you are seeking a waiver and justify why the REB should consider a waiver of consent:** Click here to enter text.

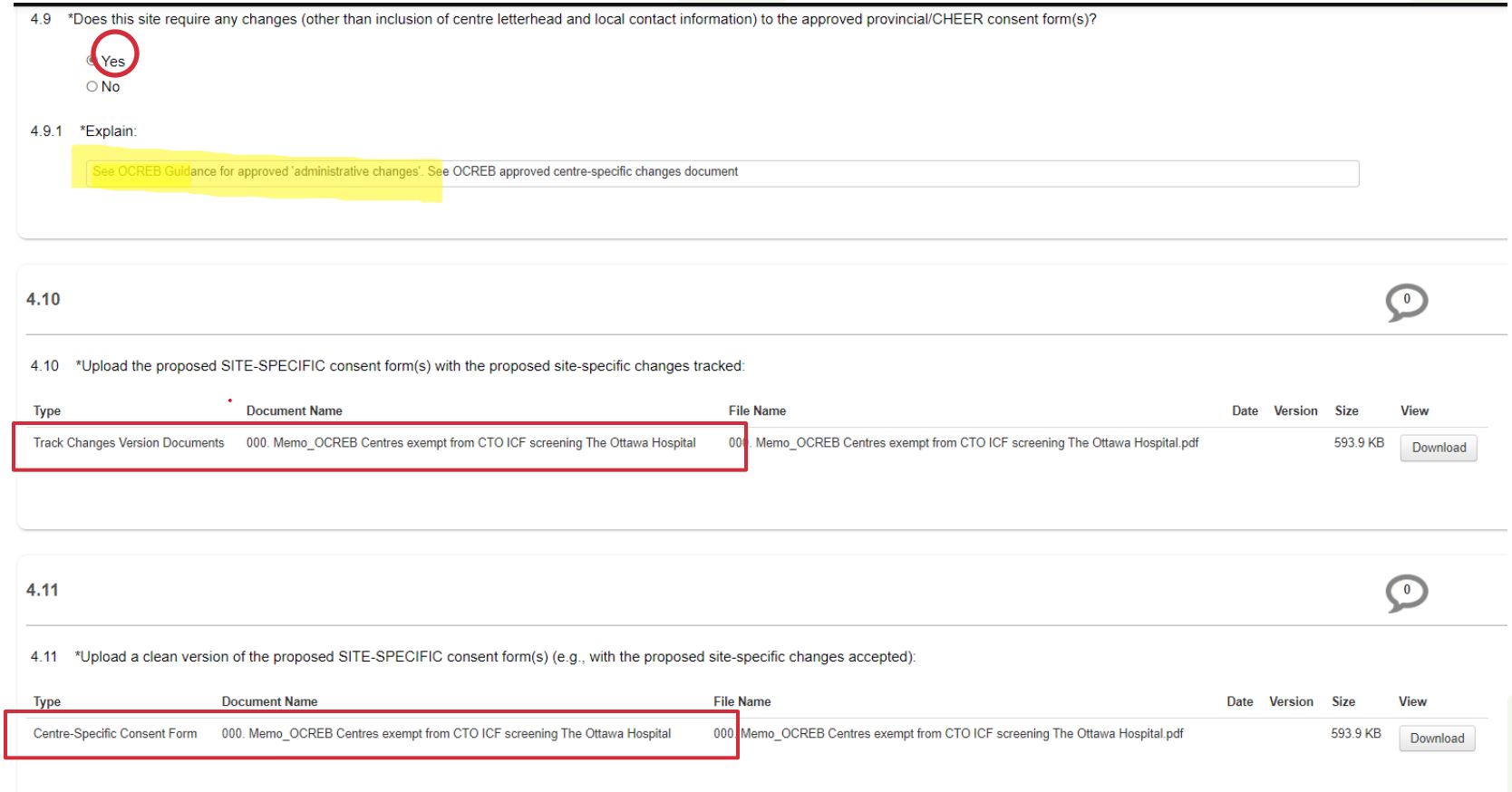
If 'No' to question 4.1.1, questions 4.2-4.4 appear:

4.2 ***Describe the initial consent process, including how much time potential participants and/or substitute decision makers (SDMs) will be given to review the information before being asked to give consent:** Click here to enter text.

4.2.1 ***Who will be explaining the study and/or treatments to the potential participants?** Click here to enter text.

4.2.2 ***Will there be opportunity for participants and/or substitute decision makers (SDMs) to discuss the study with family members or others before signing the consent form? Describe the environment and location where consent will be obtained?** Click here to enter text.

Participating Site Initial Applications



4.9 *Does this site require any changes (other than inclusion of centre letterhead and local contact information) to the approved provincial/CHEER consent form(s)?

- (•) Yes
- ( ) No

4.9.1 *Explain:

See OCREB Guidance for approved 'administrative changes'. See OCREB approved centre-specific changes document

4.10

4.10 *Upload the proposed SITE-SPECIFIC consent form(s) with the proposed site-specific changes tracked:

Type	Document Name	File Name	Date	Version	Size	View
Track Changes Version Documents	000. Memo_OCREB Centres exempt from CTO ICF screening The Ottawa Hospital	000. Memo_OCREB Centres exempt from CTO ICF screening The Ottawa Hospital.pdf			593.9 KB	Download

4.11

4.11 *Upload a clean version of the proposed SITE-SPECIFIC consent form(s) (e.g., with the proposed site-specific changes accepted):

Type	Document Name	File Name	Date	Version	Size	View
Centre-Specific Consent Form	000. Memo_OCREB Centres exempt from CTO ICF screening The Ottawa Hospital	000. Memo_OCREB Centres exempt from CTO ICF screening The Ottawa Hospital.pdf			593.9 KB	Download

Participating Site Initial Applications

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Study Information and Informed Consent Form

See Instruction Guide

Study Title for Participants: *(Insert Lay Title here)*

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: *(Insert Study Number, "Insert Official Study Title")*

Trial Code/study #: *(insert here)*

Study Doctor: Dr. _____

Sponsor: *(Sponsor name)*

If an REB approved French consent is not used at your institution remove this statement.
Le formulaire de consentement est disponible en français sur demande.

A 24-7 phone number is required for studies that include greater than minimal risk research procedures or interventions.
EMERGENCY contact number (24 hours/day 7 days/week): _____

Non-Emergency contact numbers are at the end of this document in the "Where can I get more information?" section.

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Participating Site Initial Applications

6.0 *What (if any) Personal Information or Personal Health Information will be SENT TO or COLLECTED BY the lead researcher/research group/sponsor for the purposes of this study (select all that apply)?

- ☐None, study participant ID only
- ☐Full name
- ☐Full initials
- ☐Partial initials
- ☑Full date of birth
- ☐Partial date of birth
- ☐Full date of death
- ☐Partial date of death
- ☐Age
- ☐Sex and/or gender
- ☐Full postal code
- ☐First 3 digits of postal code
- ☐Pathology specimen number
- ☐Medical device identifier
- ☐Admission date
- ☐Discharge date
- ☐Medical record number
- ☐Health card number
- ☐Driver's license number
- ☐Address
- ☐Telephone number
- ☐Fax number

<- responses pre-populate from the PIA.

6.2 *As per institutional privacy policies, which of the identifiers that were approved provincially/CHEER (study-wide) (shown above in question 6.0) are you authorized to disclose on the study data collection tools leaving the institution?

- ☐None, study participant ID only
- ☐Full name
- ☐Full initials
- ☐Partial initials
- ☐Full date of birth
- ☑Partial date of birth
- ☐Full date of death
- ☐Partial date of death
- ☐Age
- ☐Sex and/or gender
- ☐Full postal code
- ☐First 3 digits of postal code
- ☐Pathology specimen number
- ☐Medical device identifier
- ☐Admission date
- ☐Discharge date
- ☐Medical record number
- ☐Health card number
- ☑Other: ***Partial DOB collected instead of Full DOB because institution does not permit full PHI leaving***

Q6.2: (NEW)
Please select what identifiers your site will be collecting and disclosing outside the institution for study purposes, and as per your institutional policies. If the response or the identifiers chosen here DO NOT match the identifiers approved at the Provincial level (as noted in Q#6.0), then please also select: **OTHER,** and specify in Q#6.2.1 what identifier/s is/are collected and provide an explanation for the discrepancy

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Participating Site Initial Applications

8.1 *Will study participants and/or substitute decision makers (SDMs) be provided with compensation or reimbursement in a different amount or method than that described in the Provincial Initial Application/CHEER ~~Initial Application~~?

☐Yes ☐No

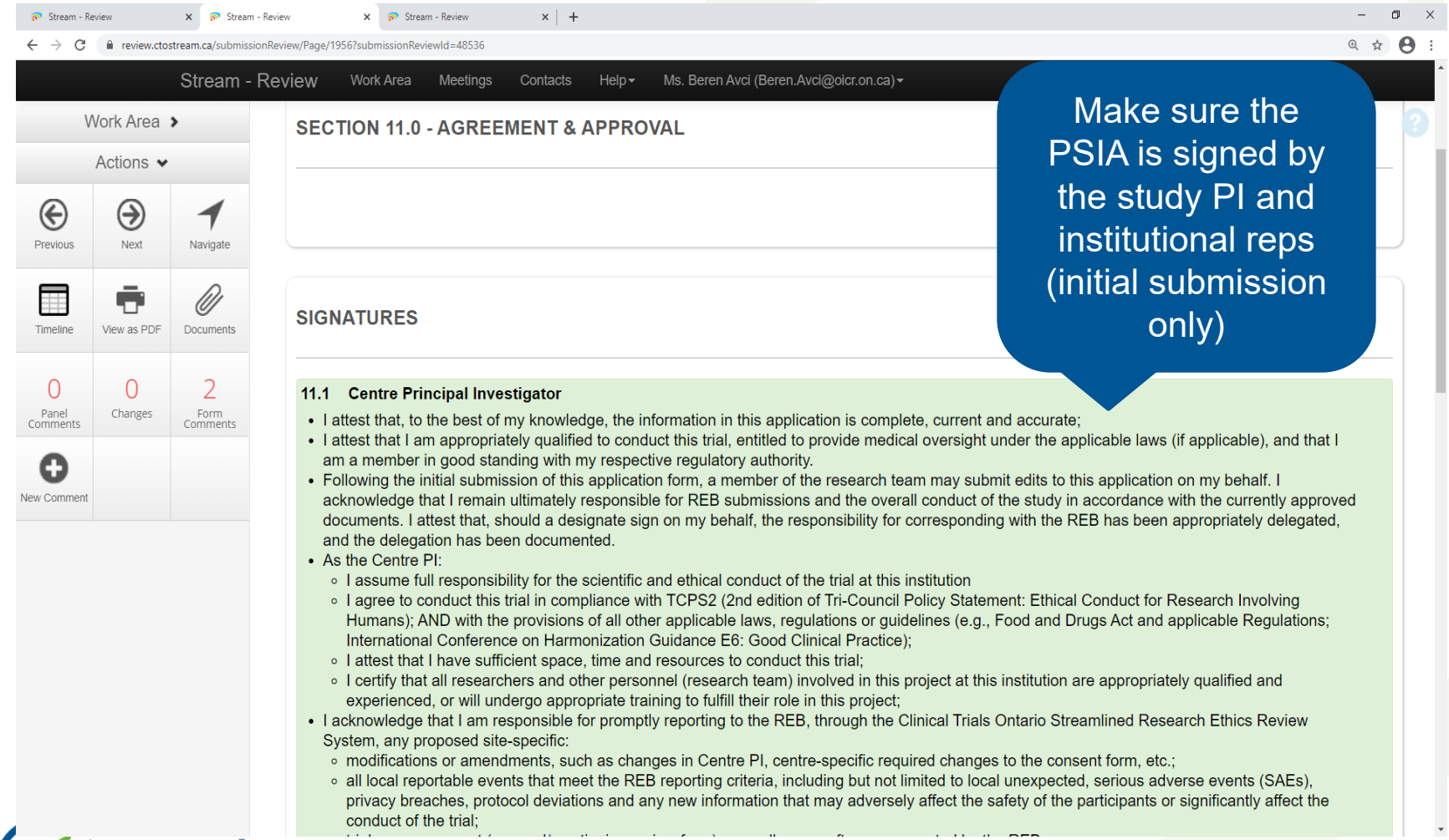
If 'Yes':

(NEW) 8.1 Please always respond **YES** here

8.1.1 ***Please Describe:** Click here to enter text.

(NEW) 8.1.1: Provide details on how your participants will be reimbursed, including what they will be reimbursed for ; approximate $ amount that may be provided and any other information that will be added to the **Compensation/reimbursement section** of your Centre consent form. If no reimbursement is provided, then please indicate that the template statement ***('You will be reimbursed for..)*** will be removed from the Centre consent.

Participating Site Initial Applications



Delegated Study Wide Amendment

2.3 ***Which of the following changes are included in the Amendment(s) (select all that apply):**

- ☐ Changes to the protocol
- ☐ Changes to biological specimen collection/use
- ☐ Changes to the consent form(s), assent form(s), debriefing material(s)
- ☐ Changes to participant materials (such as study instruments/questionnaires, recruitment materials, participant diaries, wallet cards, etc.)
- ☐ Updated/new Investigator Brochure (IB) or Product Monograph (PM)
- ☐ Translation of approved materials
- ☐ Change to the data collected and/or how data is accessed, collected, used or stored
- ☐ Changes in study funding, participant compensation/reimbursement, provision or access to product(s)/device(s), and/or financial pressure(s)/incentive(s)
- ☐ Change/updates relating to the communication of results
- ☐ Change in clinical trial registry information
- ☐ Change in US regulatory information
- ☐ Change(s) to Provincial Applicant or Provincial Co-Applicant; and/or change in study information (i.e., study title, study acronym/nickname/short name, sponsor's study ID)
- ☐ New information about a refusal to approve the study by another REB

Delegated Participating Site Amendment

SECTION 2.0 - AMENDMENT DETAILS

2.1

2.1 *Type of amendment: (Select all that apply):

- ☐ Site-specific changes to the consent/assent form(s) used at this site
- ☐ Changes in the informed consent/assent process at this site
- ☐ Site-specific translation of approved material(s)
- ☐ Changes in recruitment methods and/or recruitment material(s) (e.g., telephone, web or email scripts, flyers, brochures, etc.) used at this site
- ☐ Changes to other site-specific material(s) that will be given to study participants (including surveys/questionnaires/scripts, diaries and wallet cards)
- ☐ Changes to how personal information or personal health information is being accessed, collected, used, stored or transferred at this site
- ☐ Changes in the conflict of interest information previously provided to the REB for any of the investigators, study staff or members of their immediate families
- ☑ Changes in participant reimbursement and/or communication of study results
- ☐ Changes in site-specific study conduct (including location of visits/procedures, standard of care, and protocol implementation)
- ☐ Change in Principal Investigator
- ☐ Change(s) to contact details for the Principal Investigator and/or the name/contact details for the centre administrative study contact, or institution representative(s)
- ☐ Other changes

Study Wide Reportable Events

- The Researcher is also responsible for submitting to OCREB other types of reportable events
  - DSMB/C Reports
  - Safety notice or action letter that would cause the sponsor to modify the research and/or study documents
  - A change to the research that was initiated without prior REB review to eliminate an apparent immediate hazard to a research participant

Participating Site Reportable Events

Reportable Event Information:

1.4 *Type of Event

- ☐ Local (Internal) serious adverse event (SAE)
- ☐ Protocol deviation/violation
- ☐ Privacy breach
- ☐ Audit/inspection report

A **local SAE** is considered reportable by a centre, when the SAE meets **ALL** the following criteria:

1) **Event is serious**
2) **Event is unexpected**
3) **Event is related to participation in research**
4) **Event suggests that research puts participants at higher risk**

A **protocol deviation** is considered reportable by a centre, when **ANY** of the following criteria are met:

1) **Eligibility Waiver**
2) **Increased risk or possibility of risk for the research participant(s)**
3) **Compromises the scientific integrity (e.g., study validity or data)**
4) **OTHER, Specifically, a deviation in the consenting process (i.e., incorrect version date of the ICF used)**

Other Resources

https://ocreb.ca/

https://ocreb.ca/about-ocreb/investigators-research-teams/

Q&A

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