# OCREB Webinar Series

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**December 2024**

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

# Webinar Agenda

- Introductions
- OCREB Updates
- Ethics in the News
- OCREB Site Poll
- REC Reminders
- Q&A

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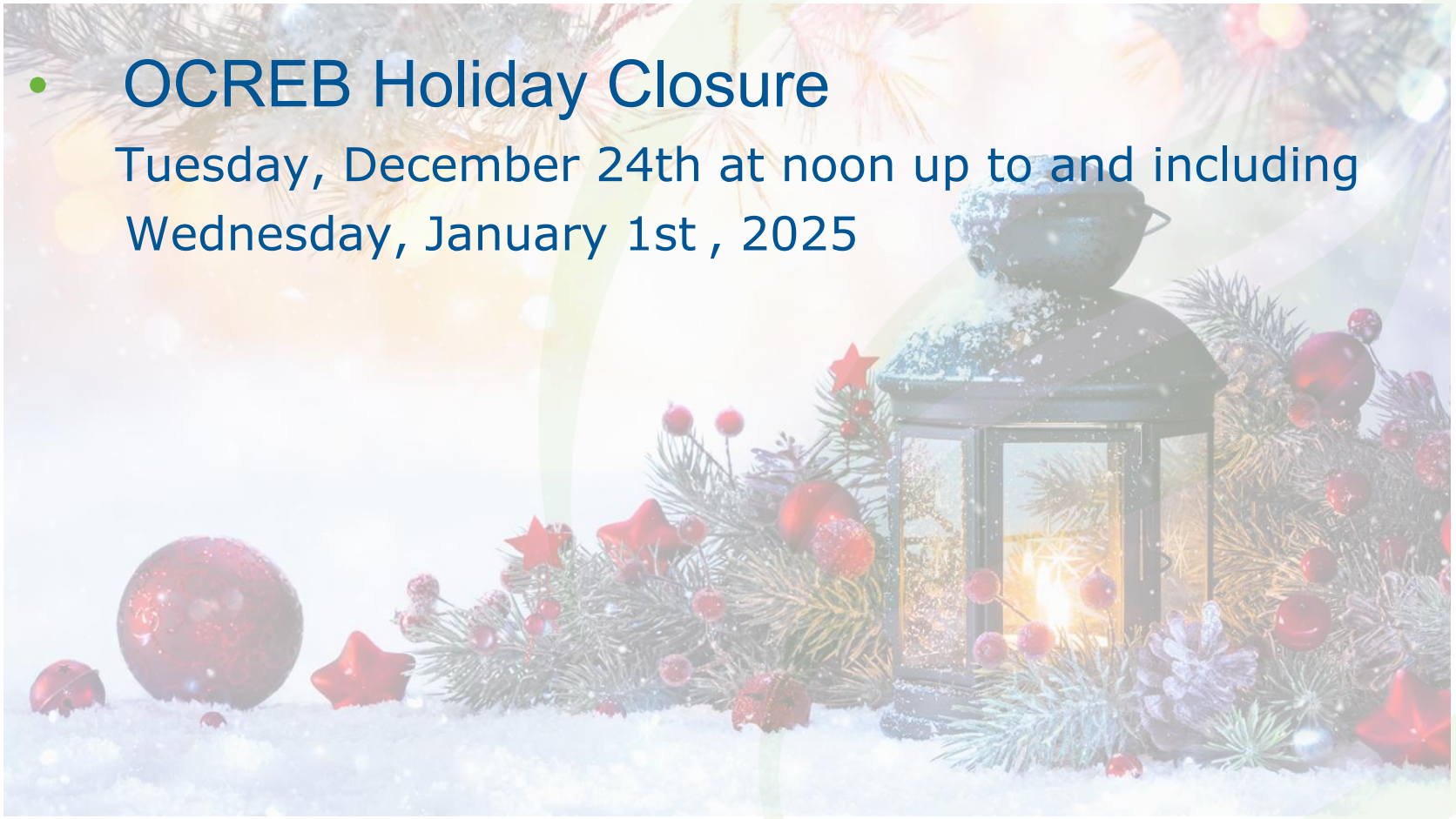
# OCREB Updates

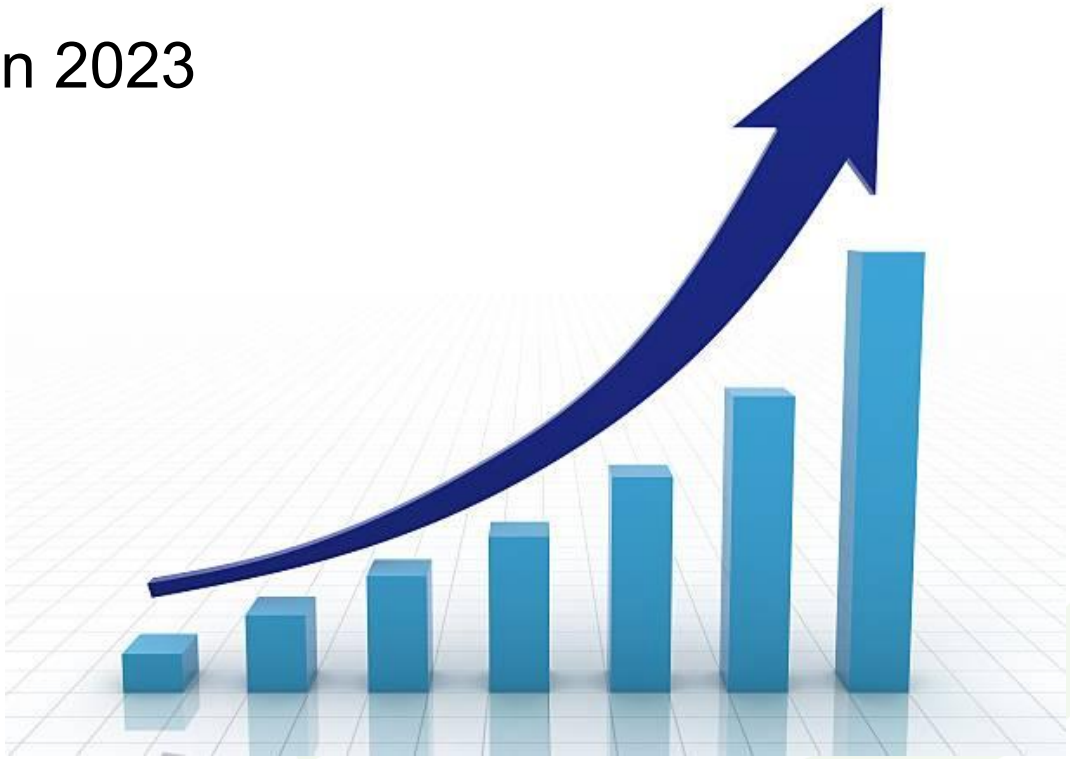


- OCREB Holiday Closure

  Tuesday, December 24th at noon up to and including Wednesday, January 1st , 2025

# OCREB Updates

- OCREB Total Submissions for 2024
  - Total of 149 submissions in 2024
  - Up from 129 in 2023



# OCREB Updates

## 2025 OCREB Meeting Schedule

| Submission Deadline | Meeting Date | Continuing Reviews for studies expiring |
|---|---|---|
| **Tuesday, December 10, 2024*** | Friday, January 10, 2025 | January 10 to February 13 |
| Tuesday, January 28, 2025 | Friday, February 14, 2025 | February 14 to March 13 |
| 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 6 |
| 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 |

https://ocreb.ca/about-ocreb/meetings-and-membership/

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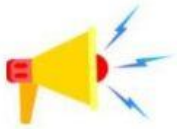
# OCREB Updates

- OCREB Guidance Documents Update
  - Appeals Process
  - Compensation/Reimbursement Guidelines
  - Conflict of Interest Guidelines & Declaration Forms(Investigators, Members)
  - OCREB Member Manual
  - Compliance Program

# Ethics in the News

## Regulatory & Ethical Updates



**The Declaration of Helsinki 2024 Revision adopted by the World Medical Association General Assembly in Helsinki**

WMA

# Ethics in the News

## Regulatory & Ethical Updates

## Declaration of Helsinki Updates include…

- **Participant-Centred Language**
- **Expanded Informed Consent**
- **Justice and Inclusion**
- **Sustainability**
- **Post-Trial Access**
- **Strengthen Role of Ethics Committees**

**https://www.wma.net/policies-post/wma-declaration-of-helsinki/**

# Ethics in the News

ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

About ▾ Our Consortium ▾ Funded Projects ▾ Meetings Education Call for Proposals Contact

## Group Selected to Run Pan-Canadian Single Research Ethics Board Review Process

# Ethics in the News

U.S. FOOD & DRUG ADMINISTRATION

**FDA grants accelerated approval to zanidatamab-hrii for previously treated unresectable or metastatic HER2-positive biliary tract cancer**

**FDA approves durvalumab for limited-stage small cell lung cancer**

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On December 4, 2024, the Food and Drug Administration approved durvalumab (Imfinzi, AstraZeneca) for adults with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

# Ethics in the News

Saskatchewan · **CBC Investigates**

- **'No consequences' for violating human rights in privately funded research in Canada, says ethics expert**

Roughly 85 per cent of clinical trials in Canada are privately funded

Geoff Leo · CBC News · Posted: Dec 02, 2024 4:00 AM EST | Last Updated: 5 hours ago

# OCREB Poll

## Electronic Study Documents

# REC Reminders – CIAs (1 of 4)

**Q#1.0: Is this a resubmission in response to a request from CTO or the Research Ethics Board to make changes to your application?**

- **Reminder**: *If OCREB sends back the CIA for changes, please revise response to "YES." PI Delegate can choose to sign the form upon resubmission OR request PI signature*

- **Exception**: *If Q#11.1-11.3 Signatures are incorrect (i.e., the correct PI/staff member needs to sign) and Q#1.0 response can remain as "NO."*

**Q#1.6.1: List any Co-Investigators at this site (including name, address, organization and contact details):**

- **Reminder**: *Listing Co-Investigators is not required. This field can be left blank.*

**Q#2.1: Expected start date of this study at this site:**

- **Reminder**: *Ideally, respond in MMM/YYYY format (i.e., Jan, 2025)*

- **Note**: *The date indicated here should not be earlier than the date the application is being submitted. For example, if you are submitting a CIA on December 12, 2024, the date provided in this section cannot be before December 12, 2024.*

# REC Reminders – CIAs (2 of 4)

**Q#3.4: How will initial contact be made (select all that apply)?**

- **Reminder**: *This question is about initial contact which should be done by someone that is part of the circle of care.*

- **Note**: *We've seen sites select 'Other' and then state that patients will be followed up via email after a phone call or in person visit, but this does not mean that initial contact is via email so please avoid including these types of responses*

**Q#3.5: Will initial contact/identification of participants be made by someone within the patient's circle of care?**

- **Reminder**: *'NO' is never an acceptable response. Initial contact/identification of potential participants should always be made by someone within the patient's circle of care*

**Q#4.9.1: Explain (this will appear after Q#4.9 Response "Yes")**

- **Reminder:** *As per the CTO Annotated Form, the response should always be "See OCREB Guidance for approved administrative changes." We have seen 'pre-approved' many times, but please note that this does NOT mean the same thing.*

**Q#4.10 AND Q#4.11: Upload the proposed SITE-SPECIFIC consent form(s)**

- **Reminder:** *This has been the case for a while, but please only upload the site-specific memo (version date should be sometime in 2024). One of the memos will be acknowledged in the approval letter*

# REC Reminders – CIAs (3 of 4)

**Q#5.6: Describe how coercion and undue influence will be minimized**

- **Reminder:** *Please ensure the response includes specific details. We've seen responses like: "Undue influence will be minimized" or "There will be no coercion" which is not acceptable.*

- **Example:** *"The study doctor may also be the participants' treating physician. To minimize undue influence, the consent discussion will be delegated to the study coordinator and participants will be informed that participation is voluntary. Participants will be told that they can change their mind about participation at any time etc..."*

**Q#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?**

- **Reminder:** *There are TWO ways to respond (you can refer to the Annotated Form as well)*

  - **A)** *Ensure all selected boxes MATCH the ones selected in Q#6.0*

  - **B)** *If all selected boxes DO NOT MATCH the ones selected in Q#6.0, then please select 'Other' and explain why the specific PHI(s) is or is NOT being collected.*

- **Note:** *Please do NOT select 'Other' and then specify things like Subject ID and/or Medical History. These are not relevant to the question. Also selecting 'Other' and specifying 'As per institutional policy' is no longer an acceptable response.*

# REC Reminders – CIAs (4 of 4)

**Q#7.6: Will or does the Investigator or sub-investigator or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any association or connection with an entity that is sponsoring or otherwise interested in the outcome of the study? (e.g., consultant, advisor, board member, employee, director, etc.)**

- **Reminder:** *Most recent COIs have been falling under this category where the PI provides consulting services to a Sponsor. A signed copy of the management plan should be on hand and available for upload*

**Q#11.1 – 11.3 (Centre Principal Investigator, Department Approver/Department Head, Institutional Representative):**

- **Reminder:** *Ensure that the correct staff members (i.e., from Section 1.0) sign in this section.*
- **Note:** *PI cannot have more than one role (i.e., PI Signature should not appear more than once here)*

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**SECTION 1.0 - GENERAL INFORMATION**

**1.0** *Is this a resubmission in response to a request from the Research Ethics Board to make changes to your application?

Choose an item.

**HELP TEXT:**

**If this is the FIRST TIME this application is being submitted, please select "No".**

**If this is a re-submission for modifications requested by the REB please select "Yes".**

***If 'Yes' to question 1.0:***

***If required, please ensure that you upload a PI response letter in question 7.1, outlining how each comment/question from the REB has been addressed in this re-submission.***

**1.0.1** *Is this a Canadian Collaboration for Child Health (CHEER) study?

☐ Yes ☐ No

**1.1** *Please enter the complete study title:

**1.2** Please enter the Study ID/Number:

**1.3** *What is the acronym or nickname/short title for the study? (NOTE: The acronym or nickname/short title will be used to identify the study and will be included in all notifications and emails. The short title is not included in REB letters))

**Reportable Event Information:**

**1.4** *Type of Event

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

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# REC Remi

**SECTION 2.0 - LOCAL (INTERNAL) SERIOUS**

***If 'Local (Internal) Serious Adverse Event***

Refer to
CRE ONL
question

***Ensure that the local SAE meets REB r***
***withdraw submitted local SAE reports***

**2.1** *Report Type:

☐ Initial
☐ Follow Up
☐ Final

**HELP TEXT:**

Subsequent reports (e.g., follow-
must be submitted to the REB by

If this is a follow-up or final repor
unlock the initial reporting form a
the report type, please update th

**2.2** *Is the event serious?

☐ Yes ☐ No

**HELP TEXT:**

Serious refers to a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.

**2.3** *Is the event unexpected in terms of nature, severity or frequency?

☐ Yes ☐ No

**HELP TEXT:**

Unexpected refers to a drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug.

**2.4** *Is the event related or possibly related to participation in the research?

☐ Yes ☐ No

**HELP TEXT:**

Related or possibly related refers to related or possibly related to participation in the research and means that there is certainty or a reasonable possibility that the incident, experience, or outcome



was or may have been caused by the investigational product(s) or procedures involved in the research.

**2.5** *Is the event suggesting that the research puts participants at greater risk of harm than previously known or recognized?

☐ Yes ☐ No

**HELP TEXT:**

Greater risk of harm refers to an elevated likelihood of a similar event occurring to other participants in the study including physical, psychological, economic ethical or social harm than was previously known or recognized.

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# REC Reminders – Reportable Events

**SECTION 3.0 - PROTOCOL DEVIATION/VIOLATION**

***If 'Protocol Deviation/Violation' selected in question 1.4, questions 3.1 - 3.11 appear:***

**3.1** ***Description/summary of the protocol deviation/violation:** Click here to enter text.

**3.2** ***Date the protocol deviation/violation occurred:** Click here to enter text.

**3.3** ***Does the protocol deviation/violation include any of the following (select all that apply)?**

- ☐ Eligibility (inclusion/exclusion criteria) waiver
- ☐ Increased risk or possibility of risk for the research participant(s)
- ☐ Compromises the scientific integrity (e.g., study validity or data integrity) of the study
- ☐ Other

Hind Amzil
Research Ethics Coordinator, OCREB

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# REC Reminders – Reportable Events

**SECTION 5.0 - AUDIT/INSPECTION REPORT**

***If 'Audit/inspection report' selected in question 1.4, questions 5.1 – 5.4 appear:***

**5.1** ***Select the type of audit or inspection that was conducted:**

- ☐ Health Canada inspection
- ☐ 'For cause' audit (do not include standard monitoring visits)
- ☐ FDA audit
- ☐ Internal institutional audit (e.g., QA)
- ☐ Other

**HELP TEXT:**

**Audit or inspection refers to a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory and ethical requirement(s).**

# Provincial Approvals – Reminders

- Applies to all participating sites
- Center amendments NOT required
- For consents: Centres to use the Provincially approved ICF and add centre-specific changes (does not require submission to the OCREB).
- Yellow highlight = centre-specific details
- If questionaries are embedded within Protocol, please ensure to ALSO submit the QOLs as separate participants materials within the CTO application system

Roxanne Fernandes
Research Ethics Coordinator, OCREB

# Provincial Translation – Reminders

- Translate the Provincial version of the currently approved English ICF, include a Certificate of Translations (COT)
- Translated validated paper questionaries (i.e., PRO-CTCAE, EORTC QLQ-C30, EQ-5D-5L, etc.) do not require a COT with submission
- English US to English CAD translations are not required

Roxanne Fernandes
Research Ethics Coordinator, OCREB

# REC Reminders

Angela Mendolia
Research Ethics Coordinator, OCREB

## Application Requirements

- **Provincial Amendments**
  - Section 2.4: Include a summary of participant status at the Provincial level.
  - Section 2.13.1: We require the Summary of Changes and Tracked Changes versions to be uploaded.
- **Application Resubmission:** Don't forget to respond "yes" to Q #1.0
- **Withdrawal of an Application:** Contact CTO Help Desk
- **Consent Update Forms**
  - Ensure the re-consent instructions in the relevant application sections align with Sponsor instructions regarding participant updates.
- **Application Clarifications**
  - Refer to the Annotated Application Forms on the OCREB website or use the information icon in the application itself

# REC Reminders

Angela Mendolia
Research Ethics Coordinator, OCREB

## Study Documents

- **When resubmitting tracked consent forms:**
  - Please ensure they include ALL tracked changes and COMMENTS.
  - Comments should not be deleted or resolved within the tracked versions.
- **When saving a clean version of a revised consent form:**
  - Ensure that it is clear of ALL COMMENTS
- **Recruitment Materials:**
  - Per OCREB Policy, these documents should NOT include the study drug name, Sponsor name, or logo..

# Q&A

- Questions for OCREB?