OCREB Webinar Series

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May 2025

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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
- REC Reminders
- Q&A

OCREB Updates

- OCREB Guidance Documents Update
  - Compensation/Reimbursement Guidelines
  - Consent Form Compliance Program
  - Pre-approvals for new sites
  - SOPs updated OCREB Addendas online
  - General website update forth coming

OCREB Updates - Website

Deadlines & Meeting Dates

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 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

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

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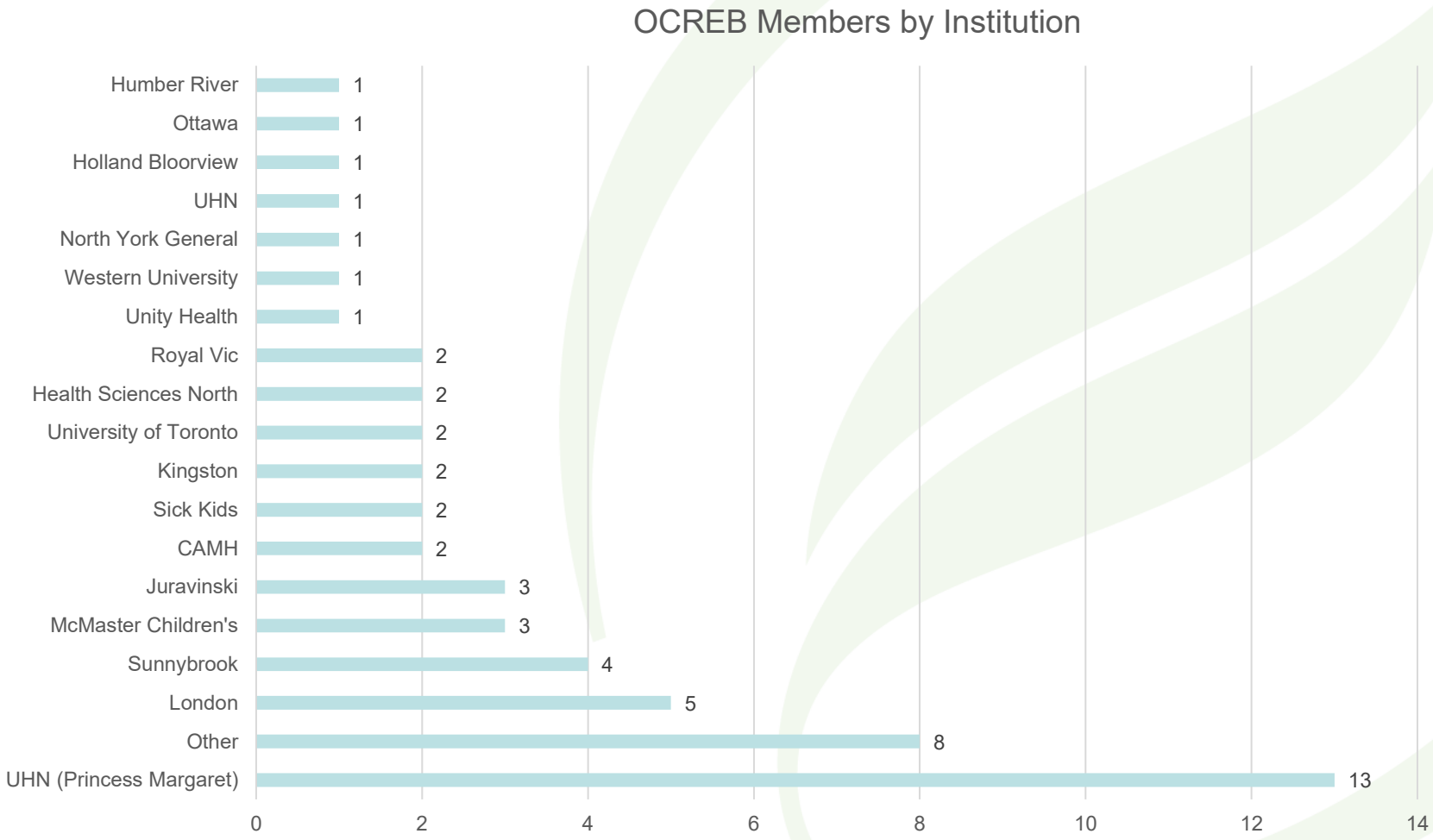
OCREB Membership by Site



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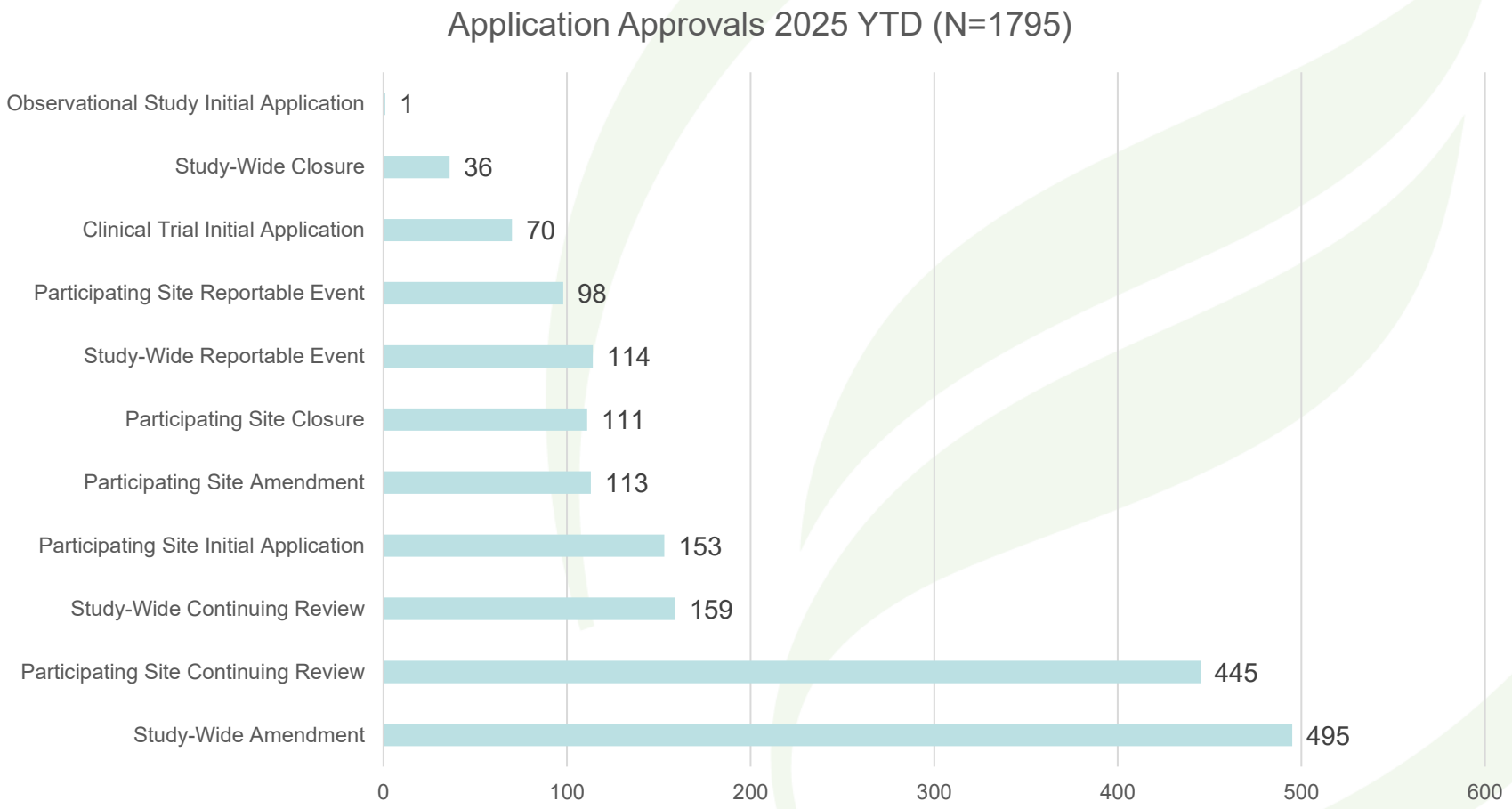
OCREB Metrics



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Ethics in the News

Regulatory & Ethical Updates

Trump order prompts Canadian cancer research group to scrub gender-inclusive language from U.S.-funded trials

Federal advisory panel on ethical, legal issues in human health research disbanded

The panel provided guidance to HHS for more than two decades

REC Reminders – Application Section 1.14 / 1.14.1 – CTIA

1.14

1.14 *How many sites do you expect will participate in this study through CTO Stream?

2

1.14.1 *Select all provinces/territories with research sites participating on this study in CTO Stream (select all that apply):

- ☐ Alberta
- ☐ British Columbia
- ☐ Manitoba
- ☐ New Brunswick
- ☐ Newfoundland & Labrador
- ☐ Northwest Territories
- ☐ Nova Scotia
- ☐ Nunavut
- ☑ Ontario
- ☐ Prince Edward Island (P.E.I)
- ☐ Quebec
- ☐ Yukon

1.14.2 *Select the name of each Ontario site participating on the study in CTO Stream (answer question once per site):

Grand River Hospital- Kitchener-Waterloo Campus

REC Reminders – Application Section 1.8 – Organization

- OCREB Approval and Acknowledgement letters pull information from applications, such as the Study Sponsor

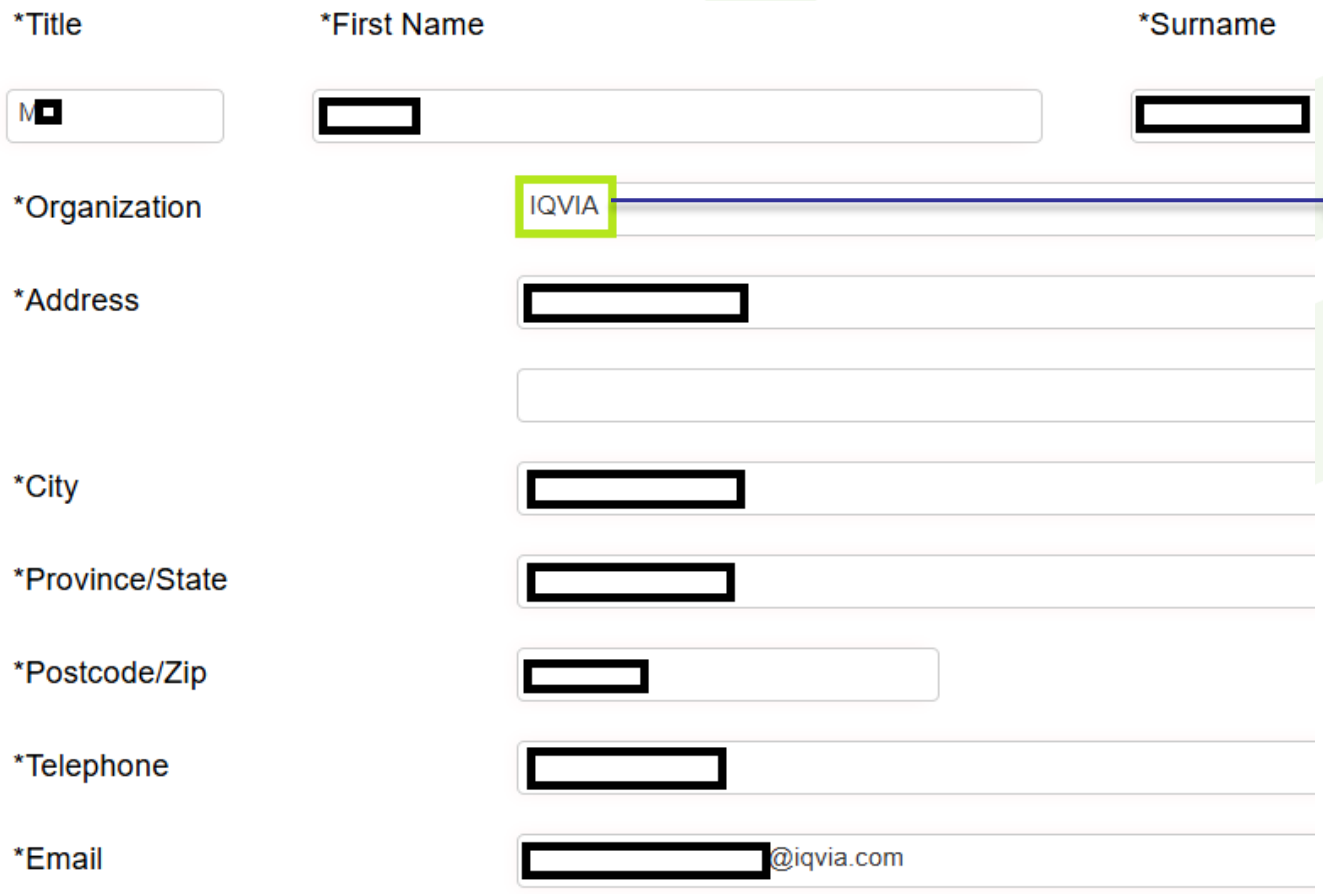
- If the Organization name indicates a different name (i.e. CRO Organization) – that name will be reflected on ALL Approval/Acknowledgement Letters for that study.

- OCREB may issue 1 – 2 corrected letters if the error is identified shortly after occurrence. OCREB **will not** reissue corrected letters if the error occurred several years ago.

- OCREB **will not** issue a NTF/Memo. Sites can create a NTF/Memo to explain the discrepancy and file it with their Regulatory Binder/TMF.

REC Reminders – Application Section 1.8 – Organization

1.8 *Please complete the Main Sponsor Contact details:



This section should always reflect the **Study Sponsor Organization** that is in the Protocol and Consent Form(s). All other contact details for a CRO, if applicable, can be included in the respective fields.

ED Reminder – Applications

OCREB's mandate is limited to multi-centre oncology clinical trials.

- "Multi-centre" = >1 participating Ontario centre
- "Clinical trial" = research that prospectively assigns human participants to one or more health-related interventions to evaluate the effects on health outcomes.

Observational Initial Application (OSIA) (different from CTIA)

If 'Cancers and Other Neoplasms':

2.7.2 *Have you obtained confirmation from OCREB that they will accept this study?

☐Yes ☐No

Ensure you connect with OCREB before submitting. An OSIA may not be the correct application to use.

ED Reminder – Resubmissions

- Timely resubmissions are the goal
- Complete responses to review letter facilitates review
- OCREB will soon be sending delayed response letter to applicants (60 day post letter)

REO Reminder – Privacy Breaches

Required elements:

- Description of what occurred in clear language
- How many participants are affected
- Notifying a Privacy Officer/Office
- Notification of patient