OCREB Webinar Series

September 2025

Webinar Agenda

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

OCREB Updates

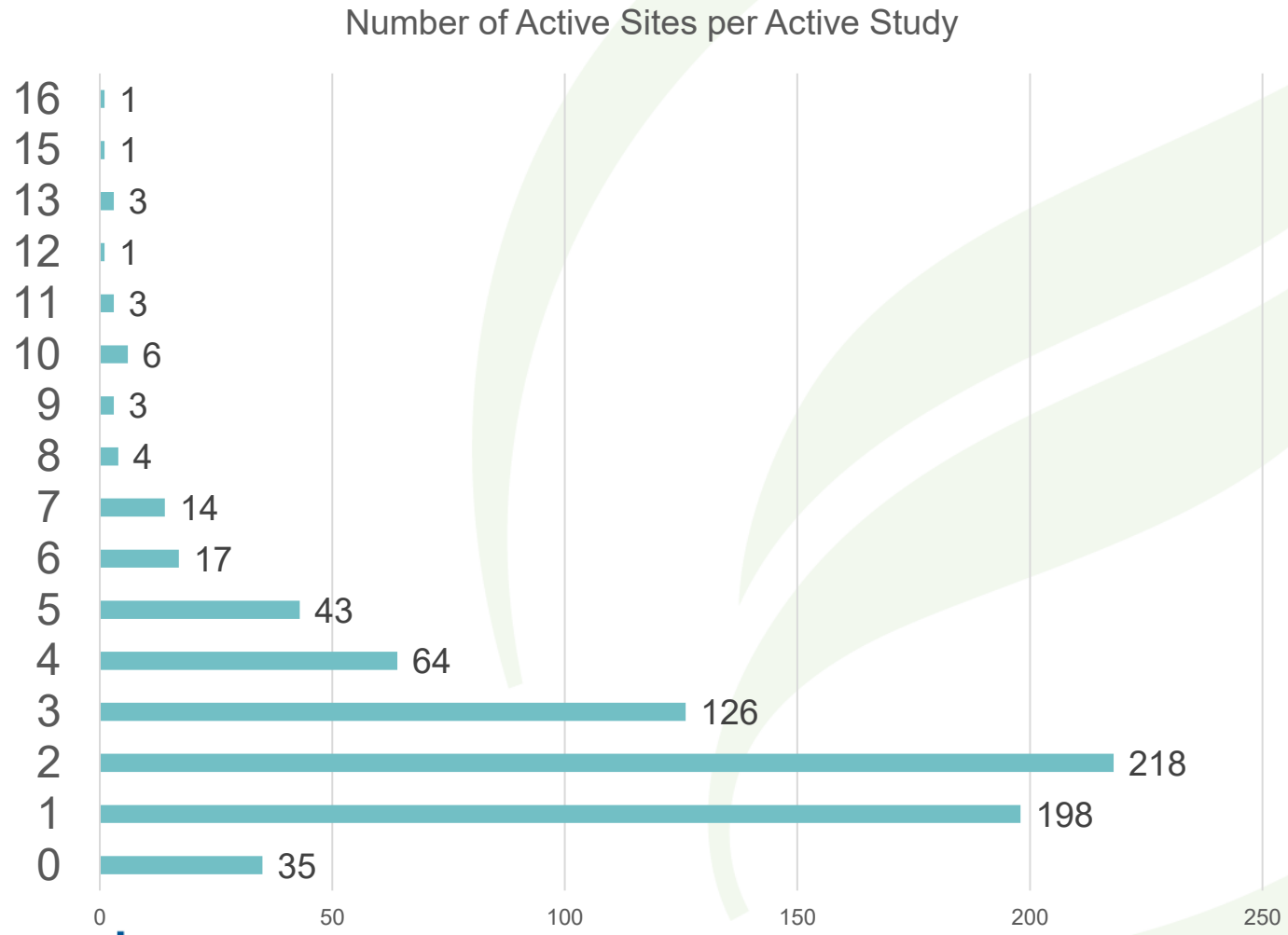
- OCREB Metrics
- Holiday closure & deadlines
- Consent form updates
- OCREB training sessions
- Guidance documents & Pre-approval
- Reminder – Health Canada logos
- QC Pilot Program – Overview & findings

2025 Metrics at a Glance

- 736 Active Trials
- 1949 Active Participating Sites
- Full Board: 100 CTIAs, 28 SWAMs and 290 SWCRs
- Total 6272 submissions resulting in 3957 approvals

- Timelines (Submission to Approval)

Average 72 calendar days (Min 37, Max 140)



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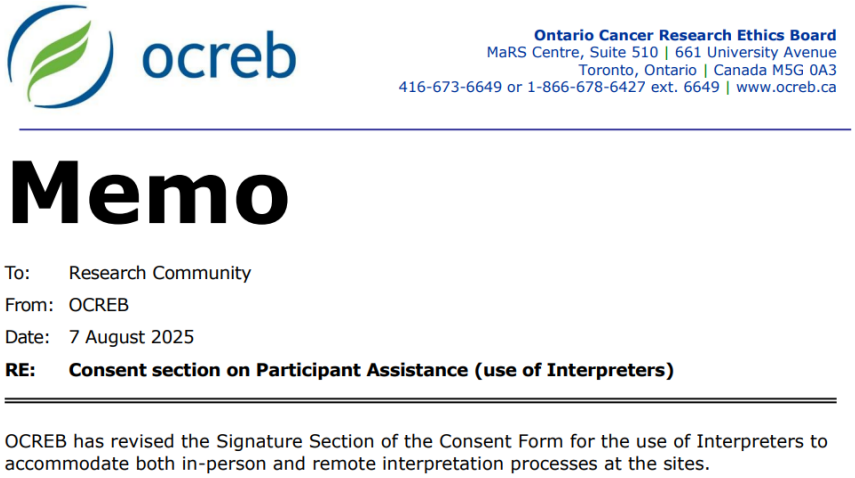
Ontario Cancer Research Ethics Board…
safeguarding the rights and well-being of cancer research participants

OCREB Updates

- Holiday closure & deadlines
- COG Consent
- REC Listing
- Meeting capacity

OCREB Updates

- Consent form updates



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Toronto, Ontario | Canada M5G 0A3
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Memo

To: Research Community
From: OCREB
Date: 7 August 2025
RE: Consent section on Participant Assistance (use of Interpreters)

OCREB has revised the Signature Section of the Consent Form for the use of Interpreters to accommodate both in-person and remote interpretation processes at the sites.

- https://ocreb.ca/wp-content/uploads/2025/08/Memo_-for-Signature-Section-Participant-Assistance-For-interpreter-use.pdf

OCREB Updates

- CTO Form Updates

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OCREB Updates

- **Upcoming OCREB training session:**
- https://ocreb.ca/about-ocreb/whats-new/

What's New?

OCREB 101 Training Session:

Please use the below link to register for the OCREB 101 Training Session held on **Wed. September 10th at 10AM.**

Registration Link: https://oicr-ca.zoom.us/meeting/register/eYbKS7aIRVCMUmxeIMFtaA

OCREB Updates

- Guidance documents & Pre-approval
- Remote Consent
- Recruitment (Outside the circle of care)
- &
- Health Canada – Use of Sponsor Logos

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OCREB Updates

- OCREB ICF Quality Control Pilot & Rollout
- **Purpose**: Ensure ICFs used in oncology clinical trials are accurate, compliant, and consistent with OCREB-approved versions, TCPS2, and Health Canada standards.
- **Pilot (2025):**
- Systematic QC reviews of ICFs at selected sites.
- Criteria: representative mix of study types and sites.
- Process: site notification → document submission → ICF review checklist → follow-up/feedback.
- Goal: refine workflow, templates, training, and escalation procedures.
- **Full Rollout (January 2026)**
- Routine ICF compliance reviews integrated into OCREB oversight
- Ongoing audits and monitoring with corrective action reporting.
- Standardized policies, checklists, and training materials for researchers.
- Supports consistency, participant protection, and regulatory compliance.

Ethics in the News

Regulatory & Ethical Updates

U.S. Department of Health and Human Services

Enhancing the health and well-being of all Americans

Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2025)

Ethics in the News

- **IRB Written Procedures – OHRP/FDA Guidance**
- **Purpose**
  - Help IRBs develop clear, harmonized SOPs for human subjects research
  - Align HHS (45 CFR 46) & FDA (21 CFR 50/56) requirements
- **Key Points**
  - *"Must"* = required by law; *"Should"* = recommended practice
  - Includes **Written Procedures Checklist** (requirements + suggestions)
  - Promotes **consistency, compliance, & subject protection**
  - Institutions may use alternative approaches if compliant
- **Audience**
  - IRB chairs, administrators, staff, institutional officials
- **Benefit**
  - Streamlined oversight, reduced burden, stronger protections

Ethics in the News

Regulatory & Ethical Updates

ASPE

OFFICE OF THE ASSISTANT SECRETARY
FOR PLANNING AND EVALUATION

Use of Participant Compensation in U.S. Clinical Research Studies

Ethics in the News

Participant Compensation in U.S. Clinical Research (ASPE, 2025)

Purpose
- Assess how often studies pay participants & variation by study type

Key Findings
- **59.5%** of 7,648 trials (1994–2025) offered compensation
- Use ↑ over time: 22% (pre-2010) → 68% (2021–present)
- By intervention: Behavioral (84%), Device (58%), Drug (44%), Radiation (10%)
- By phase: Early Phase 1 highest; Phases 2–3 lower
- By condition: High – Diabetes (83%), Neuropsychiatric (80%); Low – Cancer (22%, Leukemia 4%)

Takeaway
- Compensation is **common but uneven**
- Patterns vary by intervention, phase, and disease
- Further research needed on **amounts, equity, and impact on recruitment**

Ethics in the News

Compensation in Cancer Clinical Trials (ASPE, 2025)

Overall

- Only **22%** of cancer (malignant neoplasm) trials offered compensation
- Among the lowest compared to other conditions (e.g., Diabetes 83%, Neuropsychiatric 80%)

By Cancer Type

- **Breast cancer** – 41%
- **Colorectal cancer** – 37%
- **Lung cancer** – 36%
- **Prostate cancer** – 20%
- **Brain/CNS cancers** – 11%
- **Lymphomas/Myeloma** – 7%
- **Leukemia** – 4% (lowest observed)

Implications

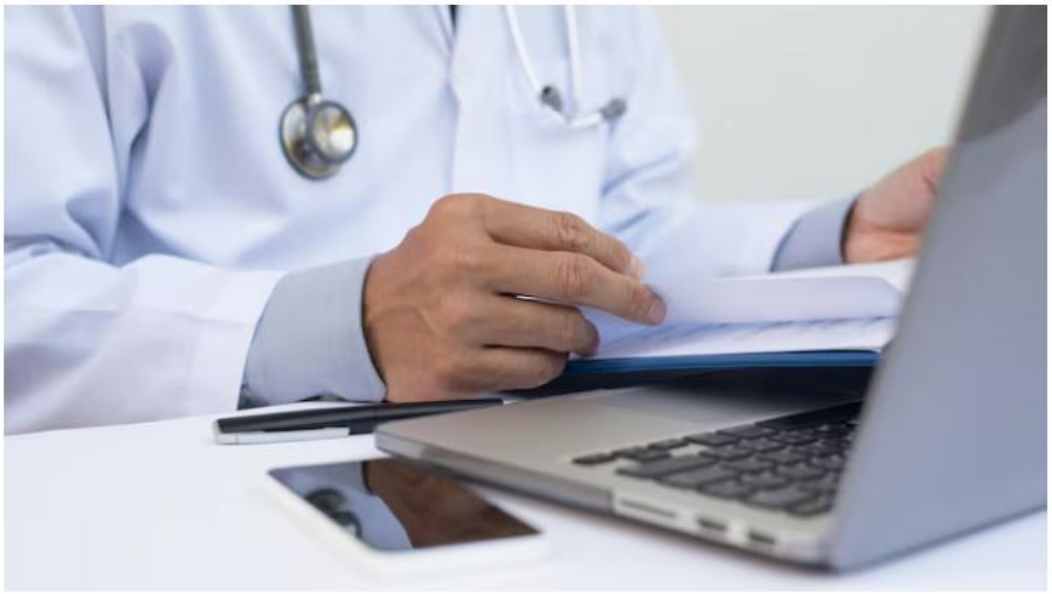
- Cancer trials are **least likely** to compensate participants
- May reflect perceived access to direct clinical benefit
- Raises questions about equity, recruitment, and financial burden for patients

Ethics in the News

Canadians' health data at risk of being handed over to U.S. authorities, experts warn

Canadian health data stored on servers owned by U.S. companies, subject to U.S. laws

Alison Northcott · CBC News · Posted: Jul 31, 2025 4:00 AM EDT | Last Updated: July 31



Commentary in the Canadian Medical Association Journal says millions of Canadians' health data is stored on cloud servers owned by U.S. companies. (TippaPatt/Shutterstock)

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Ethics in the News

Canadian Health Data Sovereignty (CMAJ & CBC, 2025)

Issue

•Canada's health data often stored on **U.S.-owned cloud servers** (Microsoft, AWS, Google)
•Raises risks of **foreign surveillance** under U.S. laws (e.g., CLOUD Act) and loss of control over data used for AI

Risks

•Unauthorized foreign access to sensitive health data
•Monetization/use of Canadian data outside Canada's control
•Encryption alone may be insufficient (e.g., quantum decryption threats)

Recommendations

•**Encrypt by default** + adopt quantum-safe privacy technologies
•Mandate **data localization**: require hosting on Canadian-controlled servers
•Strengthen privacy laws with **blocking statutes** against foreign data orders
•**Invest in sovereign Canadian cloud infrastructure**
•Promote safe AI innovation via **de-identification, anonymization, or synthetic data**

Takeaway

•Safeguarding health data is key to protecting **privacy, sovereignty, and trust**, while enabling **responsible AI development** in Canada

Ethics in the News

Links for further reading:

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html

https://aspe.hhs.gov/reports/compensation-clinical-research

https://www.cbc.ca/news/health/health-data-cloud-servers-canada-us-1.7597441

https://www.cmaj.ca/content/197/26/E763

Q&A