CHEO

Research Ethics Board

Annual Report 2024

TABLE OF CONTENTS

WHAT WE DO

WHAT WE'VE DONE

WHERE WE'RE GOING

WHAT WE'VE HEARD

WHO WE ARE

WHAT WE DO

What is the mandate of the CHEO REB?

The CHEO REB is an oversight body that determines the ethical acceptability of the design and conduct of human research conducted under the auspices of CHEO to fundamentally protect the rights and dignity of research participants and to pragmatically protect the institution from liability. To that end, the REB reviews and approves studies to ensure they meet and comply with the highest scientific and ethical standards, including proposing modifications, monitoring safety, determining remediation for protocol deviations, serious adverse events, or non-compliance, and/or rejecting or terminating any proposed or ongoing unethical or non-compliant research. The CHEO REB functions independently of the Hospital and Research Institute with respect to all deliberations and decisions.

Why it matters?

A fundamental premise of standards governing the ethical conduct of research is that research can benefit human society. Researchers have the primary responsibility to ensure that research involving humans meets high scientific and ethical standards that respect and protect the dignity and welfare of participants. Research, by definition, is a process of discovery. It necessarily entails or increases risk to participants and others. Risks can be trivial or profound, physical or psychological, individual or communal. There are many tragic examples where research participants and communities have been harmed by research. To minimize the risks of such harms, ethical principles and guidelines play an important role in advancing the pursuit of knowledge in a responsible and respectful manner.

Having robust processes and appropriate safeguards to ensure compliance with the necessary ethical and regulatory requirements for human research is a shared institutional responsibility.

What is the scope of activities of the CHEO REB?

Oversight and compliance

Risk management and mitigation

Conflict resolution

Advisory

Capacity building and education

Collaboration with research ethics community

A snapshot of the review process

2 types of review:

Full Board Reviews

Full Board reviews involve greater than minimal risk to the participant. This includes studies involving regulated drugs or clinical research with vulnerable populations.

Delegated Reviews

Delegated reviews involve minimal risk to the participant. This includes prospective and retrospective studies with children, families and/or staff.

Submissions, especially delegated submissions, significantly vary in complexity and quality. They may be investigator-led, unfunded, and not peer-reviewed for their scientific viability.

The review process:

1 Submission to CHEO REB

For example:

- New applications
- Modifications
- Annual renewals
- Protocol deviations
- Serious adverse events

2 Review of all study documentation based on ethical, regulatory, administrative requirements

- For delegated studies, minimum 2 reviewers
- For greater than minimal risk studies, Full Board

3 Develop and synthesize feedback, send to research team

4 Review of Investigator Response and revised study documentation

5 Approve or provide additional feedback (repeat until approval)

Throughout the review process:

Administrative review of all submissions for completeness and accuracy of study documentation

Discussions/ meetings with PIs and research teams

Consultation with Quality Assurance, Privacy, other REBs, research ethics colleagues

Risk management and mitigation to preserve the scientific and ethical integrity of studies and the research enterprise at CHEO

WHAT WE'VE DONE

2024 Highlights

Oversight and Compliance

935	**Oversight of 935 active studies**
207	**New studies**
192	**New delegated studies**
15	**New greater than minimal risk studies**
1553	**Post approval activities**
369	**Modifications**
760	**Annual renewals**
51	**CTO Board of Record for 51 provincial and 139 centre applications[1]**
100+	**Over 100+ meetings with PIs and research teams**
3500+	**Over 3500+ hours reviewing studies**

[1] Clinical Trials Ontario's (CTO) streamlined system enables a single CTO-qualified REB to provide ethics review and ongoing oversight for multiple research sites participating in the same study. The CHEO REB became a qualified Board of Record in 2017.

Governance

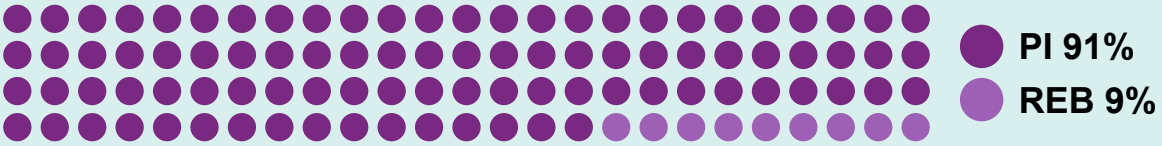
- Implemented a harmonized ethics review process with Bruyère Health, enhancing the capacity to support important collaborations in research and innovation
- Established the first inter-provincial agreements under the national pilot pediatric ethics review program (CHEER), enabling ethics oversight for studies outside of Ontario
- Contributed to provincial working groups focused on standardizing essential documents and tools with the goal of enhancing research ethics review efficiency

Operations

- Continued to refine the operations of the Research Ethics Office through targeted process improvements, ensuring the effective and efficient administration of CHEO's Human Research Protections Program
- Focused on diverse initiatives to advance REB professional development, support the launch of the Research Connection program, and contribute to the RI Indigenous Engagement Working Group
- Enhanced research ethics resources and education to foster regulatory compliance and support the development of high-quality research

FIGURE 1: Review and Approval Timeline Greater than Minimal Risk 2024

Division of timeline from submission to approval:



Submission to First Feedback:

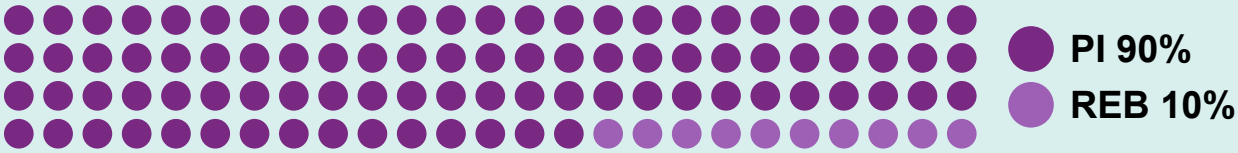
1 MEDIAN DAYS

Submission to Final Approval:

63 MEDIAN DAYS

FIGURE 2: Review and Approval Timeline Prospective Minimal Risk 2024

Division of timeline from submission to approval:



Submission to First Feedback:

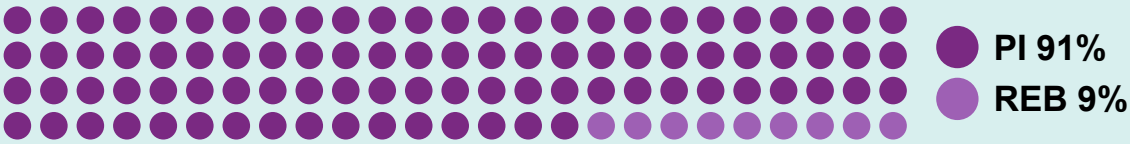
2 MEDIAN DAYS

Submission to Final Approval:

30 MEDIAN DAYS

FIGURE 3: Review and Approval Timeline Retrospective Minimal Risk 2024

Division of timeline from submission to approval:



Submission to First Feedback:

1 MEDIAN DAYS

Submission to Final Approval:

8 MEDIAN DAYS

FIGURE 4: New study submissions (Initial Applications)

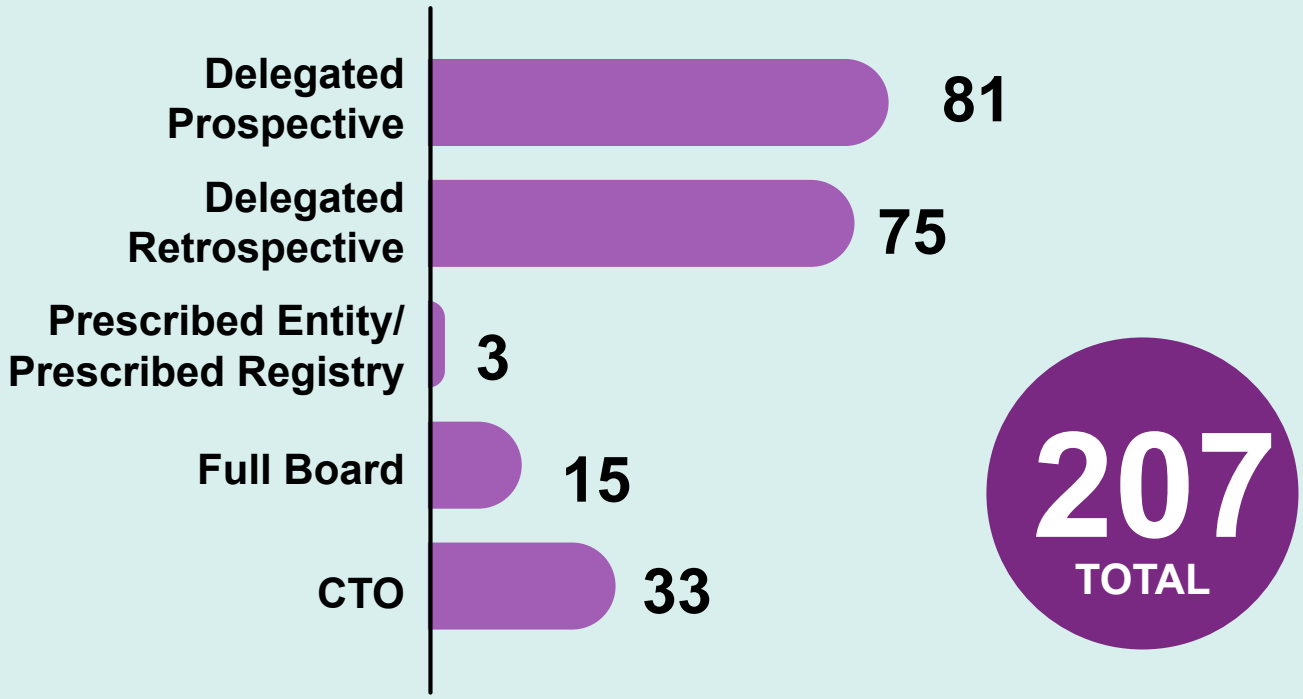
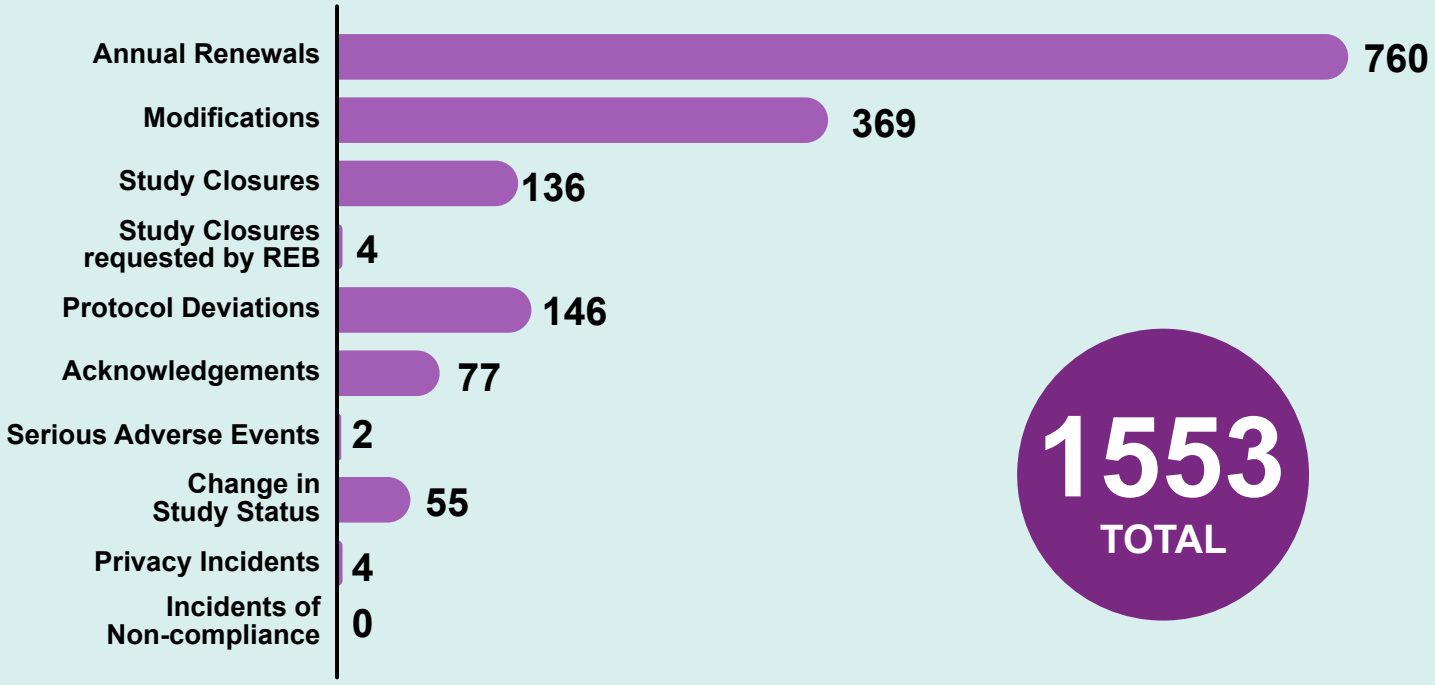


FIGURE 5: Post-approval activities



WHERE WE'RE GOING

2025 Strategic & Governance Goals

1. **Enhance Efficiency in Ethics Review:** Strengthen the CHEO REB's capacity to streamline the ethics review process by exploring innovative approaches and critically assessing existing review requirements for continuous improvement

2. **Promote Education and Consultation Excellence:** Maintain and expand the delivery of high-quality, research ethics-focused education and timely consultation services, encouraging a 'research ethics by design' mindset across CHEO

3. **Focus on Professional Development in Emerging Areas:** Prioritize professional development initiatives that address evolving regulatory changes and technological advancements, ensuring that ethics reviews remain aligned with the latest clinical trial developments and research ethics standards

4. **Position CHEO REB as a National Leader:** Establish CHEO REB as a leader in the Canadian research ethics landscape through active involvement in provincial and national initiatives, fostering collaboration and impact in the field

WHAT WE'VE HEARD

Voices from our research community

As a new researcher, CHEO REB has been incredibly supportive. Everyone at the REB is willing to answer questions and provide feedback throughout the review process. They have been wonderful to work with.

Brennah Holley, Nursing

The CHEO REB has helped support and guide our team through multiple Health Canada medical device trials which has enabled CHEO to provide innovative and groundbreaking care for children!

Kevin Smit, Orthopedics

The CHEO REB is one of the most helpful and collaborative research ethics boards I have ever worked with. Staff go above and beyond to answer questions to ensure that scientists are well informed, prepared, and conducting the best possible science. I am grateful for the special care and attention my projects have received through the CHEO REB.

Nicole Racine, Knowledge Institute

Our research team really views the REB as a partner. Their advice and support up front ensures that we submit the best protocol possible at the outset. We are the envy of so many institutions in terms of the efficiency and engagement of our REB.

Care4Rare Research Program

We value our collaborative working relationshipwith the CHEO REB. Through a true partnership, we are able to meet ethical requirements while moving our research forward in a timely manner. The CHEO REB's ethical guidance is invaluable, and we appreciate their knowledge and expertise. Their understanding of the pragmatic nature of clinical research and complex ethical issues has facilitated the success of our research program.

Roger Zemek & Monica Lamoureux,
360 Concussion Care

The REB's dedication to performing and providing thoughtful consideration of complex study reviews is enhanced by their continuing endeavour to improve the process. In addition, their insight in challenging intellectual discussions is most appreciated. Suggestions into approaches for our research are helpful and convey a desire to welcome research at CHEO.

David Mack, Gastroenterology

What we heard about REB consultations

- Our questions were answered very thoroughly and excellent suggestions from similar studies to ours were provided. The REB office was quick to meet and very helpful. I am glad that CHEO REB offers this kind of support.
- Even though I had additional questions that were not written in the initial request email, I was free to ask them and get a very informed response. I could also ask specific questions about my specific protocol, for example, how could we execute e-consents in our proposed project with our methods. Being able to ask those specific questions and getting a response instead of trying to interpret general guidelines is really useful when we are developing our protocol.
- Truthfully, my consultations with the REB are always helpful. The REB office came to the meeting having pre-met and reviewed my queries and gave me practical and helpful guidance on how to navigate my question.

WHO WE ARE

Research Ethics Board

Cécile Bensimon MA, PhD

Cécile is Chair of the CHEO REB. She is the National Ethicist at Correctional Service Canada. She is a member of the CIHR Committee on Ethics and Governor for Canada and Vice-President, North America for the World Association for Medical Law.

Sandra Djuric RN, MScN

Sandy completed her nursing studies at the University of Ottawa where she graduated with a Master of Science in Nursing. In her career at CHEO she worked in Pediatric Medicine, Oncology and Discharge Planning. She is a long-standing Faculty member at the University of Ottawa where she teaches courses in Community Health and Professionalism and Ethics.

Sabrina Heyde JD

Sabrina holds a law degree from Queen's University and works as a Senior Investigator for the Office of the Privacy Commissioner of Canada. She has served as a community/legal member of the CHEO REB since 2017, and as a legal consultant to the Canadian Pediatric Surveillance Program since 2020.

Sophia Hrycko PhD, MD, FRCP(C)

Sophia is a child and adolescent psychiatrist at CHEO and Assistant Professor at the University of Ottawa since 1998. She works on the Consultation-Liaison service.

Marie-Ange Janvier PhD

Marie-Ange is a certified clinical engineer (CCE) at CHEO. She has a PhD in biomedical engineering from the University of Montreal/ Polytechnique. She also holds a degree from electrical engineering from the University of Ottawa. She is a part-time Professor at the University of Ottawa in the biomedical engineering program, an Adjunct Research Professor at Carleton University in the Department of Systems and Computer Engineering, and an Adjunct Professor at the Ottawa University in the Department of Mechanical Engineering.

Robert Klassen MD, FRCP(C)

Robert is a Pediatric Hematologist/ Oncologist at CHEO, Professor at the Department of Pediatrics, University of Ottawa and Clinical Investigator at the CHEO Research Institute. His clinical focus is on the care of patients with non-malignant hematologic disorders.

Siddika Mithani PhD

Siddika holds a BSc in Pharmacy and a PhD in psychopharmacology. She is the past President of the Public Health Agency of Canada as well as the Canadian Food Inspection Agency. She has extensive background and experience in the regulatory and scientific review, evaluation, and approval of clinical trials in Canada.

Scott Murray Hon BA

Scott is the President, DataAngel Policy Research Inc., a Canadian policy research company serving a broad range of clients. Prior, he was Director, Education Outcomes at the Unesco Institute for Statistics (UIS). Scott holds an Honors BA from the University of Western Ontario.

Stevie O'Brien JD

Stevie, a seasoned government relations leader and lawyer, has advised top politicians, including the Prime Minister. She served as Chief of Staff to key ministers, driving Canada's COVID-19 vaccine efforts and cannabis legislation. Stevie has also held different positions within provincial government.

Alex Petiquan MD

Alex is Anishinaabe from Wabauskang First Nation and graduated from the Northern Ontario School of Medicine. His work spans Indigenous public health, policy, governance, epidemiology, and data sharing agreements, both as a Senior Analyst in the Federal sector and as a member of the Health Expert Advisory Panel for Grand Council Treaty #3.

Lori Pope LLB

Lori is a community member of the CHEO REB. She is the mother of two children, both of whom were treated for life-threatening medical conditions at CHEO. She is also a lawyer who has worked in private practice, legal aid clinics, and for a federal regulatory tribunal. She has a particular interest in human rights, privacy, and community legal education.

Vincent So MD

Vincent (he/him) is a resident at the University of Ottawa in Anesthesiology and previously a pediatrics resident at CHEO. His research interests include post-operative outcomes in children following anesthesia, as well as risk prediction and prognostication tools. Outside of residency, Vincent is a board member with LGBT Youthline, a provincial non-profit, providing anonymous peer support to 2SLGBTQ+ youth across Ontario.

Régis Vaillancourt OMM, CD, PharmD, FCSHP

Régis is a pharmacist with 40 years of experience. He is currently the Vice President of Pharmacy Affairs at BCE Pharma, a software company focusing on supporting compounding pharmacies in meeting practice standards. Throughout his career, Régis has worked with different pharmacy organizations. He has published more than 100 peer-reviewed articles on pharmacy practice with a focus on medication safety and health literacy.

WHO WE ARE

Research Ethics Office

Sarah Tagliapietra HBSc, BEd

Sarah is the Manager of the CHEO REB. She has worked with multiple academic and community based REBs in Ontario for over a decade, and also has experience in global clinical trial management.

Natalie Anderson

Natalie is a Research Ethics Officer of the CHEO REB and brings a wealth of experience as a longstanding member of the Research Ethics Office.

Yulia Rosenstein Levin PhD

Yulia is a Research Ethics Officer of the CHEO REB. She has expertise in academic administration and a background in conducting human participant research in the areas of Cognitive Psychology and Behavioral Sciences.

Reagan Wallace BA

Reagan is a Research Ethics Administrator with the CHEO REB. She holds an Honours Bachelor's degree in Anthropology with a focus on medical anthropology from Carleton University and is currently pursuing a Master's in Bioethics at Ohio State University. Inspired by CHEO's support for her sister and family, she is dedicated to giving back to the community that once supported her own.