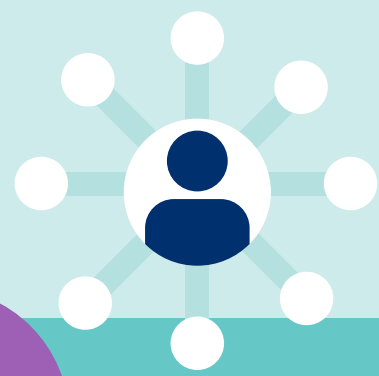
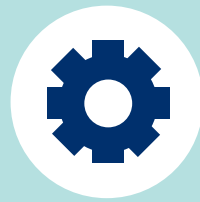


CHEO



Research Ethics Board

Annual Report 2023



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WHAT WE DO

What is the mandate of the 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 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



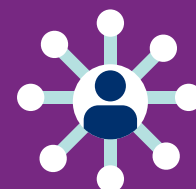
Conflict resolution



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.

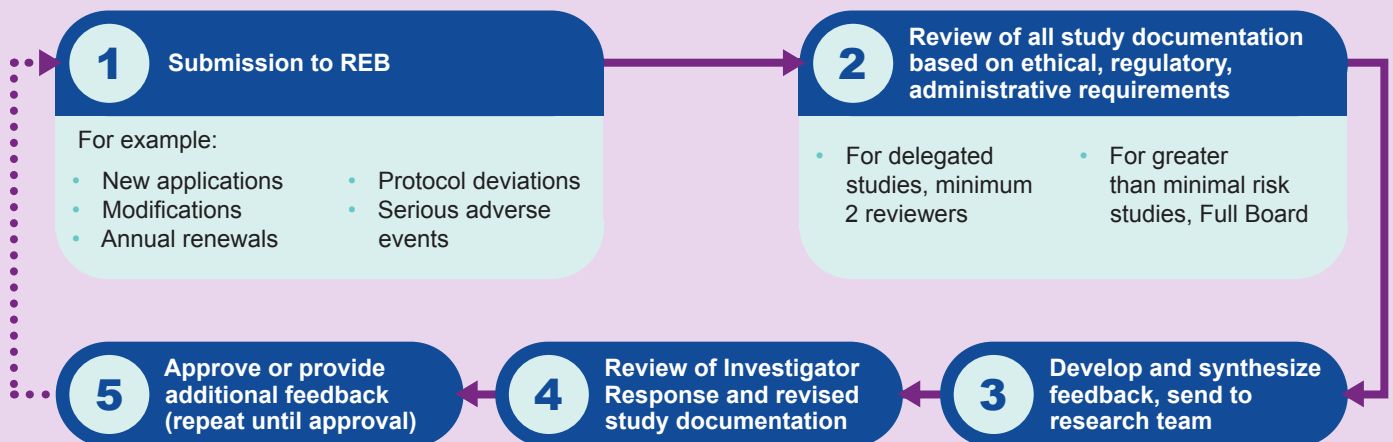


Delegated Reviews

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- or learner-led, unfunded, and not peer-reviewed for their scientific viability.

The review process:



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

2023 Highlights

Oversight and Compliance

1017

Oversight of 1017 active studies

155

New studies

141

New delegated studies reviewed by Chair and Research Ethics Office

14

New greater than minimal risk studies reviewed by the Full Board

1620

Post approval activities

450

Modifications

751

Annual renewals

35

CTO Board of Record for 35 provincial and 100 centre applications¹

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

- Developed new and modernized governance frameworks (e.g., REB Terms of Reference, institutional reporting structure)
- Promoted streamlining of review and approval processes through existing and new harmonization efforts (e.g., The Ottawa Hospital, Bruyère Hospital)
- Achieved requalification under a novel dual-audit process for the provincial streamlined ethics review program (CTO) and the national pilot pediatric ethics review program (CHEER)
- Continued growth of REB infrastructure with addition of a new position and recruited 3 new REB members

Operations

- Continued to streamline and optimize operations of the Research Ethics Office to ensure the successful and efficient administration of the human research protections program at CHEO
- Invested in ongoing educational development to stay current on relevant topics and to promote standardization with other Canadian REBs
- Enhanced supporting tools and resources to promote regulatory compliance and high-quality research development
- Participated in key CHEO RI initiatives and provided ongoing support to strategic working groups (e.g., Research Data Management strategy)

FIGURE 1: Review and Approval Timeline for Greater than Minimal Risk Studies

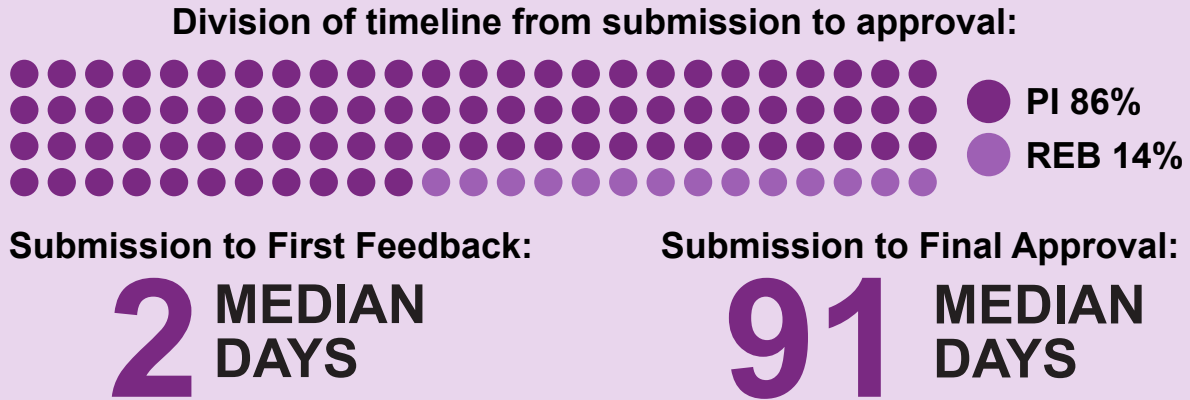


FIGURE 2: Review and Approval Timeline for Prospective Minimal Risk Studies



FIGURE 3: Review and Approval Timeline for Retrospective Minimal Risk Studies



FIGURE 4: New study submissions (Initial Applications)

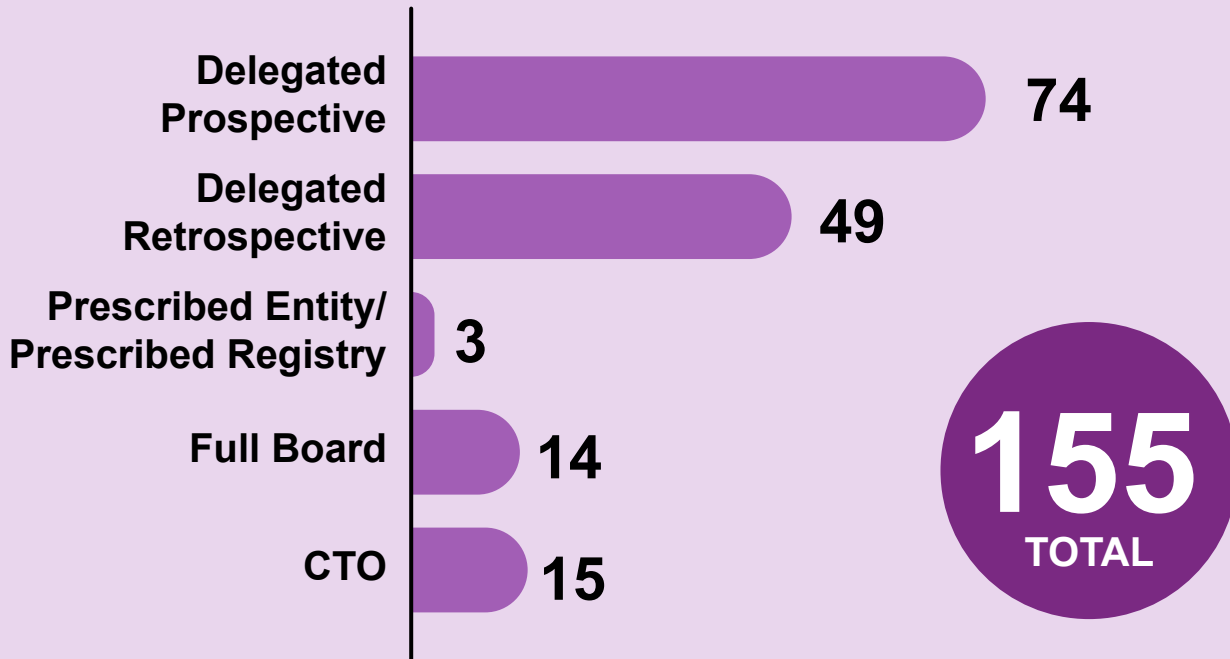
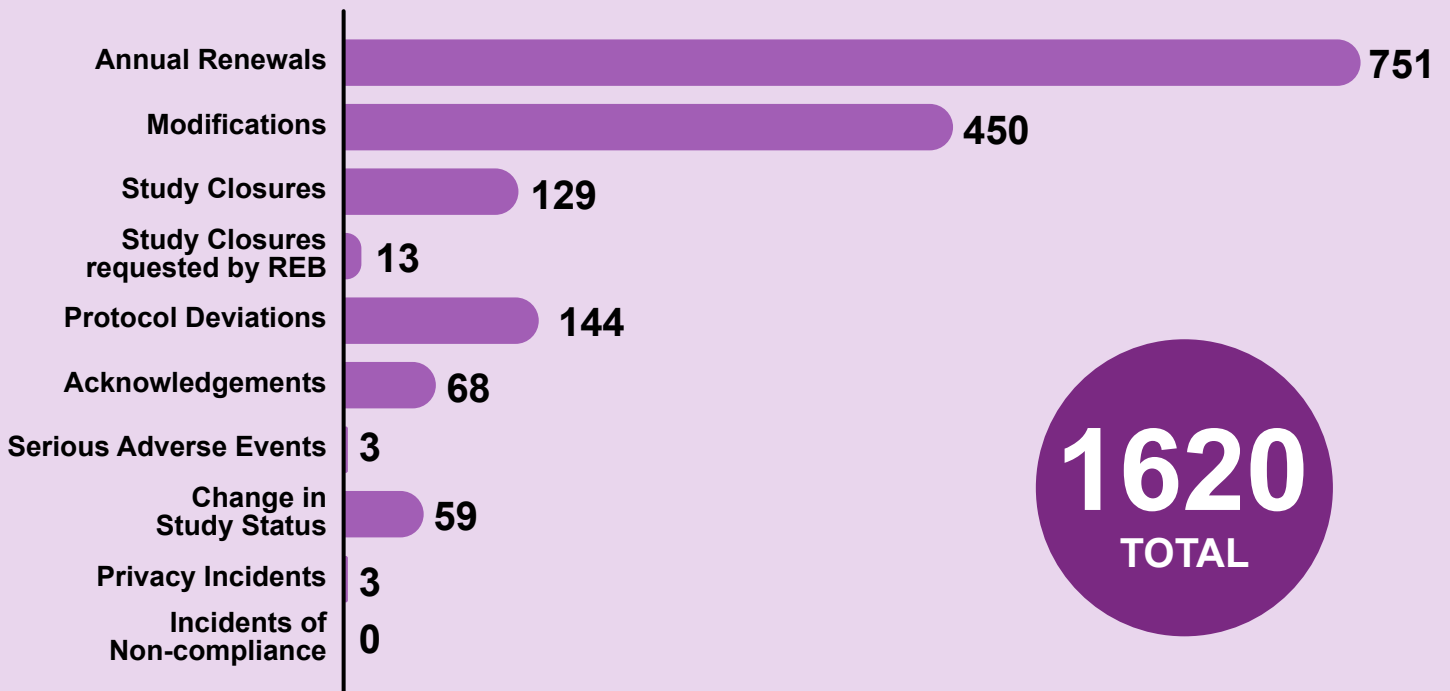


FIGURE 5: Post-approval activities



WHAT WE'VE HEARD

Voices from our research community

”

We and our collaborators are absolutely floored with how helpful and efficient the CHEO REB process is.

As an early-career researcher, I have learned a lot from the CHEO REB.

The REB has provided us with new insight into participants' rights and challenged us to view research from a participants' lens.

The dedication of CHEO REB in ensuring consultations are reviewed quickly has allowed us to initiate new studies and implement protocol amendments within very short time frames.

I have found the REB to be extremely helpful and pragmatic. The REB helped us to implement an innovative model of consent for our trial which we modified over the course of the study through discussions with the REB. It has been a game changer for the study and for our participating families.

Guidance obtained through consultations has been extremely valuable to our team and has allowed us to navigate the REB submission and review process more efficiently, with less back and forth.

The REB has been very helpful and efficient in turnaround of feedback.

“

WHERE WE'RE GOING

2023 Strategic Goals

1

Further integrate the CHEO REB within the CHEO ecosystem of care and support efforts towards increasing participation in research in a safe and ethical manner

2

Continue to build research ethics capacity within the CHEO research community through engagement and education

3

Support high-quality research at CHEO through robust resource and tool development

4

Position CHEO REB as a frontrunner in the Canadian research ethics community through provincial and national partnerships and initiatives

2023 Governance and Operational Objectives

- Support the development of resources and processes to facilitate the conduct of Indigenous health research in a culturally appropriate manner and respect Indigenous data sovereignty
- Collaborate with the CHEO RI to ensure institutional policies and procedures are aligned with current research ethics standards and best practices
- Continue development of a robust research ethics education and training program to support research teams to apply requirements in collaboration with the CHEO RI
- Bolster professional development for the CHEO REB to stay current with evolving research ethics standards and culture

WHO WE ARE

Research Ethics Board



Cécile Bensimon MA, PhD

Cécile is Chair of the CHEO REB. She is Vice-Chair of the Pharmaceutical Advertising Advisory Board, Governor for Canada for the World Association for Medical Law, and a member of the CIHR Advisory Committee on Ethics and the US Pharmacopeia DEIB Expert Panel. Cécile serves on the RCPSC Expert Working Group, Professional Role to update the CanMEDS Physician Competency Framework. She is on the Editorial Board of the Canadian Journal of Bioethics and Frontiers in Genetics.



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.



Elaine Leung MD, FRCP(C)

Elaine is a dually trained Pediatric Hematologist/Oncologist and Hematopathologist. She joined CHEO's Department of Laboratory Medicine in 2006, and has served as the Head of the Division of Hematology and Transfusion Medicine since 2014.



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.



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 Pope 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.



Ellen Song HBSc

Ellen is a former CHEO patient and former member of the CHEO-RI's Patient and Family Advisory Committee. She is also a medical student at the University of Ottawa Faculty of Medicine.



Régis Vaillancourt OMM, CD, PharmD, FCSHP

Régis Vaillancourt is 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 meetings practices 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.



Vincent So MD

Vincent (he/him) is a resident at uOttawa 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.



Reagan Wallace BA

Reagan is a community member of the CHEO REB. She holds a BA Honours in Anthropology from Carleton University. Reagan's familial ties to CHEO through her sister, a recent patient graduate, have spurred her ambition to contribute to the healthcare sector of bioethics. Inspired by CHEO's support for her family, Reagan aims to pursue a career in healthcare, fostering communities that provide care and support for families facing health obstacles.



Stevie O'Brien JD

Stevie O'Brien, 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.

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 10 years, 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.