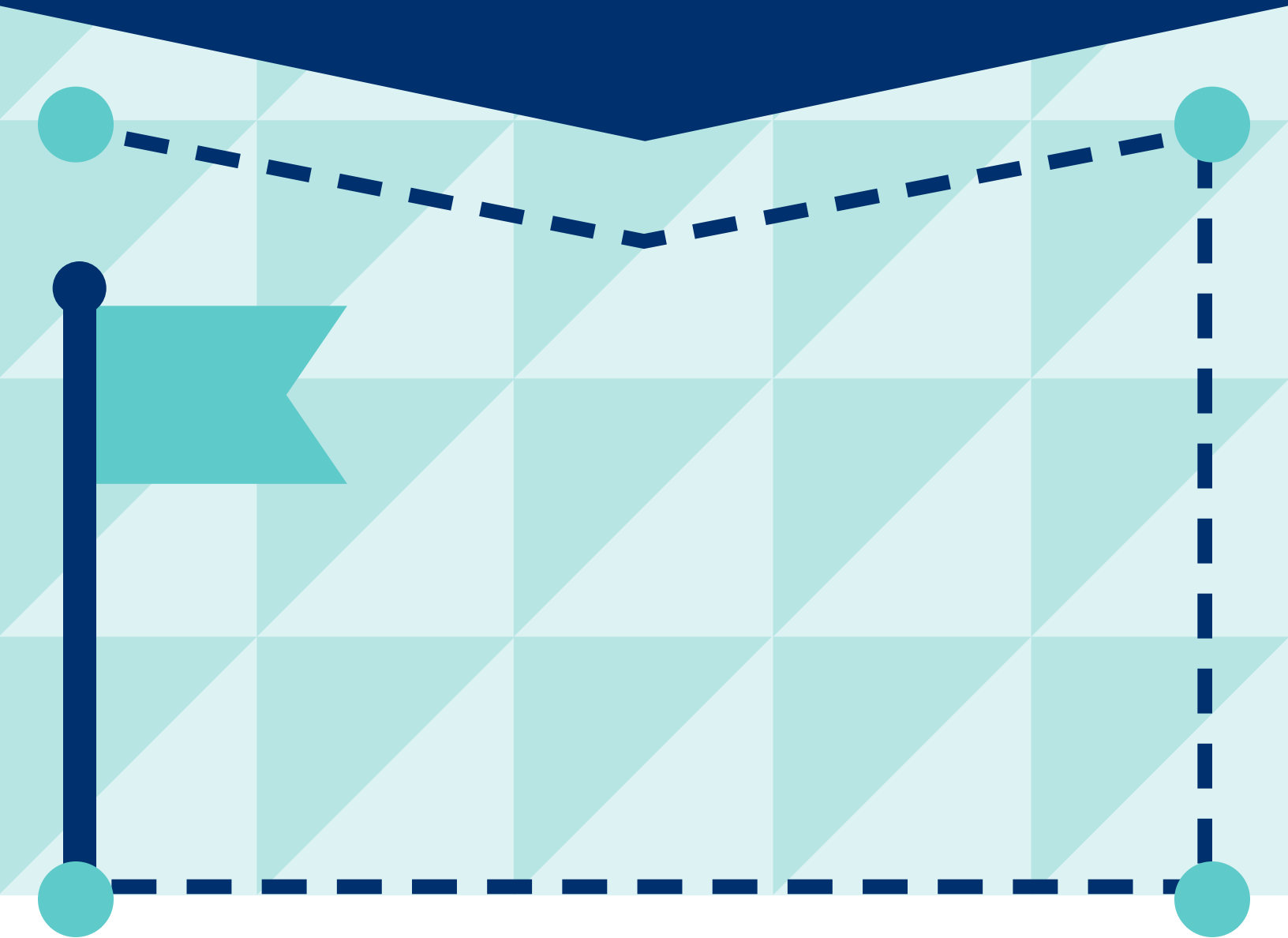


RESEARCH ETHICS BOARD

ANNUAL REPORT

2021



CHEO

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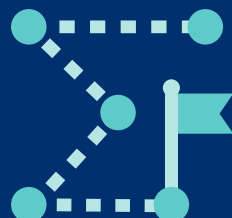
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WHAT WE DO

What is the mandate of the REB?

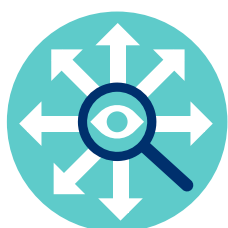
The CHEO REB is an oversight body that determines the ethical acceptability of the design and conduct of human research conducted under the auspices of CHEO to fundamentally protect the rights and dignity of research participants and to pragmatically protect the institution from liability. To that end, 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



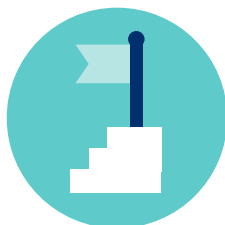
RISK MANAGEMENT
AND MITIGATION



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.

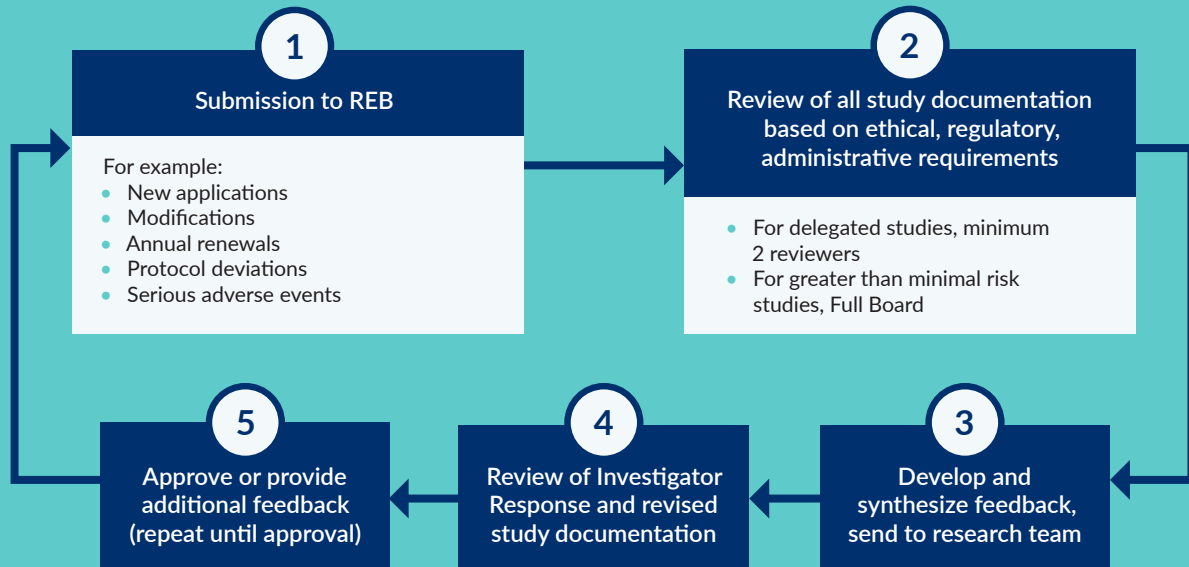


Delegated Reviews

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

2021 HIGHLIGHTS

OVERSIGHT AND COMPLIANCE

1025

Oversight of 1025 active studies

221

new studies

202

new delegated studies reviewed by Chair and REB office

19

new greater than minimal risk studies reviewed by the Full Board

1621

post-approval activities

367

modifications

715

annual renewals

33

CTO Board of Record for 33 provincial and 103 centre applications ¹

100+

Over 100 meetings with PIs and research teams

2500+

Over 2500 hours reviewing studies

GOVERNANCE

- Created and recruited two new positions (Vice-Chair and REB Administrator) and recruited 2 new REB members
- Established new standards for research ethics review as it relates to Equity, Diversity, Inclusion and Indigeneity
- Continued to streamline and enhance review and approval processes through existing and new harmonization agreements (e.g., Ottawa Health Sciences Network, Royal Ottawa Hospital)
- Participating in the development of oversight mechanisms for all quality improvement (QI) activities
- Participating in the national pilot pediatric ethics review program (CHEER); nominated to be the REB of Record to review the first CHEER study

OPERATIONS

- Continued to streamline and optimize operations of the REB Office to ensure the successful and efficient administration of the human research protections program at CHEO
- Updated guidance and processes to facilitate the virtual conduct of research
- Updated requirements regarding data management and security
- Participated in the development and implementation of the CHEO RI institutional approval process (START SMART)

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.

FIGURE 1: Review and Approval Timeline Greater than Minimal Risk 2021

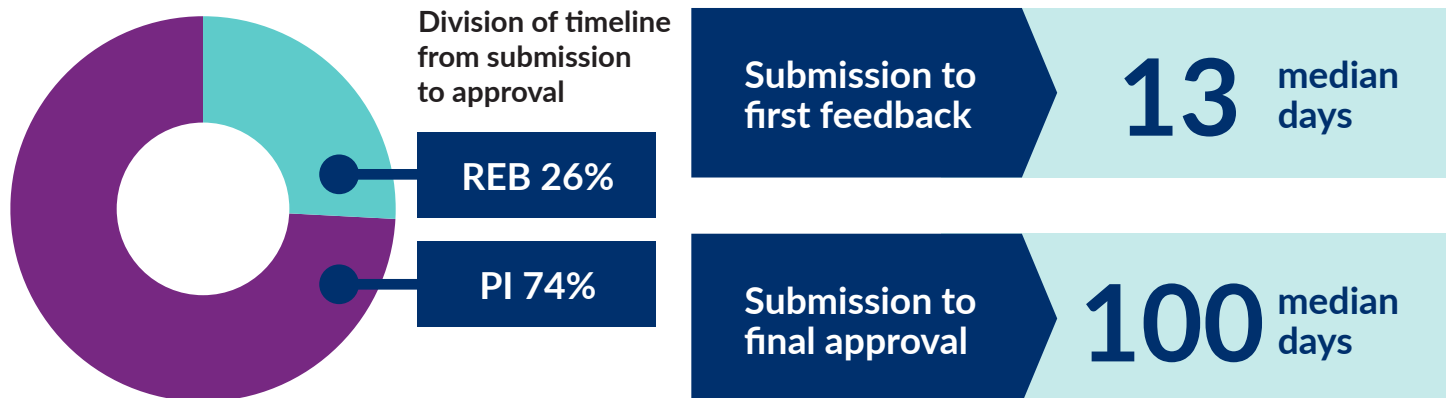


FIGURE 2: Review and Approval Timeline Prospective Minimal Risk 2021

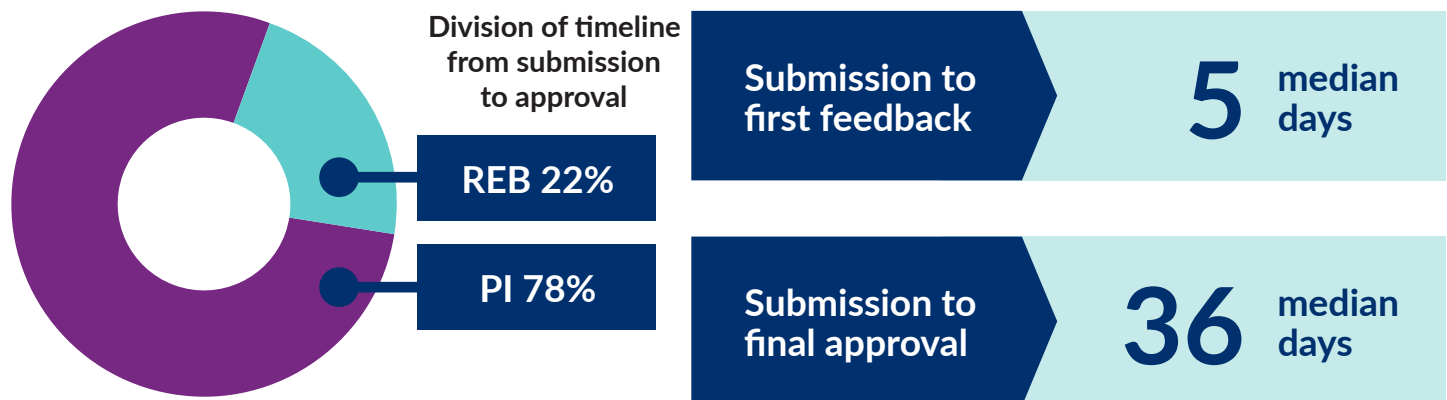


FIGURE 3: Review and Approval Timeline Retrospective Minimal Risk 2021

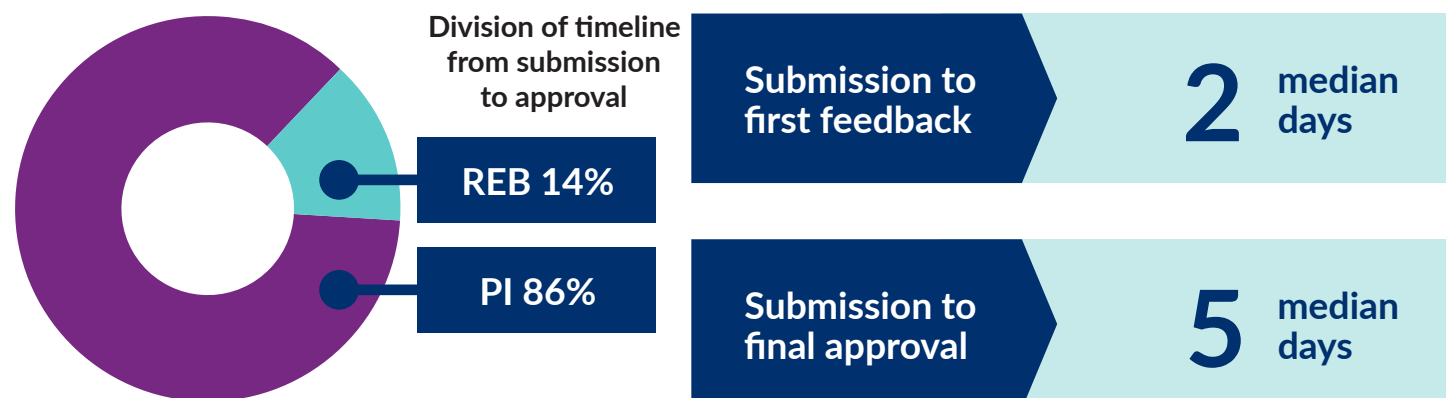


FIGURE 4: New study submissions (Initial Applications)

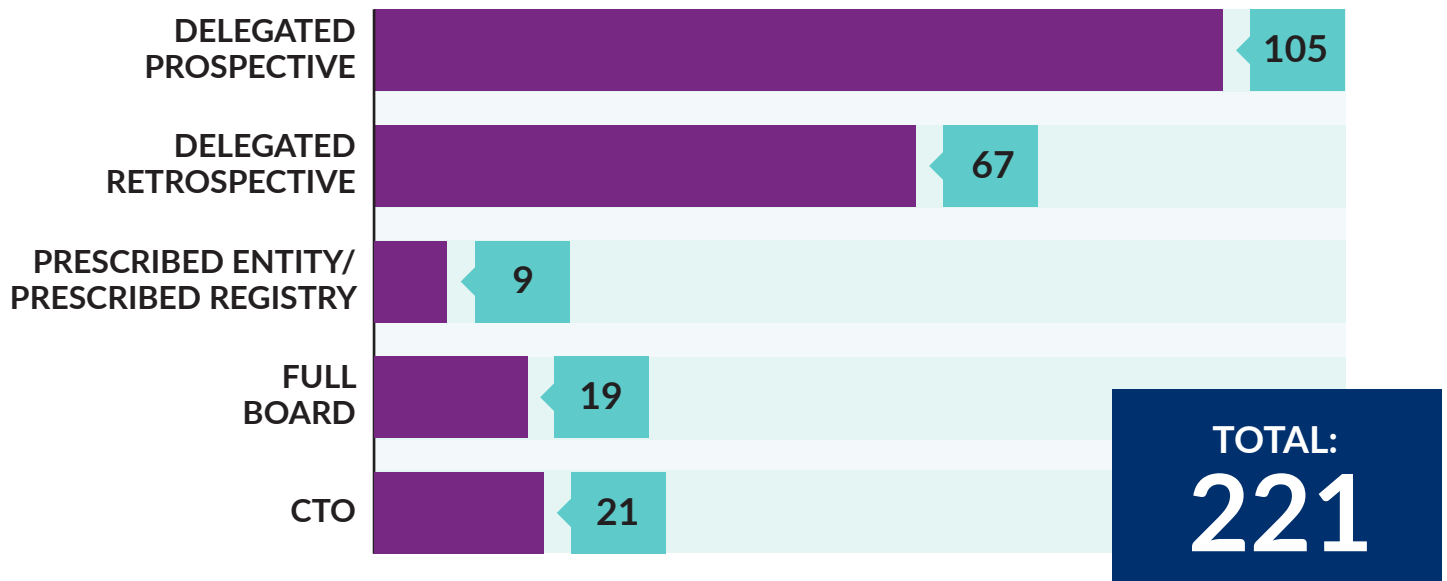
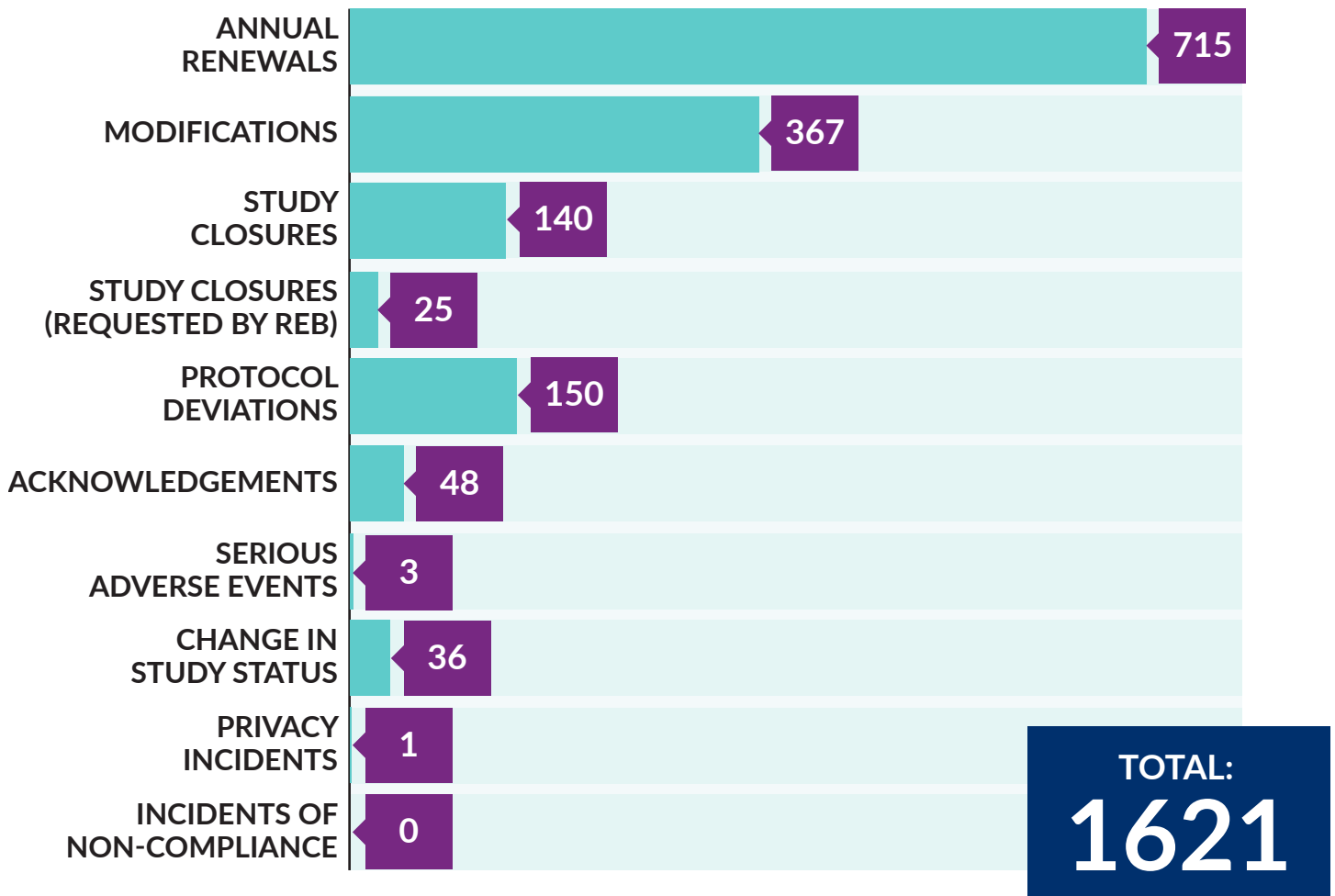
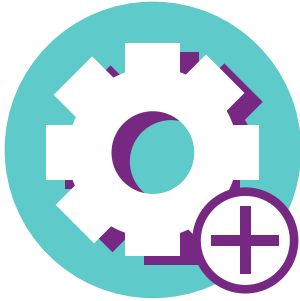


FIGURE 5: Post-approval activities



WHERE WE'RE GOING

2022 STRATEGIC GOALS



Implement structural and operational changes to augment governance best practices, oversight, and compliance to bolster a well-functioning and compliant human research protections program at CHEO



Increase support and resources for the REB to address resource and efficiency gaps to align REB capacity with the growing research enterprise at CHEO



Improve REB and institutional accountability and effectiveness to be congruent with CHEO's Safety First philosophy

2022 GOVERNANCE AND OPERATIONAL OBJECTIVES

1

Develop resources and processes to facilitate the conduct of Indigenous health research in a culturally appropriate manner

2

Work with the CHEO RI to help develop a robust research ethics education and training program to support research teams to apply requirements in collaboration with the CHEO RI

3

Update institutional policies on the ethical conduct of research, Terms of Reference, and Standard Operating Procedures in collaboration with the CHEO RI

4

Bolster professional development opportunities for REB members 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 and Director of Ethics and Professional Affairs at the Canadian Medical Association. She has acted as an ethics advisor on pandemic ethics, most recently on the Ontario COVID-19 Bioethics Table. She is a member of the CIHR Committee on Ethics and RCPSC Ethics Committee, and editor of the Canadian Journal of Bioethics.



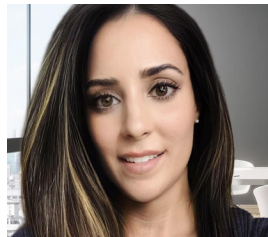
Dawn Davies
MD, MA, FRCP(C)

Dawn completed her medical degree at McMaster University in 1993 and has a Masters degree in Health Care Ethics and Law from the University of Manchester, UK. Dawn is a physician with the CHEO Palliative Care Team and an Associate Professor in the Faculty of Medicine at University of Ottawa.



Sandra Djuric
RN, MScN

Sandy completed her nursing studies at the University of Ottawa where she graduated with a Masters 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.



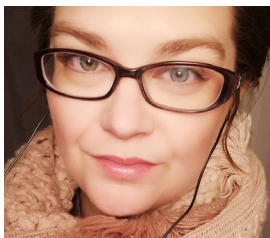
Sabrina Heyde
JD

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.



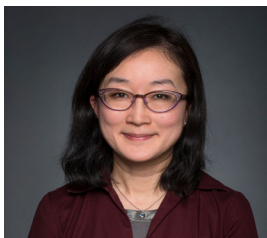
Jennifer Hunter
RECE

Jennifer has spent the last 11 years working as a permanent Early Childhood Educator in Full Day Kindergarten, with the Ottawa Catholic School Board.



Robert Klaassen
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.



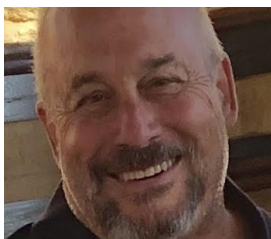
Claudia Malic
MD, MRCS(Eng), FRCS (Plast), MD(res), FRCSC

Claudia has been caring for pediatric plastic surgery and burn patients since 2014 at CHEO. Claudia was appointed as Director of Research for the Division of Plastic Surgery, University of Ottawa in 2016. She is an Associate Professor at the University of Ottawa.



Michelle Mullen
PhD

Michelle is the consultant bioethicist at CHEO, an Associate Professor of Paediatrics and the inaugural Vice-Chair of the CHEO REB. Michelle's current research interests include methods in bioethics and health policy with a focus on transforming vulnerabilities, attention to voices historically silenced, and truly informed decision-making.



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.



Lori Pope

Lori 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

Ellen is a former CHEO patient and sits on the CHEO RI's Patient and Family Advisory Committee. In addition to these roles, she is a medical student at the University of Ottawa Faculty of Medicine.



Régis Vaillancourt
OMM, CD, PharmD, FCSHP

Régis was the Director of Pharmacy at CHEO for 16 years. 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.

RESEARCH ETHICS OFFICE



Valerie Bourada
MSc

Valerie is the Manager of the CHEO REB. She holds a Master's degree in Science from the University of Ottawa. Her career has been linked to health care research, starting as a clinical research coordinator in Oncology.



Natalie Anderson

Natalie is the Senior Coordinator of the CHEO REB.



Yulia Rosenstein Levin
PhD

Yulia is Administrator 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.