ETHICS ARE CENTRAL
Research Ethics Boards (REBs) are independent, multi-disciplinary committees that review the ethical acceptability of research involving humans. REBs that review biomedical research generally include doctors and other members of the scientific community, as well as non-scientific members with specific expertise, including ethicists, lawyers, privacy experts and community members. The REB’s role is to safeguard the rights and welfare of the individuals who volunteer to participate in research, by ensuring that the study sponsor and the researchers have adequately considered and applied the required ethical principles into the design and conduct of the research.

The Ontario Cancer Research Ethics Board (OCREB) has radically changed the research ethics environment for multi-centre cancer trials in Ontario. OCREB is a central, expert oncology REB serving the hospitals/cancer centres in Ontario that conduct oncology clinical trials. OCREB’s centralized model means that once a study has been approved by OCREB, participating study sites can receive OCREB approval within days. This model not only provides a robust ethical focus on oncology research, but also streamlines the review process, minimizes redundancy, promotes consistency, and saves the time and cost of having the study reviewed by an REB at every participating institution/study site. Since its first meeting in January 2004, OCREB has been working with researchers, institutions and sponsors to safeguard the rights and welfare of research participants in Ontario, while advancing ethically sound cancer research.

For a list of institutions authorized to use OCREB, visit Institutions with OCREB Affiliations.

OCREB is accountable to the Ontario Institute for Cancer Research’s Board of Directors through the OCREB Governance Committee.

To learn more about OCREB, visit www.ocreb.ca.
As another year comes to an end, the notion that time flies when you’re busy truly resonates with us. The 13th year of operation of the Ontario Cancer Research Ethics Board (OCREB) was the busiest yet! OCREB saw a 20 per cent increase in new studies over the annual average and managed the highest volume to date of active studies and participating study-centres. The fact that OCREB received double the number of new studies in the first three months of 2017 compared to the previous year suggests that the increase could be a trend.

Despite the demanding day-to-day activities in support of a busy REB, reasonable progress was made on this year’s goals, which included investigating the role of patients, research participants and the public in research, other ethics-related initiatives such as collaborative consent form development, and harmonization efforts including the transition from OCREB’s online system to Clinical Trials Ontario’s system – CTO Stream. Once the move to CTO Stream is complete, there will be a single system for the ethics review of all multi-centre research in Ontario. In phase 1 of this transition, 10 new studies were submitted to OCREB in the first month. Talk about trial by fire! The next steps will be to move the active studies currently in the OCREB system over to CTO Stream. This will make the coming year challenging for institutional research teams, as well as for OCREB members and staff as they navigate two different online systems until the transition is complete. An emphasis on the system left a little less time to advance the remaining OCREB goals. However, as you will read in this report, solid foundational work was completed in exploring opportunities for OCREB to engage in research participant, patient and public outreach activities, and an OCREB web page for Research Participants and the Public was launched in October. In a related initiative, Richard Sugarman continues to serve on a Research Participant Education Sub-committee that is advising the Panel on Research Ethics on the development of educational materials for research participants. Efforts in this area will carry on into the coming year.
OCREB continues to participate in a variety of ethics-related initiatives both provincially and nationally. We are close to implementing a model for the safe and ethical conduct of pediatric study activities at Satellite Centres in Ontario. This means that children will be able to receive some of their study-related care closer to home. In another area, Janet Manzo and Ray Saginur served on the Canadian Clinical Trials Coordinating Centre (CCTCC) Research Ethics Board Accreditation Working Group, which issued its final recommendations in August 2016. Janet was invited to present a summary of the recommendations at the Canadian Association of Research Ethics Boards national conference this April. The recommendations and the CCTCC/Health Canada response can be accessed at REB Accreditation WG Recommendations.

The year closed on a sad note with news of the death of Dr. Suzanne Richter. Suzanne had served as a member of OCREB since April 2015, and as one of the Vice-Chairs since July 2016. She was widely respected and known to colleagues, family and friends as smart, funny, dedicated and compassionate. We miss her terribly. OCREB members generously made a donation in Suzanne’s memory to the World Eye Cancer Hope, an organization working to save the lives and the sight of children with retinoblastoma eye cancer.

We would like to thank the OCREB members and staff for their ongoing commitment to OCREB’s success. We are honoured to work with such talented and dedicated individuals. As members rotating off the OCREB Governance Committee, we would like to take this opportunity also to thank Ray Saginur and Michael McDonald for their significant contributions to OCREB over the years. Ray was one of the founders of OCREB and has served on multiple related committees since 2003, most recently as Chair of the OCREB Governance Committee. Michael has served on the OCREB Governance Committee since 2009, tirelessly advocating for effectively engaging with research participants and with the public and for an evidence-based approach to the protection of research participants.

The fact that OCREB received double the number of new studies in the first three months of 2017 compared to the previous year suggests that the increase could be a trend.
OCREB establishes its goals based on stakeholder input, as well as on changing regulations and guidelines and emerging ethical issues. Although these goals often include a strong operational emphasis, OCREB’s focus remains on the protection of research participants and on centring ethics in all of its activities. On the following pages are some of the key accomplishments last year, beyond the demanding day-to-day activities of a busy REB.
There is a growing movement to engage more effectively with research participants, patients and the public as active partners in research, to ensure that the research is relevant and that ethics are central to the research. Although Research Ethics Board membership always includes community representatives, OCREB also partnered with existing initiatives to assess other opportunities to engage and collaborate with research participants, patients and the public. A few of those efforts are described below.

**BC Clinical Research Infrastructure Network**

Information from a BC Clinical Research Infrastructure Network (BCCRIN) survey, which included individuals who had participated in research and those who had declined participation, provided relevant information about patient concerns and priorities when considering participation in research. Some of those concerns included the burden of participation, the influence of the treating clinician and the potential for adverse events. The results of the survey also provided valuable information about participant concerns arising during participation in research, such as the relationship with research staff, compensation for participation and return of results. The survey results were shared with OCREB’s affiliated centres and are being used to inform consent form revisions as well as recruitment strategies, focusing on issues of importance and relevance to potential participants.

**Recruiting Participants**

The ability to recruit participants for research can be very challenging. In a national public opinion poll on health and medical research (Canada Speaks 2015), a majority of Canadians expressed interest in participating in research; however, few were familiar with research happening in their province and even fewer were aware of opportunities to participate in their own communities. OCREB continues to work with the grassroots organization the Network of Networks (N2) and with the Canadian Cancer Clinical Trials Network (3CTN) to assess a Permission to Contact (PTC) program developed by the Office of Biobank Education and Research in British Columbia. PTC is a patient enrollment strategy that involves asking patients for permission to screen their health records and to be contacted about future research, in compliance with the legislative requirements for access, collection, use and disclosure of personal health information. A PTC Tool Kit launched by N2 provides practical information and resources for organizations interested in setting up a PTC program. Some Ontario centres are investigating the possibility of implementing PTC; however, movement is
slow and resources appear to be a barrier. OCREB will continue to facilitate awareness and recommend adoption of PTC at centres in Ontario to promote patient engagement, to democratize the invitation to participate in research and to facilitate recruitment into research.

**3CTN Decision Tool Project**

OCREB became a member of the 3CTN decision tool project, working to enhance decision-making processes by patients who are exploring participation in research trials. The tool will be launched in 2017 at four Ontario research sites. The sites will complete a survey at the end of an initial period of use, and the results will be used to refine the tool. The results also will inform the work of the national consent form working group. The decision tool is a means of broadening the conversation around research participation by enabling the participant to focus on areas of concern that are relevant to them.

**Engagement Initiatives**

A panel session at the November OCREB education retreat provided a forum for updates and discussions on patient/participant/public engagement initiatives. Panel members included the Canadian Institutes of Health Research (CIHR), 3CTN, N2 and OCREB community members and patient advocates. New engagement activities were proposed, starting with the development of a role description for the community members on OCREB. A webpage geared to research participants and the public also was created. OCREB is committed to enhancing its engagement with research participants, patients and the public, and efforts in this area will continue.
Common Consent Form

The use of common consent documents promotes consistency in the written materials given to participants, assists with the REB review processes and reduces duplication. A common consent form was developed through a project initiated by Canadian Cancer Trials Group (CCTG) in collaboration with OCREB and the British Columbia Cancer Agency Research Ethics Board (BCCA REB) and was adopted by OCREB following input from its affiliated Ontario centres. This enables participating centres to adopt the approved provincial consent form, which adheres to the OCREB template, with minimal to no changes. Since the publication of the first common consent form in 2012, it has been revised once and is currently under review by a broader group of collaborators, which now includes CCTG, OCREB, BCCA, CTO, Alberta Innovates Health Solutions, the University of Saskatchewan REB and Eastern Health. The efforts of this group facilitate a common national approach to the development of consent documents for oncology trials. OCREB continues to investigate ways to facilitate the adoption of the OCREB templates.

Ethics-Related Initiatives and Harmonization Efforts

OCREB continues to actively participate in a variety of other ethics-related initiatives and harmonization efforts in Ontario and Canada. This includes leading the national REB Standard Operating Procedures (SOP) Committee and participating with N2 in the development of draft pediatric SOPs. OCREB will use these documents to inform its own policies and procedures and to collaborate in the development of common consent and assent templates for use in pediatric research.

CTO’s Online System

Last, but certainly not least, a major operational focus this year was on the move to CTO’s online system, CTO Stream. A feasibility assessment was completed over the summer and a decision to proceed was made in September. A project plan subsequently was implemented and in February 2017, OCREB – through its parent organization, the Ontario Institute for Cancer Research (OICR) – entered into a Participation Agreement with CTO. Phase 1 of the transition (new studies only) commenced in March 2017, at which time 10 new studies were submitted to OCREB in CTO Stream. Phase 2, which involves the migration of all active studies from OCREB’s system to CTO Stream, is expected to occur in the second quarter of 2017-18. Once the move to CTO Stream is complete, there will be a single system for the ethics review of all multi-centre research in Ontario.
TIMELINE METRICS

New Studies
OCREB received 84 new studies in 2016 compared to 92 in 2015 and to an average of 71 new studies per year. The overall time from submission to approval remains constant at around three months. The greatest delay in time to overall approval continues to be the time to receive the final Provincial Applicant’s response to the OCREB review letter.

New Centre Applications
OCREB received 294 centre initial applications in 2016 compared to 306 in the 2015. This included centres joining studies approved in 2010, 2012, 2013, 2014 and 2015. Centre initial applications are generally approved in under three days.

Volume: Active Studies and Active Study-Centres
Of the 823 studies submitted to OCREB since January 2004, 371 remained active at the end of 2016, with 1,143 active study-centres. This compares to 338 active studies with 1,001 active study-centres at the end of 2015.

Once the move to CTO Stream is complete, there will be a single system for the ethics review of all multi-centre research in Ontario.
Once a study is up and running, it is associated with multiple post-approval submissions. These include applications from centres for approval to join an approved study, changes related to new information gleaned during the conduct of the study, reports of events that occurred during the study, reports of the study’s progress, and study closure forms. Below is a table illustrating the number of submissions each year since 2012.

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<td>Centre Closures</td>
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<td>216</td>
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<td><strong>TOTAL</strong></td>
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<td><strong>3,179</strong></td>
<td><strong>2,937</strong></td>
<td><strong>2,867</strong></td>
<td><strong>3,121</strong></td>
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**Quality Improvement Initiatives**

OCREB employs a variety of approaches to continuous quality improvement (QI), including:

**Policy and Procedures Committee**

Established in 2006, this Committee serves as an advisory group to OCREB, with a mandate to investigate emerging issues and to develop relevant policies and procedures.

**National Consent Form Template Development Group**

A joint effort between OCREB and its affiliated Ontario centres, the CCTG, the BCCA REB, CTO and representatives from organizations in Alberta, Saskatchewan and Newfoundland. The efforts of this group provide a common national approach to the development of consent documents in oncology trials and promote consistency in the information provided to research participants across Canada.

**Continuing Education**

The third annual Education Retreat was held the evening of November 11, 2016. The topics covered at the sessions were:

**Pragmatic Clinical Trials**

- Pragmatic trial design. Merrick Zwarenstein, Director, Centre for Studies in Family Medicine, Western University
- Ethical, regulatory and practical considerations from a researcher/field perspective. Mark Clemons, Medical Oncologist, Ottawa Hospital.

**Engaging Patients in Clinical Research (panel)**

- CIHR Ethics Policy Project on Patient Engagement in Research. Geneviève Dubois-Flynn, Manager of Ethics at CIHR
- N2 resources for patients/the public. Dawn Richards, N2 Project Manager
- 3CTN patient & public involvement (PPI). Karen Arts, Executive Director, 3CTN
- Patient advocate & community member experience. Antonia Palmer, community member & patient advocate, OCREB, Ac2orn, Neuroblastoma Canada & N2.
Monthly Webinars/Teleconferences
Since 2006, OCREB has been hosting monthly sessions for study staff to provide education and to promote dialogue on research participant protection. The sessions also provide a forum for communicating updates on relevant regulations and on OCREB’s policies and procedures. The 10 sessions held in 2016-17 were attended by an average of 12 centres (range eight to 19).

COST RECOVERY
On April 1, 2013, OCREB began charging for the initial and annual review of industry-sponsored studies. The final fee structure took into consideration the amounts charged by REBs in Canada and the U.S., the review activities required over the lifecycle of a trial, and a pragmatic approach to managing the overall process. The total amount recovered each year represents approximately 25 per cent of the overall annual operating costs of OCREB.

THE PEOPLE ARE WHAT MAKE OCREB SPECIAL
Accompanying her young son through his cancer journey exposed Antonia Palmer to the importance of clinical trials. Following a relapse of his cancer, Palmer’s child was fortunate enough to be enrolled in a promising clinical trial in New York City. Palmer went on to form Neuroblastoma Canada in 2010 and co-founded Advocacy for Canadian Childhood Oncology Research Network (Ac2orn) in 2014. Her patient advocacy work with those and other oncology organizations led to her appointment to OCREB. “In addition to the knowledge you gain about new health interventions, the people are what makes OCREB special,” says Palmer. “The level of dedication is astounding. I feel honoured to be a member.”

ANTONIA PALMER
KEEPING ETHICS CENTRAL TO OUR OBJECTIVES

Through consultation with our members, research teams, trial sponsors and others, OCREB sets annual objectives that keep participant safety and ethics at the centre of what we do. By working together, OCREB will continue to improve the ethics review process while keeping the focus on our most important partners – research participants.
The objectives for next year arose primarily out of findings from OCREB member exit interviews and ongoing consultation with our stakeholders.

**ENGAGE**

Continue to pursue opportunities to engage in relevant public, patient and research participant outreach activities, including the development of formal descriptions of the REB member roles, starting with the community member role.

**ENHANCE**

Enhance the ethics review guidelines to ensure that the relevant ethical criteria are the primary focus of the reviews and to promote the involvement of all OCREB members in the review process.

**EVALUATE**

Continue to conduct exit interviews with departing OCREB members and establish a forum for obtaining ongoing feedback from current OCREB members.

**EDUCATE**

Facilitate ongoing education by introducing relevant education sessions at designated OCREB meetings.

**COLLABORATE**

Promote the streamlining and harmonization of ethics reviews across provinces by collaborating with other groups working on similar efforts.

To learn more about OCREB’s objectives, visit [www.ocreb.ca](http://www.ocreb.ca).
OUR CENTRAL TEAM

2016–2017 OCREB MEMBERSHIP

CHAIR
Richard Sugarman
Reappointed September 2016
Chair, OCREB, Ontario Institute for Cancer Research, Toronto

VICE-CHAIRS
Yoo-Joung (Yooj) Ko
Reappointed September 2016
Vice-Chair, OCREB
Medical Oncologist, Sunnybrook Health Sciences Centre, Toronto

Mark Whissell
Stepped down August 2016
Vice-Chair, OCREB
Clinical Research Manager, Health Sciences North/Horizon Santé-Nord, Sudbury

Suzanne Richter
Appointed as Vice-Chair July 2016
Stepped down January 2017
Medical Oncologist, London Health Sciences Centre, London

MEMBERS
James Anderson (alternate)
Steped down March 2017
Clinical and Research Ethicist, Holland Bloorview Kids Rehabilitation Hospital, Toronto

Laura Bailey
Clinical Research Coordinator/Recruitment Specialist, London Health Sciences Centre, London

Patti Bambury (alternate)
Co-Coordinator, Resource Nurse, Children’s Out-patient Clinic, Grand River Hospital, Kitchener

Catherine Barker
Stepped down August 2016
Clinical Program Manager, Ontario Regional Biotherapeutics Program, Ottawa Hospital Research Institute, Ottawa

Sally Bean
Senior Ethicist and Policy Advisor, Sunnybrook Health Sciences Centre, Toronto

Kate Besel
Appointed September 2016
Clinical Research Associate, Sunnybrook Health Sciences Centre, Toronto

Savta Brar (alternate)
Surgical Oncologist, Sinai Health System, Toronto

Scott Bratman
Radiation Oncologist, Princess Margaret Cancer Centre, University Health Network, Toronto

Catriona Buick
Advanced Practice Oncology Nurse, Princess Margaret Cancer Centre, University Health Network, Toronto

Lindsay Carlsson
Transferred to regular member July 2016
Advanced Practice Oncology Nurse/ Clinical Research Coordinator, Princess Margaret Cancer Centre, University Health Network, Toronto

Carol Cheung
Pathologist, Princess Margaret Cancer Centre, University Health Network, Toronto

Elvina Chow (alternate)
Lawyer, California

Christine Elser (alternate)
Medical Oncologist, Princess Margaret Cancer Centre, University Health Network, Mount Sinai Hospital, Toronto

Joseph Ferenbok
Director Translational Research Program, University of Toronto, Toronto

Graeme Fraser
Hematologist, Juravinski Cancer Centre, Hamilton

Lee Ann Gallant
Pediatrician, Gallant Medical Clinic, Toronto

Janet Gammon
Clinical Program Coordinator/ Contact Nurse, Neuro-Oncology, The Hospital for Sick Children, Toronto

Ronald Grant (alternate)
Pediatric Medical Oncologist, The Hospital for Sick Children, Toronto

Rebecca Greenberg (alternate)
Reappointed January 2017
Bioethicist, The Hospital for Sick Children

Karen Haas
Community Representative, Brampton

Janice Hodgson (alternate)
Community Representative, Newmarket

Annie Huang (alternate)
Stepped down January 2017
Pediatric Medical Oncologist, The Hospital for Sick Children, Toronto

Michael Huyhn
Reappointed September 2016
Lawyer, Toronto

Swati Kulkarni (alternate)
Medical Oncologist, Windsor Regional Hospital Cancer Program, Windsor

Eric Leung (alternate)
Radiation Oncologist, Sunnybrook Health Sciences Centre, Toronto

Jacqueline Limoges (alternate)
Appointed December 2016
Professor (Nursing), Faculty of Health, Wellness and Science, Georgian College, Barrie

Alexander Louie (alternate)
Radiation Oncologist, London Health Sciences Centre, London

Arif Manji (alternate)
Pediatric Medical Oncologist, Stronach Regional Cancer Centre, Southlake Regional Health Centre, Newmarket and The Hospital for Sick Children, Toronto

Mihaela Mates
Appointed July 2016
Medical Oncologist, Cancer Centre of Southeastern Ontario, Kingston

Andrea Mattiussi (alternate)
Clinical Pharmacist, The Hospital for Sick Children, Toronto

Michelle Mullen
Biostatistician, The Hospital for Sick Children, Toronto

Liz Strevel (alternate)
Medical Oncologist, Trillium Health Partners, Credit Valley Site, Toronto

Ranuka Srinivasan (alternate)
Stepped down February 2017
Clinical Research Manager, Division of Medical Oncology and Hematology, Princess Margaret Cancer Centre, University Health Network, Toronto

George Tomlinson
Biostatistician, University Health Network and Mount Sinai Hospital, Toronto

Deborah Van Seters
Appointed September 2016
Community Member, Waterloo

Lisa Wang (alternate)
Biostatistician, Princess Margaret Cancer Centre, University Health Network, Toronto

Sheila Weitzman
Pediatric Medical Oncologist, The Hospital for Sick Children, Toronto

Sameer Parpia (alternate)
Biostatistician, McMaster University, Ontario Clinical Oncology Group, Hamilton

Sara Rask (alternate)
Stepped down June 2016
Medical Oncologist, Simcoe Muskoka Regional Cancer Centre, Royal Victoria Regional Health Centre, Barrie

Elizabeth Scheid
Research Associate, Tumour Immunotherapy Program, Princess Margaret Cancer Centre, University Health Network, Toronto

Anne Smith
Term ended August 2016
Medical Oncologist/Hematologist, Cancer Centre of Southeastern Ontario, Kingston

Lawrence (alternate)
Medical Oncologist, Sunnybrook Health Sciences Centre, Toronto

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Sara Rask (alternate)
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Elizabeth Scheid
Research Associate, Tumour Immunotherapy Program, Princess Margaret Cancer Centre, University Health Network, Toronto

Anne Smith
Term ended August 2016
Medical Oncologist/Hematologist, Cancer Centre of Southeastern Ontario, Kingston

Lawrence (alternate)
Medical Oncologist, Sunnybrook Health Sciences Centre, Toronto
CHAIR
Raphael (Ray) Saginur
Chair, Ottawa Health Science Network
Research Ethics Board and Infectious
Disease Physician, The Ottawa
Hospital, Ottawa

MEMBERS
Derek Cathcart
Partner, First Canadian Investment Properties
Managing Partner, Cathcart & Associates

Christopher M. Henley
Founder and President, Henley Capital Corporation, Toronto

Michael McDonald
Professor Emeritus of Applied Ethics and Founding Director, W. Maurice Young Centre for Applied Ethics, School of Population and Public Health, University of British Columbia, Vancouver

James (Jim) Wright
Associate Professor, McMaster University
Division Head, Radiation Oncology, Juravinski Hospital and Cancer Centre, Hamilton

EX-OFFICIO MEMBERS
Richard Sugarman
Chair, OCREB

Yooj Ko
Vice-Chair, OCREB

Janet Manzo
Executive Director, OCREB

OCREB GOVERNANCE COMMITTEE

OCREB PERSONNEL

Alison van Nie
Research Ethics Officer

Katherine Zeman
Research Ethics Coordinator

Janet Manzo
Executive Director

Aurora de Borja
Research Ethics Coordinator

Victoria Shlep
Research Ethics Coordinator

Cindy Sandel
Research Ethics Coordinator
FCM MORE INFORMATION

Ontario Cancer Research Ethics Board
c/o Ontario Institute for Cancer Research

MaRS Centre
661 University Avenue, Suite 510
Toronto, Ontario M5G 0A3
416-673-6649
www.ocreb.ca

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Ontario Ministry of Research, Innovation and Science

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