Onward. Upward.

B E Y O N D.

ocreb

ONTARIO CANCER RESEARCH ETHICS BOARD
ANNUAL REPORT 2018–19

Innovative. Collaborative.

ADVANCING

ethically sound research.

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 members of the general public (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 is approved by OCREB, participating study centres can submit their centre-specific applications to OCREB, and typically receive OCREB approval to conduct the study within days. This includes centres joining studies that were originally approved by OCREB months or sometimes years earlier. 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.

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

To learn more about OCREB, visit ocreb.ca.

A year of progress and POSSIBILITIES

MESSAGE FROM THE CHAIRS AND EXECUTIVE DIRECTOR

Onward, upward and beyond are three words that encapsulate OCREB's accomplishments last year, and symbolize 15 years of continuous progress. Onward signifies the unwavering focus on protecting research participants. Upward represents the continuous improvements in quality. Beyond underscores collaborative efforts outside of Ontario.

While the report highlights the year's achievements and metrics, in the next few pages, you also will read about progress on national initiatives, including collaborative efforts with researchers and research ethics boards (REBs) in other provinces. OCREB continues to actively participate in a variety of ethics-related projects, including leading the national REB Standard Operating Procedures Committee, as well as the National Consent Form Working Group.

Improving timelines in parallel with quality requires a multi-pronged approach, including ongoing education and communication with applicants and sponsors. We are pleased to report that our intensive efforts paid off! Last year the median time from submission to approval of new studies was 9.4 weeks despite a 13 per cent increase in volume. This is close to our best time ever, which was in 2012 with a median of nine weeks.

On another positive note, the pediatric research community signaled their intent to expand the use of OCREB to all multi-centre pediatric clinical trials. Doing so would bring OCREB's mandate in pediatric oncology in line with its mandate in adult oncology. We will continue to work with the pediatric research community over the coming year to accomplish this expansion.

(continued on page 3)

MESSAGE (CONTINUED)

Last year brought changes in our cast of characters. Victoria Shelep moved on after 12 years as a Research Ethics Coordinator with OCREB, and we welcomed Beren Avci as her replacement. We also welcomed new OCREB and Advisory Committee members and bid farewell to others as their terms came to an end (page 13). In a sneak peek at a major change on the horizon, Richard Sugarman's second term as OCREB Chair ends in August 2019 and Dr. Yoo-Joung (Yooj) Ko – member of OCREB since 2006 and Vice-Chair since 2013 – was appointed as his replacement, effective September 1.

OCREB's accomplishments would not be possible without the talent, support and dedication of countless individuals, teams and organizations: the members of OCREB, the OCREB office team, the researchers and their study teams and institutions, the Ontario Institute for Cancer Research and the Government of Ontario. We thank all of them for their ongoing commitment to the advancement of ethically sound research.

DR. JAMES WRIGHT
Chair, OCREB Advisory Committee

MR. RICHARD SUGARMAN
Chair, OCREB

MS. JANET MANZO
Executive Director, OCREB

Activities within our province

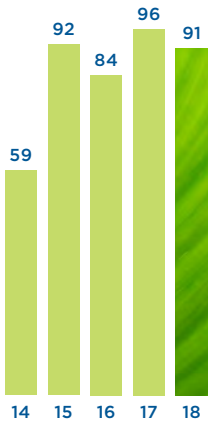
AND BEYOND

Metrics (data relates to the calendar year)

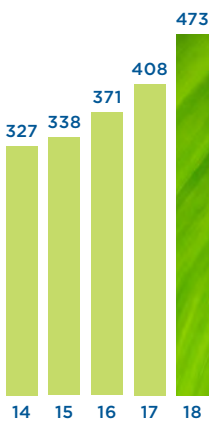
VOLUME METRICS

OCREB received 91 new studies in 2018 compared to 96 in 2017, and compared to an average of 80 new studies per year in the previous five years (2013 to 2017). Of the 1,012 new studies submitted to OCREB since January 2004, 473 studies associated with 1,379 study-centres remained active at the end of 2018. This compares to 408 and 1,176 at the same time in 2017, and represents a 16 and 17 per cent increase, respectively in the number of active studies and active study-centres.

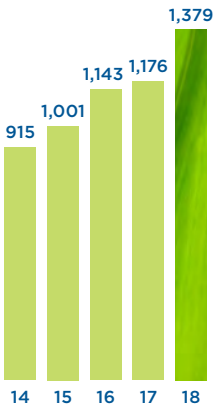
NEW STUDIES



ACTIVE STUDIES



ACTIVE STUDY-CENTRES



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 (centre initial applications), changes related to new information gathered during the conduct of the study (amendments), reports of events that occurred during the conduct of the study (reportable events), progress reports (continuing reviews) and study closures.

The table displays the volume of each application type submitted each year over the past five years, and the change in volume between 2017 and 2018. The highlighted fields show the year with highest number.

APPLICATION TYPE	2014	2015	2016	2017	2018	% change from 2017
Provincial Initial Applications/New Studies	59	92	84	96	91	-5
Centre Initial Applications	183	306	294	312	297	-5
Provincial Amendments	677	550	579	709	919	+30
Centre Amendments	109	136	159	167	256	+53
Provincial Continuing Reviews	286	270	310	345	386	+12
Centre Continuing Reviews	901	886	1,043	1,187	1,254	+6
Provincial Reportable Events	224	227	229	290	295	+2
Centre Reportable Events	221	193	206	220	241	+10
Provincial Study Closures	61	51	54	46	51	+11
Centre Closures	216	156	163	155	207	+34
TOTAL	2,937	2,867	3,121	3,527	3,997	+13

TIMELINE METRICS

NEW STUDIES/PROVINCIAL INITIAL APPLICATIONS

In 2018, OCREB reviewed 91 new studies: 34 involving academic sponsors and 57 involving industry sponsors. Four studies met the criteria for delegated review, with a median time from submission to approval of seven weeks. Of the 87 studies reviewed by the full Board (i.e., at a convened meeting), six were withdrawn prior to approval and all but one (81) were approved at the time of preparing this report. The median time from submission to approval was 9.4 weeks. This represents a 29 per cent improvement over last year and a 14 per cent improvement over the average of the previous eight years. Ten studies were approved in six weeks or less, including a Merck-sponsored study that was approved in 4.0 weeks and a Canadian Cancer Trials Group (CCTG)-sponsored study that was approved in 3.3 weeks.

CCTG is a cooperative oncology group that is well-known and respected in Canada and internationally. OCREB has a longstanding collaborative relationship with CCTG, and both use a similar consent form template that was developed through a collective effort. CCTG was the sponsor of 13 new studies submitted last year, which were approved within a median of 7.1 weeks (range 3.3 to 13.7).

There also were 13 new Merck-sponsored studies submitted last year, with a median time of 6.3 weeks to approval (range 4.0 to 16.3). At the time of publishing this report, OCREB was overseeing 52 active Merck-sponsored studies involving the immunotherapy medicine called pembrolizumab (KEYTRUDA®). Over the past year, OCREB, Merck and the Provincial Applicants worked together on the consent form language to facilitate consistency in the information presented to participants across all relevant Merck studies.

In addition to other quality improvements efforts (see next section), the examples above demonstrate the benefits of teamwork, education and communication to the quality and speed of the review process.

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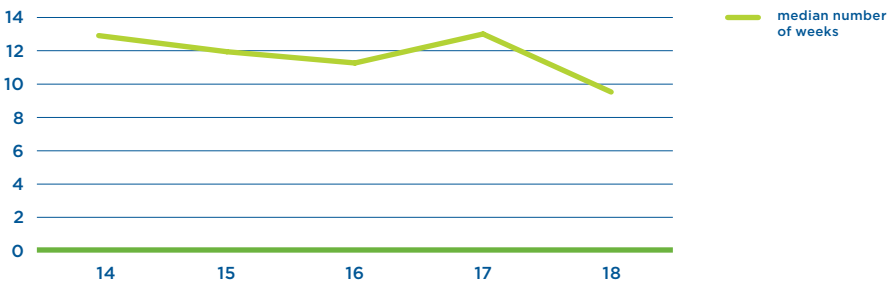
NEW STUDIES – RECEIPT TO APPROVAL



CENTRE INITIAL APPLICATIONS

In 2018, OCREB received 297 new centre applications on approved studies. The median time from submission to approval was five calendar days, which is an important benefit of the central REB model. It means that once OCREB issues study approval, participating study centres can submit their centre-specific applications and receive OCREB approval to conduct the study within days. This includes centres joining studies that were initially approved by OCREB months or sometimes years earlier.

PROVINCIAL (STUDY-WIDE) AMENDMENTS (PAMs)

OCREB received 919 study amendments in 2018. The median time from submission to approval of the 150 reviewed by the full board was eight weeks, and under a week for the 769 that qualified for delegated review.

OCREB's centralized model means that once OCREB issues study approval, participating study centres can submit their centre-specific applications and receive OCREB approval to conduct the study within days. This includes centres joining studies that were initially approved by OCREB months or sometimes years earlier.

NUMBER OF PAMs	Review Type	Submission to Approval (median calendar days)
150	Full Board Review	56 (8 weeks)
769	Delegated Review	6 (0.9 weeks)

Quality improvement efforts

Established in 2006, the Policies and Procedures Committee serves as an advisory group to OCREB with a mandate to investigate and manage emerging issues and to develop or revise policies and procedures.

POLICIES AND PROCEDURES

Established in 2006 and comprising OCREB members and staff, the Policies and Procedures Committee serves as an advisory group to OCREB with a mandate to investigate and manage emerging issues and to develop or revise policies and procedures. Following a full investigation of each issue, the Committee brings its recommendations to the full Board. There were two in-person/web meetings last year and many email consultations throughout the year, including with other REBs and regulatory bodies. The Committee made recommendations on issues such as: the European General Data Protection Regulation and its implication for research in Ontario; criteria for the disclosure of participant identifiers; 24-hour participant contact requirements; and Health Canada and Tri-Council Policy requirements on clinical trial registration, Health Canada authorizations and scientific reviews.

One of OCREB's goals is to develop role descriptions for each category of REB member, and significant progress was made last year on the role of the pharmacist. Discussions between the pharmacists and the Policies and Procedures Committee started with a holistic approach to the role of all reviewers. This process will lead to clarity in the responsibilities, perspective and expectations that each role brings to the review process.

The improvements in quality and efficiency noted in the previous section were also linked to concerted efforts by the Research Ethics Officer, the Policies and Procedures Committee and the OCREB members to enhance the reviews. This teamwork resulted in refinement of the review processes, forms and approval criteria, promoting an emphasis on the substantive ethical issues that are based on an ethical and regulatory framework. This resulted in clarity and conciseness in the requirements and recommendations that are sent back to the researcher, in particular around the requirements for the consent forms and other participant materials.

The retreat was designed to engage members in an overview of ethical review practices as they relate to their specific roles on the board, as well as within the context of the diverse membership of the REB and its primary mandate – the protection of research participants.

CONTINUING EDUCATION

Initial and ongoing education is core to REBs. OCREB board members and staff participated in various webinars and meetings last year including sessions provided by the Joint Centre for Bioethics, the Canadian Institutes of Health Research and respected North American independent research ethics committees; the national Canadian Association of Research Ethics Boards (CAREB) conference (nine OCREB members and staff); and the University Health Network-sponsored Interaction Conference. In addition, in March 2019, OCREB hosted its 4th Education Retreat. The retreat was designed to engage members in an overview of ethical review practices as they relate to their specific roles on the board, as well as within the context of the diverse membership of the REB and its primary mandate – the protection of research participants. Twenty-two OCREB members and staff attended the session. Although there was insufficient time to advance the REB member role discussion, the feedback was generally positive.

MONTHLY WEBINARS/TELECONFERENCES

Since 2006, OCREB has been hosting monthly sessions for study staff at its affiliated centres to provide education, to share noteworthy items affecting the research community and to promote dialogue on research participant protection. The sessions also provide a forum for communicating updates on relevant regulations and guidelines and their interpretation and implementation, as well as on OCREB policies, procedures and guidelines. Summaries of the sessions are posted on the OCREB website on the Monthly Centre Meetings page. Ten sessions were held last year, attended by an average of 14 of the 28 OCREB affiliated centres (range 12 to 17).

Harmonization and streamlining efforts

Over the years, a variety of stakeholders, including patient advocates, have been urging OCREB to facilitate the coordination of REB reviews of cancer studies beyond Ontario.

SHARED REVIEWS

Over the years, a variety of stakeholders, including patient advocates, have been urging OCREB to facilitate the coordination of REB reviews of cancer studies beyond Ontario. As a way to pilot the feasibility of cross-provincial ethics reviews, OCREB revived its facilitated review process last year. Under this model, one REB shares its review materials with interested REBs to facilitate their review of the study. The REBs meet afterward to discuss the findings and in particular, areas of concern or divergences in the reviews. To date, OCREB has provided its review materials to REBs at the BC Children's and Women's Hospital, IWK Health Centre in Nova Scotia, University of Manitoba, Eastern Health in Newfoundland and BC Cancer. The learnings from the responses so far will help to develop the plans, expectations and success indicators of the pilot project.

NATIONAL CONSENT FORM

The National Consent Form Working Group – chaired by the OCREB Research Ethics Officer – is a joint effort between OCREB and its affiliated Ontario centres, CCTG, the BC Cancer REB, and representatives from organizations in Alberta, Newfoundland, Ontario and Saskatchewan. The mandate of the group is to develop oncology consent form templates that can be adopted by REBs and researchers across Canada and the U.S. to promote consistency in information provided to research participants. A final draft of the national consent form template and its associated instructions was presented at the October OCREB meeting. The new consent form template is undergoing final reviews.

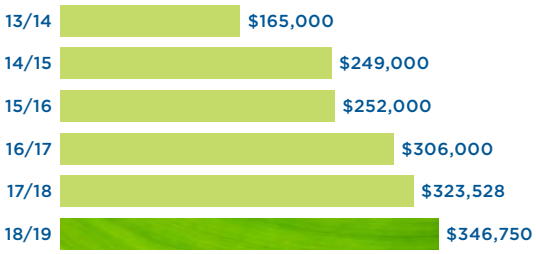
NATIONAL STANDARD OPERATING PROCEDURES

To facilitate a single standard for REBs in Canada, OCREB adopted the Network of Networks and CAREB REB Standard Operating Procedures (SOPs). Given that the N2 and CAREB SOPs were modelled on OCREB's, there were no substantive changes from the previous OCREB SOPs.

Cost recovery

On April 1, 2013, OCREB began charging for the review of industry-sponsored studies. The fee structure took into consideration the amounts charged by REBs in Canada and the U.S., the average number of centres participating in each study, the review activities required over the lifecycle of an oncology trial, and a pragmatic approach to managing the overall process. With the move to Clinical Trials Ontario's (CTO) online system in March 2017, CTO took over responsibility for the fee structure and the collection and disbursement of the review fees.

OCREB COST RECOVERY



Dedicated members who

GO BEYOND

OCREB MEMBERSHIP 2018–19

CHAIR

Richard Sugarman
Chair, OCREB, Ontario Institute for Cancer Research, Toronto
Member, Policies and Procedures Committee

VICE-CHAIRS

Yoo-Joung (Yooj) Ko
Vice-Chair, OCREB
Medical Oncologist, Sunnybrook Health Sciences Centre, Toronto
Member, Policies and Procedures Committee

Jacqueline Limoges
Vice-Chair, OCREB
Professor (Nursing), Faculty of Health, Wellness and Science, Georgian College, Barrie
Member, Policies and Procedures Committee

MEMBERS

Natasha Alexander (alternate)
Clinical Assistant, The Hospital for Sick Children, Toronto

James Anderson (alternate)
Bioethicist, The Hospital for Sick Children, Toronto

Laura Bailey
Term completed December 2018
Clinical Research Coordinator/ Recruitment Specialist, London Health Sciences Centre, London

Patti Bambury (alternate)
Stepped down May 2018
Co-Coordinator, Resource Nurse, Children's Out-patient Clinic, Grand River Hospital, Kitchener

Kate Besel
Clinical Research Associate, Sunnybrook Health Sciences Centre, Toronto

(continued on page 14)

Left to right: Yoo-Joung (Yooj) Ko, Vice-Chair, Jacqueline Limoges, Vice-Chair and Richard Sugarman, Chair

OCREB MEMBERSHIP 2018–19 (CONTINUED)

Valerie Bourada (alternate)
Research Ethics Board Manager, Children's Hospital of Eastern Ontario, Ottawa

Savtaj Brar (alternate)
Stepped down November 2018
Surgical Oncologist, Sinai Health System, Toronto

Scott Bratman
Reappointed April 2018
Radiation Oncologist, Princess Margaret Cancer Centre, University Health Network, Toronto

Catriona Buick
Reappointed June 2018
Advanced Practice Nurse, Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto

Lindsay Carlsson
Clinical Research Coordinator, Princess Margaret Cancer Centre, University Health Network, Toronto

Stephanie Chadwick (alternate)
Nurse Practitioner, Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto

Carol Cheung
Reappointed August 2018
Pathologist, Princess Margaret Cancer Centre, University Health Network, Toronto
Member, Policies and Procedures Committee

Andrew Choate (alternate)
Appointed April 2018
Community Representative, Garden Hill

Elvina Chow (alternate)
Reappointed July 2018
Lawyer, California
Member, Policies and Procedures Committee

Signy Chow
Appointed January 2019
Hematologist, Sunnybrook Health Sciences Centre

Carlo De Angelis
Appointed October 2018
Clinician Scientist – Oncology Pharmacy, Sunnybrook Health Sciences Centre, Toronto

Jeff Doi (alternate)
Appointed October 2018
Clinical Trials Pharmacist, Princess Margaret Cancer Centre, University Health Network, Toronto

Christine Elser (alternate)
Reappointed June 2018
Medical Oncologist, Princess Margaret Cancer Centre, University Health Network and Mount Sinai Hospital, Toronto

Janet Gammon
Pediatric Oncology Nurse (retired), Toronto

Ronald Grant (alternate)
Reappointed August 2018
Pediatric Medical Oncologist, The Hospital for Sick Children, Toronto

Karen Haas (alternate)
Reappointed October 2018
Pediatric Community Representative, Brampton

Michael Huynh
Lawyer, Toronto
Member, Policies and Procedures Committee

Irene Karam (alternate)
Radiation Oncologist, Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto

Swati Kulkarni (alternate)
Reappointed April 2018
Medical Oncologist, Windsor Regional Hospital Cancer Program, Windsor

Alexander Louie (alternate)
Term completed January 2019
Radiation Oncologist, London Health Sciences Centre, London

Arif Manji (alternate)
Reappointed August 2018
Pediatric Medical Oncologist, Southlake Regional Health Centre, Newmarket and The Hospital for Sick Children, Toronto

Mihaela Mates
Medical Oncologist, Cancer Centre of Southeastern Ontario, Kingston

Paula MacDonald (alternate)
Appointed June 2018
Clinical Pharmacist, McMaster Children's Hospital, Hamilton

Andrea Mattiussi
Clinical Pharmacist, The Hospital for Sick Children, Toronto

Michelle Mullen
Bioethicist, Children's Hospital of Eastern Ontario, Ottawa
Member, Policies and Procedures Committee

Krista Naccarato
Business Coordinator, Clinical Trials, Windsor Regional Hospital, Windsor

Carolyn Nessim
Surgical Oncologist, The Ottawa Hospital, Ottawa

Antonia Palmer
Reappointed April 2018
Pediatric Community Representative, Mississauga
Member, Policies and Procedures Committee

Sameer Parpia (alternate)
Reappointed January 2019
Biostatistician, McMaster University, Ontario Clinical Oncology Group, Hamilton

Melody Qu (alternate)
Appointed March 2019
Radiation Oncologist, London Health Sciences Centre, London

Elizabeth Strevel (alternate)
Reappointed April 2018
Medical Oncologist, Trillium Health Partners, Credit Valley Site, Toronto

Mary Stuart
Appointed June 2018
Nurse Practitioner, Princess Margaret Cancer Centre, University Health Network, Toronto

George Tomlinson
Reappointed January 2019
Biostatistician, University Health Network and Mount Sinai Hospital, Toronto

Hanna Tseitlin (alternate)
Appointed August 2018
Pediatric Nurse Practitioner, McMaster Children's Hospital, Hamilton

Deborah Van Seters
Community Representative, Waterloo

Lisa Wang (alternate)
Reappointed January 2019
Biostatistician, Princess Margaret Cancer Centre, University Health Network, Toronto

Sheila Weitzman
Reappointed April 2018
Pediatric Medical Oncologist, The Hospital for Sick Children, Toronto

Jason Yu (alternate)
Medical Oncologist, Royal Victoria Regional Health Centre, Barrie

OCREB ADVISORY COMMITTEE

CHAIR

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

MEMBERS

Josée Bertrand
Principal, The Osborne Group

Laurel Evans
Director, Research Ethics, University of British Columbia, Vancouver

Christopher Henley
Founder and President, Henley Capital Corporation, Toronto

Nancy Walton
Associate Professor, Daphne Cockwell School of Nursing, Ryerson University
Chair, Research Ethics Board, Women's College Hospital, Toronto

EX-OFFICIO MEMBERS:

Richard Sugarman
Chair, OCREB

Yooj Ko
Vice-Chair, OCREB

Jacqueline Limoges
Vice-Chair, OCREB

Janet Manzo
Executive Director, OCREB

OCREB OFFICE PERSONNEL

Janet Manzo
Executive Director
Member, Policies and Procedures Committee

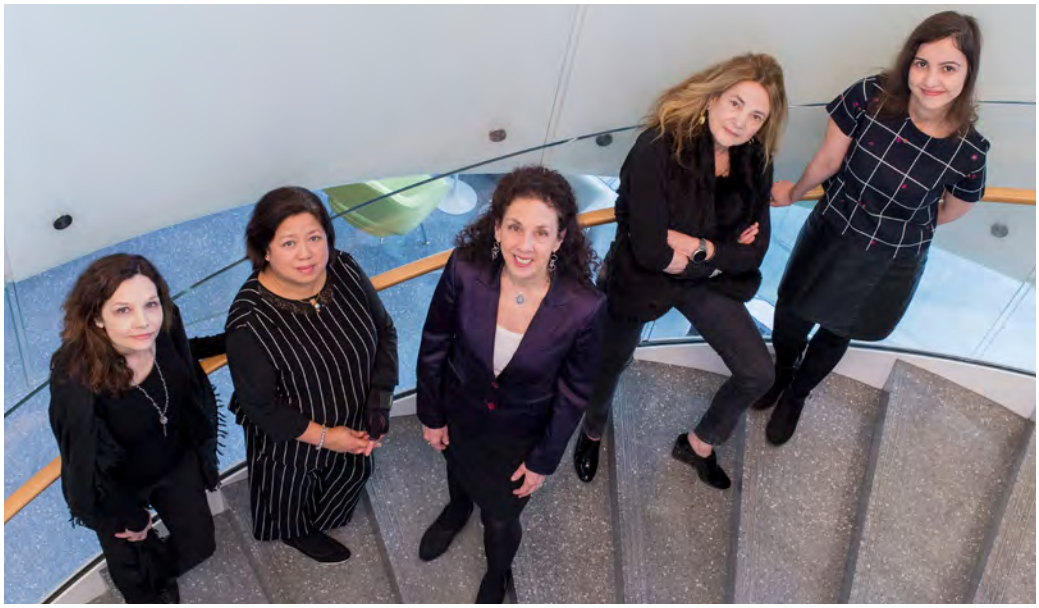
Alison van Nie
Research Ethics Officer
Chair, Policies and Procedures Committee

Aurora de Borja
Senior Research Ethics Coordinator
Member, Policies and Procedures Committee

Katherine Zeman
To December 2018 (not pictured)
Research Ethics Coordinator

Cindy Sandel
Research Ethics Coordinator

Beren Avci
Research Ethics Coordinator



Left to right, OCREB Office Personnel: Cindy Sandel, Aurora de Borja, Janet Manzo, Alison van Nie and Beren Avci

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FOR MORE INFORMATION

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c/o Ontario Institute for Cancer Research

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OICR Ontario Institute for Cancer Research

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OCREB is qualified under the Clinical Trials Ontario REB Qualification Program