

ETHICS IN



ADVANCING ETHICALLY SOUND CANCER RESEARCH IN ONTARIO



ONTARIO CANCER RESEARCH ETHICS BOARD
ANNUAL REPORT 2014–2015

ADVANCING

OUR MANDATE

*Innovative. Collaborative.
Advancing ethically sound cancer research in Ontario.*

Research ethics review is vital to the advancement of ethically sound research. Before individuals can be enrolled in a research study, the study must be approved by a research ethics board (REB), an independent committee composed of medical and scientific experts, ethicists, researchers and healthcare professionals, as well as non-scientific members such as legal and privacy experts and members representing the community.

The REB's role is to ensure that the proposed research adequately protects the rights, safety and well-being of the research participants. Since January 2004, the Ontario Cancer Research Ethics Board (OCREB) has fulfilled an important role in the ethics review process for cancer research in Ontario. OCREB is an expert central oncology REB serving nearly every hospital in the province that conducts cancer clinical trials. For more than 11 years, OCREB has been providing rigorous ethics review and oversight of multi-centred cancer trials while streamlining the review process.



For more information on OCREB, visit www.ocreb.ca

EXPANDING

OUR PURPOSE

We are pleased to share the activities and achievements of OCREB for 2014–15.

Not surprisingly, a strong theme of collaboration emerges from the pages of this year's report. Collaboration is vital to the ongoing success of any innovative undertaking and OCREB clearly embraces this philosophy.

Over the past year OCREB continued its efforts towards becoming the central REB for multi-centre Children's Oncology Group (COG) trials conducted in Ontario. To this end, OCREB collaborated with COG researchers at pediatric centres across Ontario, with the Pediatric Oncology Group of Ontario (POGO), and with C17, an organization representing the pediatric hematology, oncology and stem cell transplant programs across Canada. We are pleased to report that the first COG pediatric clinical trial was submitted in April 2015 for review at the May OCREB meeting.

While the protection of research participants is of utmost importance, a core part of OCREB's mandate is to reduce the amount of time it takes to open a multi-centre trial and thus make novel interventions accessible sooner to patients across Ontario. To that end, as a result of ongoing harmonization efforts with three of the academic or

cooperative group sponsors, OCREB exceeded its target turnaround time by a week for studies submitted by the Princess Margaret Hospital Consortium (PMHC), Ontario Clinical Oncology Group (OCOG) and NCIC Clinical Trials Group (NCIC CTG). This illustrates how effective collaboration can facilitate the ethics review process. Given that just over half of the studies overseen by OCREB are sponsored by industry, through formal or *ad hoc* meetings, OCREB also devoted a substantial amount of time in the past year communicating with industry sponsors and their contract research organizations (CROs). The meetings served as a forum for sponsors and CROs to learn about OCREB and about how they can facilitate the review process. The meetings also provided OCREB with an opportunity to obtain feedback from sponsors and CROs on the successes and challenges they face when OCREB serves as the central REB for centres across Ontario.

We also are proud of the fact that OCREB continues to be an active partner in many provincial and national research ethics initiatives.

In August of 2014, Janet Manzo, the Executive Director of OCREB was invited by the Canadian Cancer Clinical Trials Network to serve as a reviewer on proposals submitted by potential partner cancer centres across Canada.

In the fall of 2014, the Canadian Association of Research Ethics Boards and the Network of Networks released the first set of Canadian standard operating procedures (SOPs) for REBs that review health sciences research. This is exciting to us for many reasons: the SOPs will facilitate the standardization of REB procedures across the country; they were modeled on the OCREB SOPs; and Alison van Nie, OCREB's Research Ethics Officer, chaired the national SOP development working group.

Alison also was instrumental in updating the harmonized main study consent form template, a joint effort between the NCIC CTG, OCREB, the BC Cancer Agency REB and more recently, Clinical Trials Ontario (CTO). Broad adoption of the consent form facilitates consistency in the information presented to study participants across Ontario and Canada, and streamlines the consent review process. With the main consent form updates completed, the committee's focus has turned to updating the optional consent form template.

In March 2015, Janet Manzo was invited to serve on a national REB Accreditation Working Group, a Canadian Clinical Trial Coordinating Centre initiative.

Finally, a more recent collaborative project was the establishment of a national working group to facilitate the use of satellite sites in clinical research so that study participants may be able to obtain some of their study interventions closer to home. This initiative generated a lot of excitement across the country, and the working group includes representation from OCREB, NCIC CTG, CTO and institutions in Ontario, British Columbia and Saskatchewan.

We encourage our partners in the research community to take a few moments to read this report. It illustrates the important work that OCREB does in collaboration with others to promote the advancement of ethically sound cancer clinical trials for patients in Ontario.

We would like to take this opportunity to thank the OCREB members, the OCREB office personnel and the many individuals whose ongoing dedication and commitment contribute to OCREB's success. We also express our gratitude to the Ontario Institute for Cancer Research and the Government of Ontario for their ongoing support.



DR. RAY SAGINUR

Chair of the OCREB Governance Committee



MR. RICHARD SUGARMAN

Chair



MS. JANET MANZO

Executive Director

REPORT ON 2014–2015 OBJECTIVES



OUR STANDARDS OF EXCELLENCE

Metrics and other performance measures relate to the 2014 calendar year. OCREB member institutions, committee memberships and stakeholder survey results reflect the fiscal year April 1, 2014 – March 31, 2015.

OBJECTIVE

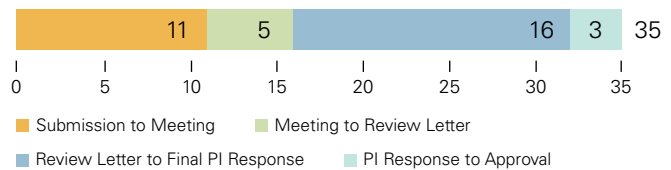
1

Target an eight-week average from submission to approval for 90 per cent of the studies submitted to OCREB for initial review by the three academic/cooperative group sponsors working closely with OCREB: Princess Margaret Hospital Consortium (PMHC), Ontario Clinical Oncology Group (OCOG) and NCIC Clinical Trials Group (NCIC CTG).

Of the 59 new studies received in 2014, 20 were sponsored by academic or cooperative groups. Of those, 11 were sponsored by PMHC, OCOG or NCIC CTG, one of which subsequently was withdrawn. For 90 per cent of the studies sponsored by PMHC, OCOG or NCIC CTG, the average time from submission to approval was 6.9 weeks (35 business days), which exceeds the target (i.e., eight weeks) by a week. It is important to note that PMHC and OCOG serve as the Provincial Applicant (PA) for their studies and submit all provincial applications directly to OCREB on behalf of the Ontario centres. NCIC CTG often assists the PA in completing their applications. The direct involvement of these academic/cooperative group sponsors in the

submission process may contribute to an increase in the quality of the applications and thus to the timeliness of the review process.

SUBMISSION TO APPROVAL (BUSINESS DAYS)
NEW NCIC CTG, OCOG & PMHC STUDIES



Time from submission to approval for 90 per cent of the studies sponsored by NCIC CTG, OCOG or PMHC in business days

OBJECTIVE

2

To improve communication and working relationships with sponsors or their contract research organizations (CROs) working with OCREB, meet with a minimum of 10 industry sponsors (and/or their designated CROs) that have three or more studies currently with OCREB, and meet with any academic or cooperative group sponsors that request a meeting.

Fifty-two per cent of the active studies overseen by OCREB are sponsored by industry and an increasing number of sponsors are contracting many of their activities to CROs. There are eight CROs and 18 industry sponsors that have three or more active studies with OCREB. The OCREB Executive Director or Research Ethics Officer met with nine of the 18 sponsors and CROs (some more than once), as well as with two others that have fewer than three active studies. This was the first time OCREB had met with any CROs on a formal basis. The meetings served as a forum for sponsors and CROs to learn about OCREB and about what they can do to facilitate the review process. The meetings also provided OCREB with an opportunity to obtain feedback directly from sponsors and CROs on the successes and challenges they face when OCREB serves as the central REB for Ontario. Although no formal feedback was

sought, the sponsors and CROs indicated that the meetings improved their awareness of OCREB processes and expectations and in particular, the rationale behind the use of the OCREB consent form template. The meetings have precipitated ongoing discussions with sponsors who are interested in collaborating with OCREB on the consent form templates, and in pursuing a commitment to the use of mutually acceptable consent language. The meetings also provided helpful information on how sponsors and CROs can assist the PA and ultimately, should result in improvements in the quality of submissions to OCREB and thus in the timeliness of the reviews. Overall, the meetings have proven to be extremely productive, and meetings with additional sponsors and CROs will be scheduled.

OBJECTIVE

3

Assess the value and feasibility of increasing the number of OCREB (full board) meetings from one to two meetings per month.

The REBs at five of the 26 institutions served by OCREB meet twice a month. Those REBs receive between 350 and 900 new studies per year. The REBs at the other 21 institutions meet once a month, although some do not meet during the summer. In the last five years, OCREB received an average of 70 new studies per year, which is roughly equivalent to double the administrative workload when factoring in the number of centres per study. In weighing the benefits and challenges of increasing the number of OCREB meetings,

consideration was given to volume, as well as to the impact on the continuity of reviews, on the membership and attendance requirements, on quorum, on the budget and on the timelines. Overall there does not appear to be sufficient justification to increase to more than one meeting a month and in a review of the volume of submissions by month, there is no consistent pattern to support an increase in the number of meetings for a few select months.

4

Assume responsibilities as the REB of record for all new non-Phase I multi-centre Children's Oncology Group (COG) trials to be conducted at the five pediatric oncology centres in Ontario.

Over the past year, OCREB continued its efforts towards becoming the central REB for multi-centre COG pediatric trials conducted in Ontario. Since the fall of 2011, OCREB has been working on this endeavour in collaboration with the COG researchers at the pediatric centres across Ontario, with the Pediatric Oncology Group of Ontario (POGO) and with C17, an organization representing the pediatric hematology, oncology and stem cell transplant programs across Canada. C17 coordinates the Health Canada regulatory aspects of the COG studies. OCREB met with relevant stakeholders at the pediatric sites in Hamilton, Toronto, London and Ottawa. A signed Letter of Intent authorizing the Hospital for Sick Children (SickKids) to use OCREB was received in July. Kingston, Hamilton and London had already agreed to expand their use of OCREB to the COG pediatric trials. The Children's Hospital of Eastern Ontario in Ottawa is in agreement in principle with the use of OCREB; however, it would like to wait until OCREB has reviewed a few pediatric studies before authorizing OCREB to serve as its REB of record. In preparation for the expansion of its mandate, OCREB updated its online application forms and its standard operating procedures (SOPs) to

incorporate the pediatric requirements. An OCREB-COG consent form template was drafted based on the harmonized consent form template – a joint effort between the NCIC CTG, OCREB, the BC Cancer Agency REB and more recently, Clinical Trials Ontario (CTO), which was reviewed by C17. Education for OCREB members and staff on the ethical issues related to research in pediatrics was provided at a retreat held in November and members with pediatric expertise were appointed to OCREB. The first pediatric COG submission was received in April 2015 for review at the May OCREB meeting.

Although four of the five main pediatric sites in Ontario are in a position to use OCREB, the use of satellite sites in the pediatric setting has not been resolved. The use of satellite sites is not limited to pediatric research. As such, a national working group recently was established to facilitate the use of satellite sites in clinical research so that study participants may be able to obtain some of their study interventions closer to home. The working group includes representation from OCREB, NCIC CTG, CTO and institutions in Ontario, British Columbia and Saskatchewan.





OBJECTIVE

5

Conduct needs-assessments with REB members, REB staff and research staff (at the institutional level) with respect to the research ethics education provided by OCREB and develop an education plan for all three target groups, based on the outcome of the needs assessments.

Strategies were employed to address the research ethics education needs of OCREB members, of OCREB staff and of research staff at the centres across Ontario.

In September 2014, OCREB hosted a Lunch and Learn session that was attended by 24 individuals from three study sites. The evaluation of the session was unanimously positive. In March 2015, the University Health Network (UHN) Cancer Clinical Research Unit invited OCREB to present at its continuing education session for study staff. Specific topics were sought prior to the session in order to target the presentation to the needs of the group. OCREB Office Personnel presented in a panel format, each addressing a set of questions that had been provided in advance by the UHN study staff. The UHN Education Specialist indicated that the results of the formal evaluation were very positive. The proposal to provide future sessions of interest to the group was well received and UHN staff are eager to schedule additional sessions.

An inaugural OCREB education retreat with invited speakers took place on the evening of November 13, 2014. Eighteen current OCREB members, four potential pediatric OCREB members and eight OCREB office personnel attended the retreat. The three presentations covered ethical issues related to research in pediatrics and to biobanking, return of results and incidental findings. A breakfast session on “The Changing Face of Phase I Trials” was held the following morning. The results of the formal evaluation were overwhelmingly positive and suggestions were received for future topics of interest.

In the annual researcher survey conducted in March 2015, 86 per cent of survey respondents indicated again this year that there were sufficient opportunities to interact with OCREB regarding ethical issues in their research.

OBJECTIVE

6

Conduct an assessment of the appropriateness and effectiveness of the current resource training programs offered by OCREB and implement appropriate changes based on the outcome of the assessment.

Since 2006, OCREB has been hosting monthly sessions for study staff across the province to learn about research participant protection, about current issues in research ethics and clinical trials and about changes in OCREB policies or procedures. Summaries of the sessions are distributed to research staff and managers and posted online. At each session, the Research Ethics Officer invites attendees to submit topics of interest to them. The 10 monthly web sessions held between April 2014 and March 2015 were attended by an average of 13 centres, up from an average of 10 last year. Excluding July and August, the average number of centres attending the sessions this year was 14. Commencing with the November meeting, the Research Ethics Officer modified the format and focus of the sessions in an attempt to better meet the needs of the attendees. In the four months since, attendance at the sessions increased to an average of 16 centres per month (14 to 17) and the Research Ethics Officer has received *ad hoc* positive feedback on the changes. Just over 50 per cent of

respondents to the annual researcher survey conducted in March 2015 rated the monthly sessions as “good” or “excellent”; another 40 per cent of the respondents had not attended a session. Two respondents noted that they were very interested in attending, but were not always able to due to workload or conflicts with other meetings.

In the past year, two OCREB Research Ethics Coordinators conducted 15 OCREB Online (O2) training sessions involving 54 attendees (including four new OCREB members). A formal evaluation was instituted in September. Overall, the attendees were satisfied with the sessions, and in particular with the hands-on aspects of the training; there were no suggestions for improvements or changes to the sessions. Close to 56 per cent of respondents to the annual researcher survey conducted in March 2015 rated the monthly sessions as “good” or “excellent”; whereas 28 per cent of respondents had not attended a session.

OBJECTIVE

7

Assume leadership in the development of a common optional consent form template (biospecimens and biobanking), working in collaboration with NCIC CTG and the BC Cancer Agency REB.

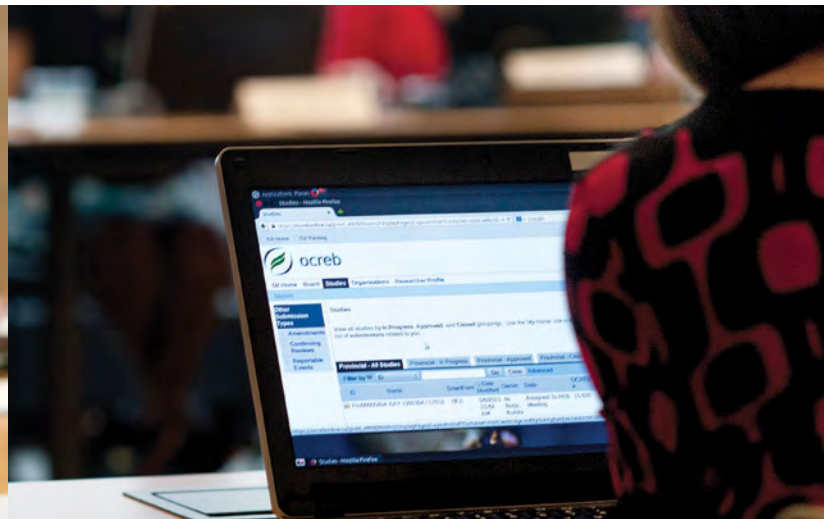
Through a joint effort last year between the NCIC CTG, OCREB, the BC Cancer Agency REB and more recently CTO, the harmonized main study consent form template was updated. In addition to the partner organizations, revisions were solicited from OCREB members, from OCREB’s affiliated centres and from study sponsors. The review process was extensive, although the revisions to the form are not substantial, with the primary change being in the risks section of the form and the addition of options to use the current categorization of risks or to use an alternative such as the National Cancer Institute (U.S.) template for risk categorization or a recognized

alternative (e.g., Council for International Organizations of Medical Sciences). Other changes to the document involve a harmonization of language and some re-ordering of information to increase readability. Broad adoption of the harmonized consent form facilitates consistency in the information presented to study participants across Ontario and Canada, and streamlines the consent review process. With the main consent form updates completed, the committee’s focus has turned to updating the optional consent form template. The OCREB Research Ethics Officer is leading the revisions to the optional sample consent form template.

Continue to be an active partner in the ongoing national and provincial research ethics streamlining initiatives: i.e., the Canadian Cancer Clinical Trials Network (3CTN), the Strategy for Patient Oriented Research (SPOR) and CTO, and in the development of national REB SOPs.

Members of the OCREB team continue to be invited to participate in a variety of provincial and national ethics-related initiatives for organizations such as CTO, the Network of Networks (N2), the Canadian Association of Research Ethics Boards (CAREB), 3CTN, NCIC CTG and the BC Cancer Agency REB. The initiatives that are new this year are listed below:

- The OCREB Executive Director was the recipient of the CAREB 2014 President's Award, which was presented at the CAREB National Conference in April. The Award recognizes a CAREB member for advancing the organization's objectives through outstanding contributions and commitment to enhancing the protection of human research participants and improving the effectiveness and efficiency of the processes of human research;
- In July 2014, the Executive Director was invited to serve on a CAREB Certification Steering Committee to create an REB professional certification program;
- In August of 2014, the Executive Director was invited by 3CTN to serve as a reviewer on proposals submitted by potential Network Affiliated Cancer Centres and Network Cancer Centres across Canada;
- In the fall of 2014, CAREB and N2 released the first set of collaboratively developed, Canadian SOPs for REBs that review health sciences research. The SOPs are compliant with applicable Canadian and U.S. regulations and guidelines. The OCREB SOPs were used as the template to develop the national SOPs and the OCREB Research Ethics Officer chaired the national SOP development working group;
- The OCREB Chair, Executive Director and Research Ethics Officer were invited to serve on the Council of Reviewers for the CTO REB Qualification Program;
- The Research Ethics Officer was invited to serve on the 3CTN Clinical Trial and Network Performance Strategy Committee;
- The Executive Director was invited to serve on a national REB Accreditation Working Group, an initiative of the Canadian Clinical Trial Coordinating Centre (CCTCC). CCTCC was created by SPOR.



SUSTAINING

OUR GROWTH

Performance measurement and reporting are critical to our success. Measuring our performance helps us understand how well we are achieving our goals and allows us to analyze what changes are needed in order to improve performance.

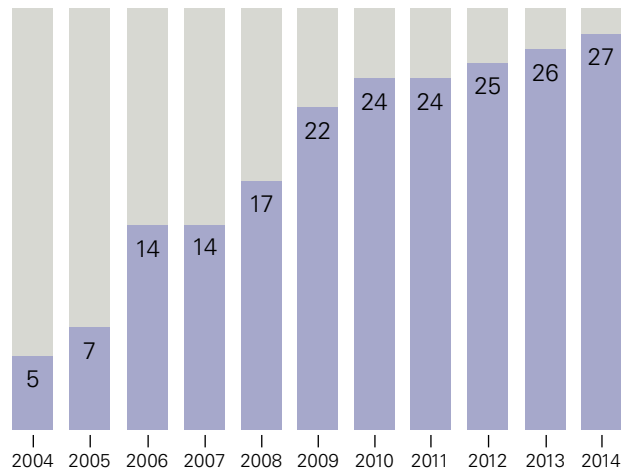
Institutional Membership

Twenty-seven of 29 Ontario institutions (with the addition of the pediatric centres) are authorized to use OCREB as their Board of Record. Three institutions expanded the use of OCREB to non-Phase I COG pediatric studies:

ONTARIO INSTITUTIONS AUTHORIZED TO USE OCREB AS THEIR BOARD OF RECORD

1. Cambridge Memorial Hospital.
2. Grand River Hospital, Kitchener.
3. Hamilton Health Sciences (expanded to pediatrics).
4. Health Sciences North/Horizon Santé-Nord, Sudbury.
5. The Hospital for Sick Children, Toronto (new institutional member).
6. Humber River Hospital, Toronto.
7. Kingston General Hospital (expanded to pediatrics).
8. Lakeridge Health, Oshawa.
9. Lawson Health Research Institute/London Health Sciences Centre (expanded to pediatrics).
10. Mount Sinai Hospital, Toronto.
11. Niagara Health System, St. Catharines Site.
12. North York General Hospital, Toronto.
13. The Ottawa Hospital/L'Hôpital d'Ottawa.
14. Royal Victoria Hospital, Barrie.
15. St. Joseph's Healthcare, Hamilton.
16. St. Joseph's Health Centre, Toronto.
17. St. Michael's Hospital, Toronto.
18. Southlake Regional Health Centre, Newmarket.
19. Sunnybrook Health Sciences Centre, Toronto.
20. Toronto East General Hospital.
21. Thunder Bay Regional Health Sciences Centre.
22. Trillium Health Partners – Credit Valley Hospital, Mississauga.
23. Trillium Health Partners – Mississauga Hospital.
24. University Health Network – Princess Margaret Cancer Centre, Toronto.
25. William Osler Health Centre, Brampton.
26. Windsor Regional Hospital.
27. Women's College Hospital, Toronto.

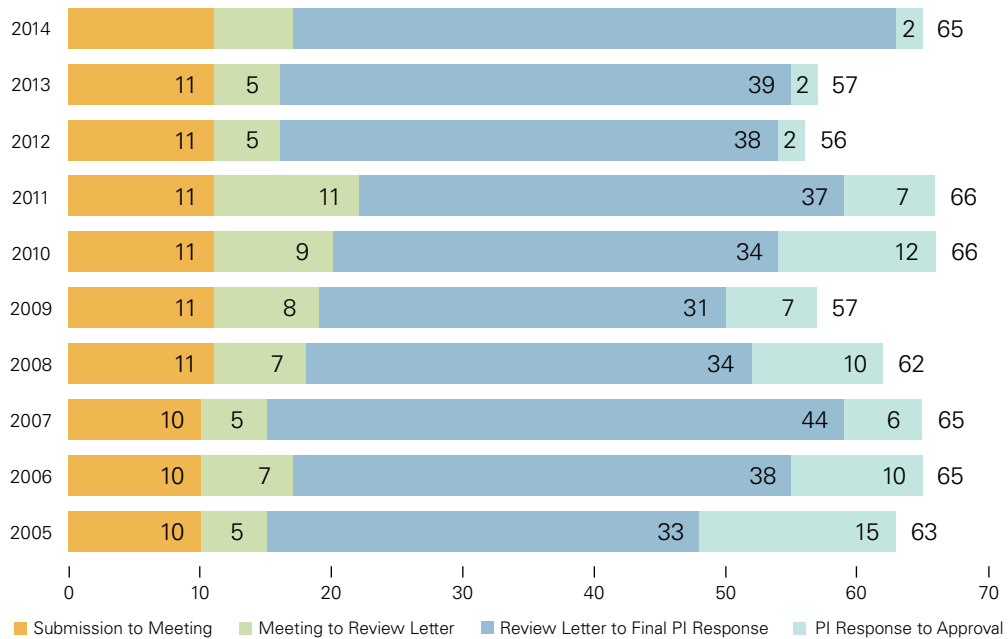
NUMBER OF CENTRES AUTHORIZED TO USE OCREB EACH YEAR
(OF 29 POSSIBLE CENTRES INCLUDING PEDIATRIC CENTRES)



Overall Timeline Metrics

OCREB received 59 new studies in 2014 compared to 70 in 2013. Of the 59 new studies, 55 were reviewed by the full Board and four met the criteria for expedited/delegated review. Four studies subsequently were withdrawn, one study was not approved, six were deferred to a second review by the full Board, and one is awaiting the PA's response. Of the 50 studies reviewed by the full Board and approved to date, the overall time from submission to approval was 13 weeks. The delay in the overall time to approval continues to be related to delays in receiving the final response to the OCREB review letter from the PA.

NEW STUDIES SUBMISSION TO APPROVAL (BUSINESS DAYS)

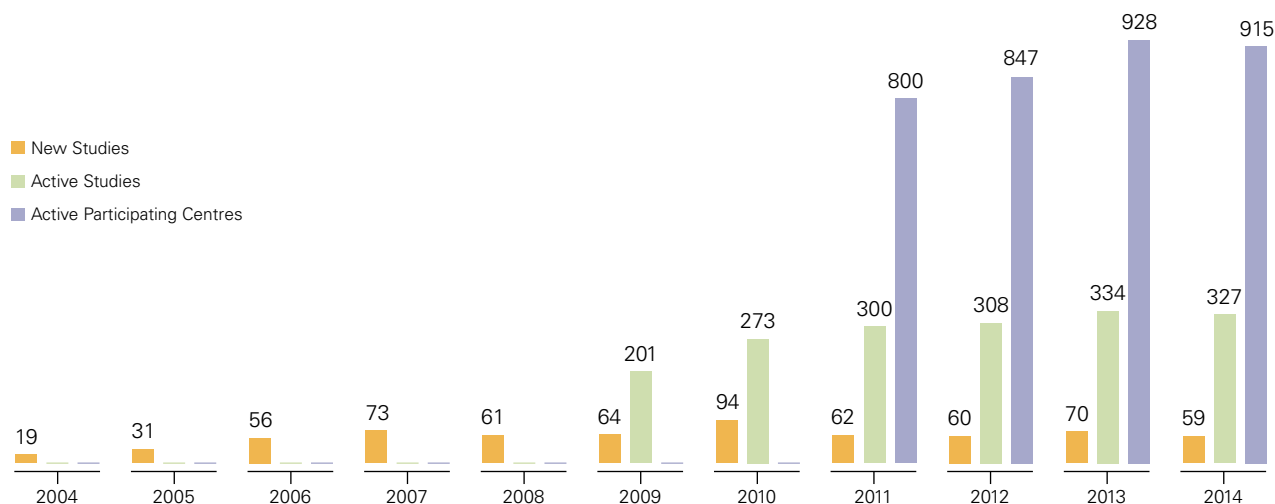


The ethics review process is measured in four stages:

- 1) The time from the deadline for receipt of submissions to the OCREB meeting/review.
- 2) The time it takes OCREB to issue a review letter after a submission is reviewed.
- 3) The time it takes to receive the final PA response to the review letter.
- 4) The time it takes for OCREB to issue its approval/final decision after the PA's final response is received.

NEW STUDIES, ACTIVE STUDIES AND RELATED STUDY ACTIVITIES

At the end of December 2014, there were 327 active studies involving 915 active participating centres compared to 334 studies involving 928 active centres last year. However, between January and March 2015, OCREB received 25 new studies compared to 11 at the same time in 2014 (i.e., more than double the number). Below is a chart showing the number of new studies submitted each year since 2004, the number of active studies at the end of each year since 2009 and the number of active participating centres on those studies since 2011.



VOLUME OF POST-APPROVAL SUBMISSIONS IN THE PAST THREE YEARS

SUBMISSION TYPE	2012	2013	2014
Centre Initial Applications	220	247	183
Provincial Amendments	538	588	677
Centre Amendments	114	140	109
Provincial Continuing Review Applications	261	314	286
Centre Continuing Review Applications	770	945	901
Provincial Reportable Events	158	231	224
Centre Reportable Events	367	434	221
Provincial Study Closures	44	44	61
Centre Closures	121	166	216

Cost Recovery

On April 1, 2013, OCREB began charging for the initial and continuing (annual) review of all new industry-sponsored studies.

OCREB had not charged for its services prior to that time because of the OICR infrastructure funding arrangement with the Ontario centres. The fees were derived from an assessment of the amounts charged by REBs in Canada and the U.S., as well as an analysis of the review activities required by OCREB over the

lifecycle of a trial. The final free structure also took into consideration a pragmatic approach to managing the overall process. OCREB recovered \$165,000 in 2013–14 and \$249,000 in 2014–15, which represents approximately 25 per cent of the overall annual OCREB operating costs.

Stakeholder Surveys

The annual stakeholder surveys are a valuable means for OCREB to gauge its performance and improve its processes, although higher response rates would provide more meaningful results. Some of the results are provided below and some are presented in relevant sections of this report.

SURVEY OF RESEARCHERS AND RESEARCH TEAMS

In March 2015, approximately 700 researchers and their research teams were invited to complete an online survey. A total of 113 responses were received (16 per cent response rate compared to 17 per cent last year), of which 24 per cent were investigators, 25 per cent were study coordinators, 20 per cent were ethics and regulatory staff and 15 per cent were data coordinators/data managers. The other 16 per cent were research/study nurses, research managers or “other”. Thirty-six per cent of the respondents have been working with OCREB for one to five years and 43 per cent for more than five years. Some of the results are presented in other relevant sections of this report.

The charts below show the percentage of respondents that rated OCREB as “good” or “excellent” this year in each of the following categories. In general the results show a change from last year in each category, with the slightly lower ratings in all but one category.

Overall, the results indicate that the benefits of using OCREB far outnumber the challenges. Similar to last year, some of the benefits noted were: expertise; efficiency; the streamlined and accessible online application process; the reduction in workload and time, especially for new centres joining an approved study; easy amendment process (simultaneous approvals); standardized consent forms and processes; prompt and

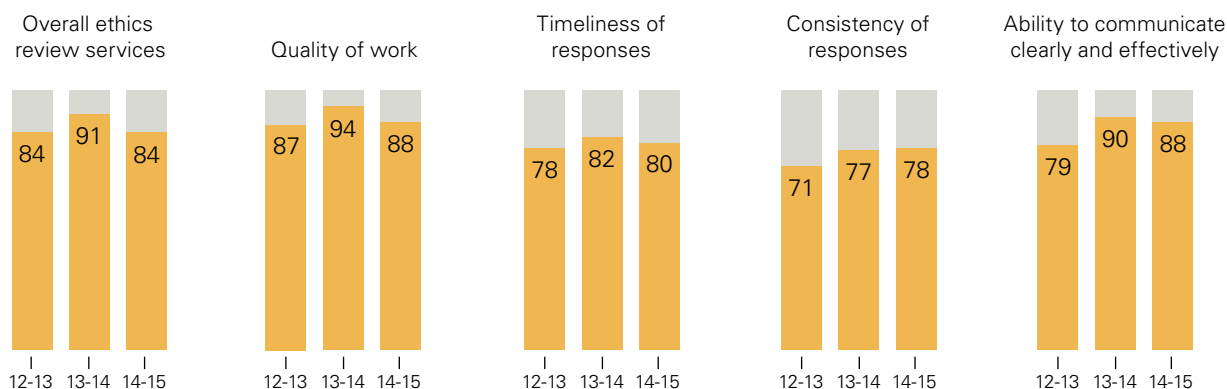
helpful feedback; collaborative and knowledgeable staff. One respondent commented that “it is fabulous to have one REB for the province; can’t wait until pediatrics are also included.” Another suggested that “it really needs to be national.”

The key challenges to working with OCREB noted were: being dependent on the PA to complete timely and quality submissions; the responsibility and workload of being the PA; difficulty navigating the online system; and inconsistencies in OCREB’s requests/reviews.

Interestingly, 28 per cent of respondents indicated that they had submitted a study to their local REB that could have been submitted to OCREB. The two key reasons given were: they initially thought that they were the only site in Ontario; and, no site would agree to serve as the PA.

As a way to reduce the workload, OCREB’s online system allows the PA to route provincial applications to the sponsor to complete. Forty per cent of respondents rated their experience with routing provincial applications to a sponsor or CRO representative as “somewhat helpful” or “very helpful” compared to 28 per cent last year. One rated the experience as “unhelpful”. Fifty-two per cent (compared to 54 per cent last year) had not requested sponsor or CRO assistance, suggesting that this feature still is not widely used. Some of the reasons given for not routing applications to sponsors or CROs

PERCENTAGE OF RESPONDENTS THAT RATED OCREB AS “GOOD” OR “EXCELLENT”





were: feature not used yet; sponsor or CRO not willing to assist; experience was unhelpful; and study staff not wanting to relinquish control of the application.

In this year's survey, respondents were asked if they thought that allowing direct provincial submissions from industry sponsors would facilitate the submission process. Fifty-seven per cent of respondents said "yes", 11 per cent said "no" and 32 per cent were not sure. Of the 53 written comments received, a majority suggested that having the sponsor submit directly would facilitate the review process, noting that the sponsor is in the best position to answer the questions; it would remove the middle layer and queries could be resolved directly; and it would save time and money for the sites. One noted that "It's about time this was brought forth. I've been wondering about this for years!" However, two indicated that serving as the PA helps the site become familiar with the study; three expressed concern about industry sponsor awareness of the local/Ontario context; two were concerned about reducing the medical scrutiny of the protocol by a principal investigator; one was generally "unsure"; one was uncomfortable with the idea of a pharma company doing an ethics submission; and another suggested that the process be piloted.

SURVEY OF SPONSORS AND CROS

For the second year, sponsors and CROs were invited to complete an online survey, and recipients were encouraged to forward the survey on to colleagues. A total of 17 responses were received down from

27 last year (nine industry sponsors, two cooperative group/academic sponsors and six CROs), although one respondent indicated that theirs was a collective response from multiple individuals within the same organization. Since the total number of survey recipients is unknown, the response rate could not be calculated. Nine respondents indicated that they had between five and 10 studies currently open with OCREB, one had 11-20, two had more than 20 and one respondent was unsure. Thirteen rated the quality of OCREB's ethics review services as "good" or "excellent" and 11 considered the quality of OCREB's ethics review services to be "somewhat better" or "much better" compared to the ethics review services of single site REBs. Ten respondents were aware that the sponsor or CRO could assist the PA with submissions using OCREB's online system; seven said that they had been asked to assist the PA and 15 said that they would assist if asked.

Overall, the comments were positive, citing quality, speed, ability to assist the PA and ease of use of the online system. One requested that OCREB continue any initiatives to work with other provinces to use the same consent form template. The few suggestions for improvements were similar to last year: more frequent meetings; more flexibility with the consent form template; providing sponsor training on the online system; length of the application form; difficulty getting an investigator to serve as the PA; and suggestions to allow direct submissions to OCREB by the sponsor.



OUR FOCUS

OCREB Governance Committee

OCREB is accountable to the Ontario Institute for Cancer Research's Board of Directors through the OCREB Governance Committee. Information about the Committee, including its meeting minutes, can be found at www.ocreb.ca

OCREB's Objectives for 2015–2016

1. Review all new 2014 studies in which the PI response time was greater than six weeks post receipt of the OCREB review letter, and identify potential reasons for the delays.
2. For all studies submitted to OCREB between 2012 and 2014, report on the time elapsed from the approval of the study (provincial initial application) to the time of approval of each participating centre and the reasons for any delays in the submission of the centre initial applications. Additionally, if the information is available, report on the time from the approval of the study to study activation at each centre and to the time of the first study participant's visit. This information will help to determine the value of investing further efforts directed at reducing the time from the submission to the approval of new studies – i.e., the provincial initial submission.
3. Review the eligibility (inclusion and exclusion) criteria in the protocols submitted to OCREB over the past one to two years to inform the board in their decision-making and review of pre-screening consent forms focused on a single eligibility criteria.
4. Investigate the feasibility of establishing a formal consultative service (i.e., the provision of education resources) that would enhance the researcher/research team's understanding of research ethics and improve the quality of their submissions to OCREB.
5. Identify the types and volume of other forms of multi-centre cancer research (i.e., non-clinical trials). These data would serve as the basis for assessing the feasibility of broadening OCREB's mandate.



For more information on OCREB, visit www.ocreb.ca

OUR DEDICATED PROFESSIONALS

OCREB Members 2014–2015

CHAIR

Richard Sugarman
Chair, OCREB,
Ontario Institute for Cancer
Research, Toronto

VICE-CHAIRS

Yoo-Joung (Yooj) Ko
Vice-Chair, OCREB
Medical Oncologist,
Sunnybrook Health Sciences
Centre, Toronto

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

MEMBERS

Rebecca Auer
Stepped down October 2014
Colorectal and Surgical
Oncologist, The Ottawa
Hospital, Ottawa

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

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

Stephanie Chadwick
Clinical Nurse Specialist,
Princess Margaret Cancer
Centre, University Health
Network, Toronto

Flay Charbonneau (alternate)
Manager, Pharmacy (Oncology),
Sunnybrook Health Sciences
Centre, Toronto

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

Caroline Chung (alternate)
Stepped down March 2015
Radiation Oncologist, Princess
Margaret Cancer Centre,
University Health Network,
Toronto

Carlo De Angelis
Oncology Pharmacy Clinician
Scientist, Sunnybrook Health
Sciences Centre, Toronto

Ronald Feld (alternate)
Medical Oncologist,
Princess Margaret Cancer
Centre, University Health
Network, Toronto

Ronan Foley
Term ended May 2014
Hematologist, Internist, Director,
Stem Cell Processing Unit

Director, Cell Diagnostic Unit,
Hamilton Health Sciences
Associate Professor,
McMaster University, Hamilton

Catherine Fortin
Clinical Program Manager,
Ontario Regional Biotherapeutics
Program, Ottawa Hospital
Research Institute, Ottawa

Graeme Fraser
Appointed May 2014
Hematologist,
Juravinski Cancer Centre
Associate Professor,
McMaster University, Hamilton

Meredith Giuliani
Stepped down April 2014
Radiation Oncologist, Princess
Margaret Cancer Centre,
University Health Network,
Toronto

Rebecca Greenberg
Bioethicist,
The Hospital for Sick Children
Assistant Professor,
Department of Paediatrics
Bioethicist Member,
Joint Centre for Bioethics,
University of Toronto, Toronto

Janice Hodgson
Community Representative,
Newmarket

Michael Huynh
Lawyer, Toronto

Paul Karanicolas (alternate)
Surgical Oncologist, Sunnybrook
Health Sciences Centre, Toronto

Peter Kesper
Stepped down March 2015
Community Member, Toronto

Sara Kuruvilla (alternate)
Medical Oncologist, London
Health Sciences Centre, London

Eric Leung (alternate)
Appointed December 2014
Radiation Oncologist,
Sunnybrook Health Sciences
Centre, Toronto

Susan MacMillan
Stepped down March 2015
Community Representative,
Ajax, Ontario

Carolyn Nessim
Appointed August 2014
Surgical Oncologist, The Ottawa
Hospital, Ottawa

Tony Panzarella (alternate)
Manager, Biostatistics, Princess
Margaret Cancer Centre,
University Health Network
Assistant Professor, University
of Toronto, Toronto

Nicole Park (alternate)
Associate, Fasken Martineau
DuMoulin LLP, Toronto

Kathleen Romano
Manager Clinical Trials,
Thunder Bay Regional Research
Institute, Thunder Bay

Elizabeth Scheid
Reappointed January 2015
Research Associate, Immune
Therapy Program, Princess
Margaret Cancer Centre,
University Health Network,
Toronto

Anne Smith
Medical Oncologist/Hematologist,
Cancer Centre of Southeastern
Ontario, Kingston

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

John Wunderlich
Privacy and Security Consultant,
Toronto

Wei Xu
Principal Biostatistician,
Princess Margaret Cancer
Centre, University Health
Network

Assistant Professor,
University of Toronto, Toronto

Karen Yee (alternate)
Stepped down September 2014
Hematologist, Princess
Margaret Cancer Centre,
University Health Network,
Toronto

OCREB Policy and Procedure Committee 2014–2015

CHAIR

Alison van Nie
Research Ethics Officer, OCREB

MEMBERS

Sally Bean
Ethicist, OCREB

Aurora de Borja
Research Ethics Coordinator,
OCREB

Michael Huynh
Lawyer, OCREB

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Vice-Chair, OCREB

Janet Manzo
Executive Director, OCREB

Victoria Shelep
Research Ethics Coordinator,
OCREB

Richard Sugarman
Chair, OCREB

Mark Whissell
Vice-Chair, OCREB

Katherine Zeman
Research Ethics Coordinator,
OCREB

OCREB Governance Committee 2014–2015

CHAIR

Raphael (Ray) Saginur
Chair, Ottawa Health Science
Network Research Ethics Board,
Ottawa

MEMBERS

Derek Cathcart
Partner, First Canadian
Investment Properties
Managing Partner,
Cathcart & Associates
Lay Member, University
Health Network Research
Ethics Board, Toronto

Geneviève Dubois-Flynn
Manager, Ethics Strategies,
Canadian Institutes of Health
Research, Ottawa

Christopher M. Henley
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, BC

Jim Wright
Associate Professor,
Department of Oncology,
McMaster University

Division Head, Radiation
Oncology & Radiation
Oncologist, Juravinski Cancer
Centre, Hamilton Health
Sciences, Hamilton

EX-OFFICIO MEMBERS

Richard Sugarman
Chair

Yooj Ko
Vice-Chair

Mark Whissell
Vice-Chair

Janet Manzo
Executive Director

OCREB Office Staff



Back row, left to right

Terry Liu
Senior Business Systems
Analyst, OCREB Online (O2)

Janet Manzo
Executive Director

Victoria Shelep
On leave
Research Ethics Coordinator

Alison van Nie
Research Ethics Officer

Front row, left to right

Safia Moosvi
Client Coordinator, OCREB
Online (O2)

Aurora de Borja
Research Ethics Coordinator

Cindy Sandel
*Replacing Victoria Shelep
while on leave*
Research Ethics Coordinator

Kathie Zeman
Research Ethics Coordinator



FOR MORE INFORMATION

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

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