

Ninth Meeting of the OCREB Governance Committee
790 Bay Street, Suite 401, Toronto
August 19, 2011
Minutes including September 2, 2011 teleconference addendum

Participants:

Chair:	Raphael (Ray) Saginur
Members:	Geneviève Dubois-Flynn Michael McDonald Derek Cathcart Kathleen Pritchard at 1:15
Ex Officio:	Jack Holland Janet Manzo
Regrets:	None
Guests:	Keitha McMurray (Sunnybrook Health Sciences Centre) Christopher Henley (Henley Capital Corporation) Jean-Jacques Rousseau (Ministry of Research & Innovation) - 2:30 to 3:00 Lorna Grey (Ministry of Research & Innovation) - 2:30 to 3:00
Quorum present?	Yes

1. CALL TO ORDER

The Chair called the meeting to order at 1:40 p.m. EST. The Chair welcomed the two observers to today's meeting: Christopher Henley and Keitha McMurray.

MOTION (McDonald/Dubois-Flynn)

To approve the revised agenda circulated on August 16, 2011.
Motion carried.

2. APPROVAL OF PREVIOUS MEETING MINUTES**MOTION** (Cathcart/Dubois-Flynn)

That the minutes of the Committee's March 22, 2011 meeting be approved with the deletion of the extra word on page 1, section 3.1.
Motion carried.

3. UPDATES FROM THE OCREB CHAIR AND EXECUTIVE DIRECTOR**3.1. Update - OCREB Chair****Internal Functions**

The OCREB Chair indicated that he has no concerns with the quality and consistency of the OCREB reviews. The OCREB members are thorough and timely in their reviews. Recruitment of members has not been an issue. Since January, the terms of three OCREB members were renewed, six alternate members were appointed and a potential Vice-Chair was identified. OCREB has 20 regular members and 15 alternate members.

The Chair would like to ensure that the members receive appropriate recognition for their role on OCREB, and plans to work on this over the coming months (e.g., providing letters to their superiors regarding the value of serving on OCREB). It took considerable time to put this in place when he was Chair of the Hamilton Health Sciences REB; however, eventually individuals saw the value of serving on an REB and began offering to serve on the REB instead of being pushed to do so.

Two core OCREB staff members resigned last summer and had ended their employment with OICR at around the time the Chair started, leaving the office in a state of transition. A third Research Ethics Coordinator was hired in December and a fourth this June. The Chair is pleased with the office staff and with the support OCREB receives. The Research Ethics Coordinators work well together and with the Chair. They are timely in their communications and appear dedicated and keen to do a good job. The Chair recognizes that retention of these individuals is important to the program and wants to ensure that measures are in place to promote a sense of value in their role.

The OCREB Chair is less enthusiastic than some about the new online system (OCREB Online, aka O2) and feels that there are areas that could be improved to better reflect the OCREB model. The Chair met with the vendor to express his concerns and to encourage them to look at the business opportunity of “getting it right” with OCREB in light of the IRB reforms being proposed in the US. He noted that the O2 support team is experienced and able to fix many of the issues without vendor assistance.

External Influences

Harmonization of the consent form between the NCIC CTG, the BC Cancer Agency REB and OCREB is in sight. The NCIC CTG provided an encouraging response this week to input on the consent template from OCREB and BCCA. NCIC CTG studies are the most widely conducted oncology studies across Canada. Once a template is agreed upon, this should make it easier to work toward consent harmonization with other study sponsors.

The Princess Margaret Hospital Drug Development group is a key OCREB stakeholder group. The Chair has been in periodic communication with their senior team to discuss levels of satisfaction and performance.

The OCREB Chair continues to serve as a Board member of the Canadian Association of Research Ethics Boards (CAREB). CAREB has voiced strong concerns with the Canadian General Standards Board (CGSB) standard. The standard appears to be taking Canada in an opposite direction from the recent proposed modernization of the rules and ethics streamlining direction in the US. The US Department of Health and Human Services recently issued an Advanced Notice of Proposed Rulemaking (ANPRM) for Revisions to the Common Rule for comment. CAREB will be preparing a response to the ANPRM.

The Chair has been invited to speak at an Insight conference this fall.

In summary, the OCREB Chair remarked that OCREB functions well overall and “is where we want to be”.

3.2. Update - Executive Director

Update on Previous Processing Delays:

There was a series of events last year that led to processing delays, as previously communicated to this Committee. The 2010 metrics show an increase of six days in OCREB-controlled processing times. The queue of items submitted under the old OCREB processes has been cleared. Of the submissions (new studies, initial centre applications, amendments, reportable events) currently in the review process in O2, few under OCREB control have been sitting more than 2 weeks with no action. Despite the processing delays under the old system and the issues related to the transition to a new system, there has been no indication that centres are submitting eligible multi-centre trials to their local REB instead of to OCREB and two large centres confirmed that they had not done so. Although there were 40 new studies submitted as of August this year compared to 69 at the same time last year, this compares to 39 at the same time in 2009.

OCREB Online

OCREB Online (O2) is a transparent, secure, web-based system designed to automate and streamline the ethics submission and review processes and alleviate the potential for human error experienced with the previous manual, multi-step processes. Training on O2 commenced in early February and the system went live February 18 for new studies only. The launch was delayed by about a year from the target “go-live” date. The legacy studies were imported and the system went live for all studies on May 17. Hands-on training

continued at the OCREB offices as well as at study centres over the next few months. Over 200 study coordinators, investigators, REB members and REB office staff have been trained to date. O2 user manuals were created; targeted, modular manuals will be developed. Recently, a video tutorial for department approvers was made available. Similar tutorials will be developed for other users and application types.

Feedback on the system seems positive although responses appear to depend on the user group (study staff, REB member, REB office staff), the user's comfort level and experience with computers, and the stage the user is at in adapting to the change. There are study staff, REB members and REB staff that find the system intuitive and easy to navigate and others that do not. Due to a queue of submissions on the legacy studies under review at the time that the new system was launched, there were dual systems in place until very recently, which made the transition for the internal staff more difficult. The O2 project team is acquiring the knowledge to fix many of the issues and to configure enhancements with minimal or no assistance from the vendor. The majority of O2 support calls are related to creating accounts, resetting passwords and obtaining study access, although there are general system use questions as well. The system is not fully adapted to a centralized model (e.g., provincial and centre applications are not well integrated in some areas) and the reporting capabilities are unsatisfactory. The O2 Team will be working with the vendor over the next few months to improve the system functionality to better suit a centralized REB model.

The ED is enthusiastic about the system despite its shortcomings. The old processes were not sustainable. In the evaluation by a multi-disciplinary team of the nine submitted proposals, the current system was superior to the others. The system provides transparency – to the sites, to REB members, to the REB office team and to sponsors. Users can see the status of the submission as it moves through the various stages of the review process. REB members can see each others' reviews, which the members find to be valuable. The system allows for ease in determination of the distribution of workload and studies can readily be reassigned in the event of a sudden absence. It is easy to see and act upon stalled items (internal or external), and the system provides an integrated document management function. In addition, the system automates and records all activities and actions, which becomes an audit trail and record of compliance. It also provides a means to report on additional metrics and to better assess volume.

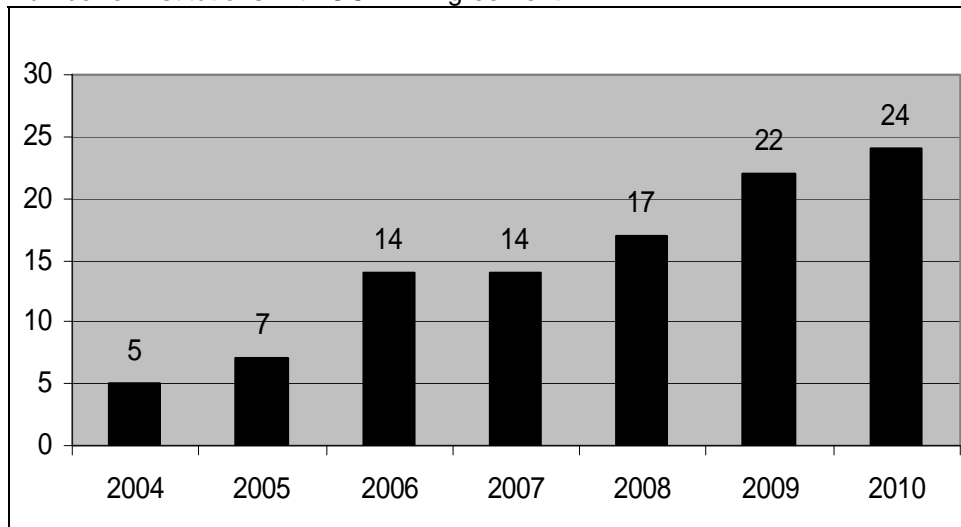
Human Resources

The Intake Coordinator resigned in May to move out West, which was unfortunate timing given the implementation of Phase 2 of the online system. The ED took the opportunity to reassess the organizational structure. In June and July respectively, a full-time O2 Client Coordinator and a fourth Research Ethics Coordinator were hired (see draft organizational chart).

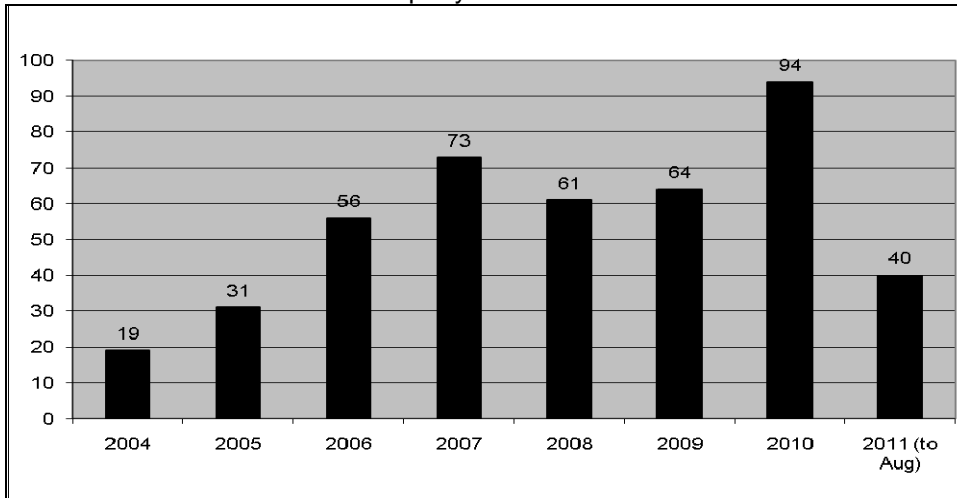
Metrics

The ED summarized the 2010 metrics and presented graphs of the year-to-year comparisons. These data will be included in the OCREB annual report.

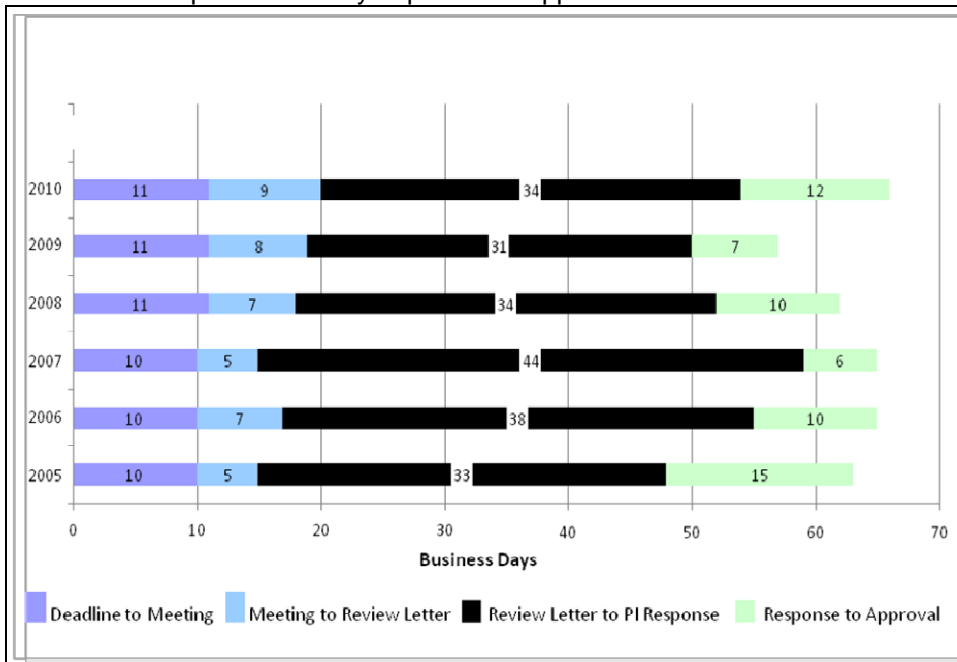
Number of institutions with OCREB Agreement



Number of new studies submitted per year



Time from receipt of new study to provincial approval



Currently OCREB is overseeing 264 approved studies involving 692 centre applications (average of 3 centres per study). There have been as many as 20 Ontario centres on some of the studies with OCREB. Fifteen new studies are in the review process and four new studies are in pre submission. Eight centre applications are in the review process and 17 are in pre submission. There are a total of 205 various applications (new studies, initial centre applications, amendments, reportable events) in various stages of review. These volume indicators could not be collected under the old system. One of the Committee members noted that there are almost as many items under review as there are studies.

OCREB Annual Report and Stakeholder Survey

Due to the workload and extensive communication associated with roll out of the online system, a stakeholder survey was not conducted this year. In addition, the annual report has not yet been drafted. A brief annual report will be prepared for distribution to stakeholders. A draft will be circulated to this Committee for review and approval prior.

Compliance with TCPS2 & CGSB

The 2nd edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, or “TCPS 2” was issued in December 2010. The following areas required revisions to bring the OCREB

Standard Operating Procedures in line with the new TCPS: mandatory clinical trial registration prior to the recruitment of the first study participant, an SOP for research ethics review during publicly declared emergencies, and updates to the SOPs on human biological materials and genetic research. Other areas requiring further investigation are: institutional responsibilities in security of information and in institutional conflict of interest. The Research Ethics Officer has reviewed and revised the OCREB SOPs to reflect the TCPS2 requirements as well as to incorporate changes required by the implementation of the OCREB Online system. The SOPs will undergo final review in preparation for sign-off by the OCREB Chair & ED.

A third draft of the Canadian General Standards Board (CGSB) Standard was issued in May 2011 with a deadline of June 11 for a vote. The third draft technically passed; however, in accordance with CGSB policies and procedures, all negative votes and all comments accompanying are considered. The CGSB Chair and Secretary are working on an action plan to seek resolution to the negative votes, which will be referred to the full CGSB Standards Committee for approval. OICR/OCREB worked with and endorsed the comments submitted by the Canadian Association of Research Ethics Boards (CAREB) and voted against the third draft due to concerns with the bureaucratizing of ethics review (similar to the regulation and accreditation-induced "check-list" approach in the US) with little or no evidence that the additional efforts contribute to the protection of research participants. Although the OCREB SOPs already reflect most of the CGSB Standard, no changes will be made until the Standard is finalized and a decision is made regarding adoption.

4. BUSINESS ARISING FROM PREVIOUS MEETING

4.1. Candidates for OCREB Governance Committee and OCREB Vice-Chair

Christopher Henley and Keitha McMurray are candidates for the Governance Committee and OCREB Vice-Chair, respectively. Their CVs or biographies were included in the meeting package. Both individuals introduced themselves before stepping out of the meeting during the discussion and vote.

MOTION (Cathcart/McDonald)

*That Christopher Henley be appointed to the Governance Committee.
Motion carried.*

OICR Board of Directors approval will be sought at its October 6, 2011 meeting.

MOTION (Saginur/Dubois-Flynn)

*That Keitha McMurray be appointed as the OCREB Vice-Chair.
Motion carried. **Note:** As per the Terms of Reference, OICR Board approval is not required for the appointment of the Vice-Chair.*

The CV of Dr. Yooj Ko (OCREB member) was included in the meeting package. The OCREB Chair and the incoming Vice Chair will both be on vacation during the same time period (late September to early October). The Committee felt it was appropriate for the OCREB Chair to delegate his duties to Dr. Ko during this time, or whenever the Chair and Vice-Chair are not available.

4.2. Measuring Human Research Protections

Michael McDonald summarized a recent workshop on this topic held in Montreal. Rather than wait for the perfect measures of human research protection, under a CIHR grant, the group is working on a set of survey tools for research participants, for researchers and for REB members. They would like to validate and pilot the survey tools at one or more institutions.

ACTION: Michael McDonald, Ray Saginur, Jack Holland and Janet Manzo to discuss the feasibility of piloting the survey(s) through OCREB. McDonald will be working with Saginur and others to develop, assess and refine survey tools and will report back.

4.3. Chair and Vice-Chair Evaluations

The first OCREB Chair and Vice-Chair performance evaluations consisted of a survey of REB members and office staff. Following a review of the process, the Committee made recommendations for improvements: 1) Vice-Chair should have a defined primary role in a particular area; 2) individual survey responses should be

reviewed in detail; 3) meeting attendance should be included in the assessment; and 4) feedback should be obtained on an ongoing basis.

As per the Terms of Reference, an evaluation of the current OCREB Chair is due. The Committee would like to review the survey first.

ACTION: ED to distribute the evaluation survey for comments.

4.4. Executive Director Job Description

The Executive Director job description had not been updated since 2006 and a draft updated version was provided to the Committee as requested.

ACTION: ED to redistribute the draft job description for any final comments.

5. NEW BUSINESS

5.1. MRI Ethics Streamlining Initiatives

Jean-Jacques Rousseau and Lorna Grey from the Ontario Ministry of Research and Innovation (MRI) joined the meeting at 2:30 to update the Committee on the MRI ethics streamlining initiative and to clarify the relationship between the Ontario initiative and OCREB. Jean-Jacques provided the update.

The MRI launched a new Life Sciences Commercialization Strategy in April 2010. The plan includes an investment of up to \$17 million for three clinical trials related initiatives, which arose out of a December 2008 meeting MRI had with Rx&D. The clinical trial initiatives include a new province-wide coordinating framework to streamline ethics and contracts for multi-centre clinical trials. In November 2010, the MRI tasked a group of key stakeholders to make recommendations on how best to streamline the process for industry sponsored multi-centre trials. A report was submitted to the MRI on January 31, 2011. In April 2011, MRI accepted the Clinical Trials Ontario (CTO) proposal with some modifications. The CTO will provide industry with a one-stop coordinated approach to initiating multi-centre trials in Ontario. A Clinical Trials Stakeholders Association has been formed with an interim Board of Directors. Upon receiving funds from MRI, this group will hire a temporary ED, write a business plan for the new organization and establish the official governance structure of the CTO. MRI expects the CTO to benefit from and build on the OCREB experience.

The Committee noted that the presentation was highly informative and that there appear to be opportunities for the involvement of OCREB in the process. Jean-Jacques and Lorna were thanked for their time.

5.2. OCREB and Children's Oncology Group (COG) Clinical Trials

Over the past six months to a year, the ED and Chair have had occasional discussions with representatives from SickKids hospital regarding a role for OCREB in paediatric oncology trials. In a letter dated August 12 from Dr. Ronald Grant (enclosed in the meeting materials), OCREB was asked to consider undertaking the review of Phase II and III clinical trials sponsored by the Children's Oncology Group (COG) as the single REB of Record for five Ontario centres. This would involve approximately 10 to 14 new studies per year, with an average of one amendment per study per year. The Phase II studies are usually open for two years; the Phase III studies five years. The average follow-up period is 10 years, which means the REB file remains open for 12 to 15 years. The request was to consider taking on the 117 historical studies in addition to new studies.

Many aspects of childhood cancer are unique and appropriate expertise would be required on OCREB. Similarly, OCREB has not experienced processes around assent in a paediatric population. Additional information is needed to determine the impact on resources and processes.

The ED noted that paediatric clinical trials fit with OICR's strategic plan, and OICR is supportive in principle of OCREB expanding to paediatric oncology trials. The Governance Committee also supports the expansion in principle, and suggests that the OCREB Chair obtain more information before a recommendation is made.

ACTION: OCREB Chair to obtain more information.

5.3. 2011/12 OCREB Budget

Although the budgets are prepared around November each year, a very early draft forecast for 2013 was circulated at today's meeting for discussion. In order to fulfill its mandates to "review the annual operating budget of the OCREB office and make recommendations regarding resource allocation and budgets; to ensure appropriate systems and controls are in place to maintain the ongoing arms-length independence of OCREB; and to make recommendations on the strategic direction, mandate, and priorities of OCREB", the Committee indicated that it needs to see the budget forecast details and underlying assumptions, as well as a summary of the budget history over at least a few years.

ACTION: More detailed financial information will be circulated and discussed at a follow-up teleconference.

5.4. Committee role in appointment of OCREB members

Per the Terms of Reference, one of the Governance Committee's duties is to "...*appoint the members of OCREB upon the recommendation of the OCREB Chair*". Currently, OCREB members are selected based on nominations by OCREB members or by the broader oncology research community, and following consultation with the OCREB Chair, members and the ED. The final appointments are made by the Chair. At a previous meeting, the Committee indicated that it does not have the local knowledge, nor does it meet often enough to be involved in the REB member selection or appointment process, and considered it appropriate to continue with the current practice. However, there may be a role for the Committee in this area. This will be discussed further before any requests for revisions to the Terms of Reference are considered.

5.5. US HHS proposal to improve rules protecting human research subjects

Plans are in development to reform IRB processes in the US. An "Advance Notice of Proposed Rulemaking" (ANPRM) has been issued entitled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators." Responses are due by September 26th. Included in the meeting package was a related July NEJM article, "Reforming the Regulations Governing Research with Human Subjects" by Emanuel and Menikoff, which lays out the rationale and the proposed approach to IRB reform. On August 8th, the ED and OCREB Chair participated in a webinar hosted by PRIM&R. OCREB will likely submit a response by the Sept 26th deadline. It was noted that many Canadian players will want to look seriously at these US proposals and the implication of their adoption on Canadian REB processes and perhaps the comments from this group can be collated.

ACTIONS:

- distribute the available information on the topic (*post-meeting note: done*)
- collate comments from the group on the ANPRM for submission

6. IN CAMERA SESSION

The voting members of the Committee met for an *in camera* session at 4 p.m. There were no motions arising from the *in camera* session.

The meeting adjourned at 4:30pm.

September 1, 2011 Follow-Up Teleconference

On September 1, 2011, a teleconference was held to follow-up on the revised budget, the ED job description and the Chair evaluation survey. All three documents were distributed prior to the teleconference.

Present: Raphael (Ray) Saginur (Chair) Jack Holland
Geneviève Dubois-Flynn Keitha McMurray
Michael McDonald Janet Manzo
Derek Cathcart
Christopher Henley

Regrets: Kathleen Pritchard

Budget:

The ED clarified that the 2012/13 budget recommendations and the program goals for 2012/13 are not due to OICR until mid-November, and will be forwarded to the OICR Board for review by at its January 2012 meeting. An Excel workbook was distributed with the information below:

- sheet one showed the actuals for 2006/07 to 2009/10, the amounts budgeted for 2010/11 and the forecast for 2012/13;
- Sheet two provided the assumptions and notes behind the 2012/13 forecast;
- Sheet three provided graphs of the volumes over time (# of institutions using OCREB, # new studies per year), and of the breakdown of the 2012/13 forecast.

The Committee found it helpful to see the financial trends, but would like more narrative for the 2012/13 forecast notes and assumptions. The Committee requested the actuals for 2010/11, and additional rows on sheet one showing the volume over the years (average head count, number of new submissions per year, number of centres, average number of centres per study). The ED noted that the actuals for 2010/11 will be provided after the second quarter.

ACTION: ED to provide an updated budget and notes prior to the next meeting.

ED Job Description

The Committee noted that the relationship between the ED and the Chair, and the ED and the OCREB Governance Committee is unclear in the job description. In addition, the relationship among the different OCREB leaders is unclear from the organizational diagram.

ACTION: The OCREB Chair offered to work with the ED to revise the job description. An updated draft will be brought to the next Governance Committee meeting for review. The organizational chart also will be discussed at that time.

Chair Evaluation Survey

The Chair evaluation survey was approved for use with the addition of "if applicable" to question 5h) "*Seeks consensus, when appropriate*". The survey will be sent to OCREB members and OCREB office staff. It is preferable to have the survey managed by a group separate from the ED's survey account. The results will be provided to the OCREB Governance Committee Chair.

ACTION: The ED will make the change to the survey and will look into having another group manage the survey.

NEXT MEETING

A meeting (teleconference) will be scheduled for late October or early November.

Respectfully submitted,
Janet Manzo