

CAREB PRE & POST



CAREB ACCER

CANADIAN ASSOCIATION
OF RESEARCH ETHICS BOARDS

L'ASSOCIATION CANADIENNE
DES COMITÉS D'ÉTHIQUE
DE LA RECHERCHE

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ATTENTION CAREB MEMBERS: THE CALL FOR NOMINATIONS IS COMING SOON!

Each year the CAREB Board of Directors retires directors as their terms on the Board expire. The Past President of CAREB chairs the Nominating Committee charged with finding new Board members who are committed to helping fulfill the CAREB mandate.

The Nominating Committee must provide a slate of candidates to act as Directors for CAREB, at least one month before the Annual General Meeting (AGM). Each candidate must agree to allow their name to stand for nomination. A brief description of each new candidate's qualifications is provided in the Annual General Meeting documentation.

During the Business Meeting there will be a call for nominations from the floor. If there are no further nominations a vote by the membership will confirm the proposed slate of Directors. If there are further nominations then a vote by ballot will take place. The CAREB Secretary and Past President will scrutinize the balloting and the winners will be declared by majority vote.

During the first meeting of the CAREB Board of Directors, post AGM, the Officers of the Board will be elected and each Board member's responsibilities will be determined.

The current membership of the Nominating Committee is:

- Ken Jenkins - Past President CAREB
- Susan Babcock - Secretary CAREB
- Alex Karabanow - former President of CAREB

A call for Board of Directors nominations will soon be broadcast to the CAREB membership. Nominations will close on March 15, 2015.

NOTE FROM THE CAREB PRESIDENT

Rachel Zand

2015 marks an important milestone for CAREB – its 15th anniversary. Well into its adolescence, this organization has already achieved great success and is in the middle of yet another growth spurt. As a member of CAREB since 2003 and on the Board of Directors since 2007, I have seen the trials and tribulations this once-fledgling association has gone through. I am proud of what has been achieved thus far and am excited by what is on the horizon. So, in honour of CAREB's crystal anniversary, I would like to reflect on the fifteen year history of this great organization, including some highlights, the role it has played in the Canadian research ethics landscape, and where it is going in the near future.

As legend has it, CAREB began as a small, impromptu get-together of Canadian REB chairs and administrators during a PRIM&R conference. From there, it has grown into a national organization of over 250 REB chairs, members and administrators with representation from every province in Canada.

In its first few years, it truly was a grassroots organization. Recognizing a need, CAREB first focused on assisting research ethics administrators to develop the skills needed to create and manage REBs efficiently and effectively. New managers and coordinators were encouraged to take the REB 101 workshop, which taught the basics of organizing an office (including how to file ethics protocols appropriately) and best ways to recruit new members. Conferences, which were always held in Toronto, included such sessions as “burrs in the

saddle” and how best to review course-based research projects. During those formative years, there was a collective understanding that the field was young and exciting, but with many challenges and aggravations that outsiders would not understand. CAREB members felt a kinship with each other, regardless of geography. The feelings of common purpose and common roadblocks were the glue that held its membership together.

By 2006, when I first joined the Professional Development Committee (PDC), CAREB was growing. Its first independent conference outside of Toronto was scheduled in Montreal, and a revamping of the REB 101, REB 201 and 301 workshops were planned. From that point on, the breadth of educational offerings increased exponentially, and current pre-conference workshops now offer up to 4 separate sessions on a variety of topics. While the REB 101 workshop, now called REB Basics, continues to be a CAREB staple, the advanced and specialized workshops allow our conference registrants to discuss cutting-edge issues with our colleagues and partners from across Canada and the U.S. Our annual national conference is practically bursting at the seams with presenters wanting to provide sessions on a multitude of topics that are relevant and important to our membership, from both biomedical and socio-behavioural backgrounds. Our poster sessions are always topical and provide a forum for new and emerging areas to be pursued. CAREB has been honoured to have many luminaries speak at our conferences on various topics of interest, with a partial list including bioethics (Eric Meslin, Jeremy Sugarman, Pearl O'Rourke), science journalism (Joe Schwarcz, Seth Mnookin) and policy (Susan Zimmerman, Ivor Pritchard, Greg Koski, Elyse Summers). In addition to the didactic content, we have continually endeavoured to bring creativity to our sessions: live dramatic theatre

(Sarah's Daughters), debate, musical theatre (you had to be there - Calgary, 2013), games, and royal wedding fascinators (you had to be there - Halifax, 2011). I anticipate this year's conference and pre-conference workshops will continue the tradition of delivering quality, informative and educational sessions.

In addition to its networking and educational purposes, CAREB has dedicated much of its activities to policy and advocacy work, and is formally recognized as a major player in the Canadian research ethics landscape. Our members have acted as experts in countless research ethics initiatives nationally, provincially and even internationally, whether as CAREB representatives or individuals. Such activities include working groups to develop the TCPS2, The Sponsors' Table Experts' Committee, creation of the Canadian Standard for Research Ethics Oversight of Biomedical Clinical Trials (CGSB), Strategy for Patient-Oriented Research (SPOR), PRIM&R committees and the global Alliance for Clinical Research Excellence and Safety (ACRES). CAREB's guidance on handling adverse event reporting has been taken up by many institutions, and Past Presidents (Raphael Saginur and Sharon Freitag) were invited to speak to the Senate Committee on Social Affairs, Science and Technology on the important role that REBs play in clinical trial oversight in Canada. Members are involved on most, if not all harmonization initiatives at the provincial and national levels. Whether CAREB attracts experts or creates them is difficult to determine, and that difficulty speaks to CAREB's immense impact on the Canadian research ethics landscape.

We have clearly accomplished a lot in 15 short years; however, we still have new roads to pave, particularly in the next two to three years. The

2015 CAREB National Conference is approaching, and it may be our most ambitious agenda yet. Based on your responses to the Needs Assessment Survey, the Membership and Communications Committee (MCC) is working full-tilt to develop both high and low-tech communication tools and membership programs to meet your needs and expectations. Similarly, the Professional Development Committee (PDC) is planning a series of webinars to meet the needs of CAREB members who want continuing education from the comfort of their desks. And finally, the REB Professional Certification Steering Committee is hard at work developing a certification program for REB professionals that will be accessible and recognized as the standard for excellence in the field.

I would like to thank all of the many committee and board members who have dedicated so much of their time and energy over the past 15 years to support and foster CAREB activities and programs. Without them, our organization would not be the success that it has become. I welcome all CAREB members to consider how they too can contribute to enabling us to meet our mission and vision. I look forward to seeing many of you in Vancouver to toast CAREB on its 15th anniversary. Until then, please enjoy this edition of the *Pre and Post*.

A special thank you to the volunteers who helped with this issue of CAREB Pre & Post:

- Editing: Sandra Reid
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BIOBANK CERTIFICATION CTRNET BIOBANK CERTIFICATION PROGRAM UPDATE

Sheila O'Donoghue, Project Manager -
Biobank Education and Certification

Research Ethics Boards (REBs) are increasingly requested to review applications for research studies using biospecimens. These reviews encompass the management and operational aspects of biobanks in order to ensure that study participants can trust that their donation to a study is used appropriately. The Canadian Tissue Repository Network (CTRNet) has developed a certification program to address national standards for the full spectrum of human research biobanking and to assist REBs in their operational review of biobanks. CTRNet's Certification program is applicable to all types of biobanks and specimen collections that are developed as part of research studies and is anchored in an education program that addresses operational, governance and quality aspects of biobanking. Uptake of the program in Canada and internationally has increased as the health research community (including REBs, research institute leaders and hospital administrators, and health research funders) recognizes the importance of quality biospecimens in research reproducibility.

There are two linked phases in CTRNet's Certification program. The first phase, known as *Registration*, involves one member of the biobank's staff completing a registration form and the online

introductory education module called "Basics of Biobanking". The second phase of the program, referred to as *Certification*, comprises completion of additional education modules customized to biobank type, and an assessment of biobank documentation to determine that the biobank has embraced best practice standards.

Participation in this program gives REBs assurance that the biobank has learnt about, and made commitments to adopt, technical and operational best practices, and allows researchers to improve the quality of their research.

AS OF DECEMBER 2014, SEVENTY-SEVEN BIOBANKS HAD OBTAINED REGISTRATION IN THE PROGRAM, TWENTY-THREE OF THESE BIOBANKS ARE NOW IN THE PROCESS OF CERTIFYING, AND EIGHTEEN HAVE SUCCESSFULLY COMPLETED CERTIFICATION.

The University of British Columbia is in the process of making enrollment into the registration phase of the program mandatory for all researchers using human biospecimens. The Fonds de Recherche du Québec - Santé has also mandated enrollment for all affiliated biobanks in Quebec. An update on the CTRNet biobank certification program will be presented at the CAREB 2015 annual meeting. For more information on our biobank certification program and other services and tools for researchers using biospecimens, visit <http://biobanking.org/brc> or contact us at info@biobanking.org.

PROGRESS AND PROMISE: STREAMLINING RESEARCH ETHICS REVIEW IN ONTARIO

Susan Marlin, President and CEO of Clinical Trials Ontario

Clinical Trials Ontario (CTO) is getting ready to launch the CTO Streamlined Research Ethics Review System in Ontario. This new approach will support any single 'CTO Qualified' Research Ethics Board (REB) in Ontario in providing high-quality and efficient ethical review and oversight for multiple research sites participating in the same clinical trial.

Six REBs are now fully qualified and a number of others are in the midst of the Qualification process (for a list of CTO Qualified REBs, see www.ctontario.ca).

WITHIN A YEAR, CTO EXPECTS TO HAVE QUALIFIED REBS SERVING MOST ACADEMIC HOSPITALS IN ONTARIO, AS WELL AS QUALIFIED REBS IN THE PRIVATE RESEARCH AND COMMUNITY HOSPITAL SECTORS.

CTO has implemented a REB Qualification Program, which evolved from the Toronto Academic Health Science Network (TAHSN) REB qualification manual, to review and qualify REBs

planning to participate in the CTO Streamlined System. With each on-site review visit, CTO learns more about the remarkable commitment and capabilities that exist to protect research participants in Ontario. CTO is grateful to members of the research ethics community who serve on the College of Reviewers, participating in site visits and contributing expertise.

Building the CTO Streamlined System has truly been a collaborative effort. Hospitals, universities, REBs, industry, government, private providers and others have played a part. The system will facilitate the timely review of both industry-sponsored and investigator-initiated multi-centre clinical trials and health research. It is expected to provide benefits to sponsors, investigators, institutions and REBs conducting multi-centre clinical research by harmonizing processes and reducing the time and effort required to initiate research across multiple sites in Ontario.

CTO Stream, a web-based electronic platform, will enable research ethics review, document management and communication between multiple institutions and REBs. CTO has created a full set of common REB application forms for requesting ethics review through **CTO Stream**.

Supporting and enhancing the clinical research environment is the focus of the CTO 2015 Clinical Trials Conference, being held on March 4-5, 2015. There is no fee to attend and seating is limited. To view the agenda and to register, please visit: www.ctoconference.ca.

RELEASE OF THE N2/CAREB REB SOPS

Karen Arts, Chair of the Board of Directors, N2

The CAREB and N2 organizations are pleased to announce the release of the first set of collaboratively developed, standardized, Canadian REB standard operating procedures (SOPs) via open access. The REB SOPs are specific to ethics boards that review health sciences research and are compliant with applicable Canadian and US regulatory, and ethics guidance criteria. The implementation of the REB SOPs will facilitate the distribution, adoption and maintenance of a single standard for REBs in Canada.

THE GOAL OF THE DEVELOPMENT OF THE CAREB/N2 REB SOPS WAS TO CREATE ONE SET OF WELL-WRITTEN SOPS. THE SOP DEVELOPMENT PROCESS WAS A RIGOROUS ONE INVOLVING REPRESENTATIVES FROM ACROSS THE COUNTRY AND FROM BOTH PARTICIPATING ORGANIZATIONS.

CAREB and N2 established a working group comprised of experienced research ethics board professionals. This group consulted original sets of REB SOPs to develop the set of documents, and final drafts of the SOPs were sent to a qualified reviewer to be audited for compliance with all applicable regulations and guidance. The recommendations of the reviewer were incorporated into the final version.

WITHIN THE HEALTH SCIENCES RESEARCH ENVIRONMENT, REGULATORY AUTHORITIES REQUIRE THAT ETHICS BOARDS THAT REVIEW HEALTH SCIENCES RESEARCH UTILIZE SOPS TO ENSURE THAT THE ETHICS BOARD IS CONSTITUTED APPROPRIATELY AND CONDUCTS ITS PROCESSES IN A WAY THAT PROTECTS THE RIGHTS AND SAFETY OF STUDY PARTICIPANTS, AND THAT MEETS ALL APPLICABLE REGULATORY AND GUIDANCE CRITERIA WHILE ENSURING ONGOING COMPLIANCE WITH ALL REQUIREMENTS.

The REB SOP Subcommittee has a formal process in place to manage comments, questions and/or concerns. Comments will be logged and then reviewed and a decision will be made to determine whether a change to a document is required.

Access to the REB SOP documents and associated information can be obtained from the following website:

<https://oicronca.box.com/s/95k7ydj574579ajvbe06>

UPDATE:

CTO IS FUNDING THE TRANSLATION OF THE N2/CAREB REB SOPS INTO FRENCH. WORK IS UNDERWAY AND ESTIMATED TO BE COMPLETE IN THE NEXT FEW WEEKS!

UPDATE: REVISION OF TCPS2

Laura-Lee Balkwill, Policy Analyst,
Secretariat on Responsible Conduct of
Research

The 2014 version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2014)* launched on the [Panel on Research Ethics website](#) in December last year. This update incorporates many of the comments the Panel received from CAREB members and from Canada's research community at large during the consultation period (September 2013 - January 2014). It replaces TCPS 2 (2010) as the official human research ethics policy of the three federal research agencies (CIHR, NSERC and SSHRC).

The Panel and the Secretariat on Responsible Conduct of Research reviewed nearly 70 sets of thoughtful comments. These [comments](#) are posted on the Panel website in keeping with its commitment to transparency in its public engagement process. The '[Highlights of Changes](#)' document describes some of the more substantive revisions to the Policy such as:

- increased emphasis on the participant's decision-making capacity;
- more detailed guidance about alterations to consent requirements; and
- the full integration of CIHR's Guidelines for Human Pluripotent Stem Cell Research.

The inclusion of these stem cell guidelines addressed the Agencies' goal of making TCPS 2

the single Agency policy for the ethics of research involving humans.

The ongoing dialogue between the Panel, the Secretariat, and the research community takes place through interpretations, consultations and education outreach activities. This exchange is crucial to the ongoing evolution of the Policy. At present, Panel sub-committees are exploring the need for guidance pertaining to population and public health research, clinical trials and material incidental findings. Secretariat staff are available to answer questions about the application of current guidance, and responses to questions posed frequently are posted on the interpretation page on the Panel website.

The TCPS 2 online tutorial (CORE) is being revised to correspond with the updated Policy. CORE will be launched as soon as possible this year. It will feature more interactive elements, accessibility for people with vision and hearing impairments, and a new module on Chapter 9: Research Involving First Nations, Inuit and Métis Peoples of Canada.

FOR UPDATES ON TCPS 2 AND THE
ACTIVITIES OF THE PANEL AND
SECRETARIAT, SEND AN E-MAIL TO
SECRETARIAT@RCR.ETHICS.GC.CA WITH
THE WORD "SUBSCRIPTION" IN THE
SUBJECT LINE.

UPDATE FROM CAREB COMMITTEES

CAREB Needs Assessment

We asked and you responded - CAREB Members, you have been heard!

Thank you to everyone who completed the CAREB Needs Assessment online survey which closed 19 December, 2014.

Representativeness of Responses:

The response rate was high with close to 80 responses (representing ~40% of total membership) providing rich data regarding our membership and communication services and upcoming professional development initiatives. Most respondents were CAREB members (94%) and the majority were research ethics administrators (66%). Feedback was distributed across the country with half originating from Ontario and 20% from each coast.

Key Findings:

We received many great ideas in terms of content for upcoming communications and webinar services which the Membership and Communications Committee (MCC) and Professional Development Committee (PDC) will be working through. Respondents confirmed that the CAREB National conference continues to be a valuable educational opportunity and acknowledged that the website, listserv and discussion forum are accessed regularly as a resource for research ethics information. Results indicated that there are some areas that we can improve upon. For example, we received lots of feedback regarding improving our media platforms

to be more accessible and user friendly, as well as requests for more frequent communications.

Next Step:

The CAREB Board and committees will be reviewing the feedback in detail to determine how we can best respond to opportunities you identified. Based on these responses, we will be prioritizing ongoing initiatives to meet the needs of our membership.

THANKS AGAIN FOR TAKING THE TIME TO PROVIDE FEEDBACK REGARDING YOUR MEMBERSHIP EXPERIENCE WITH CAREB AND PROVIDING SUGGESTIONS AND IDEAS FOR US TO WORK WITH MOVING FORWARD. IF YOU HAVE ANY QUESTIONS ABOUT YOUR CAREB MEMBERSHIP, OR ABOUT THE SURVEY, PLEASE CONTACT US AT MEMBERSERVICES@CAREB-ACCER.ORG.

Professional Development Committee

Professional Development Sub-Committee #1 has received five posters for the poster competition. The posters received to-date deal with an interesting and broad array of clinical and biomedical research issues. However the committee would still welcome additional submissions to offer insight and new ideas to our colleagues working in the social sciences and humanities disciplines! The closing date for

additional posters was February 15, 2015. Please contact Romaine Miller romainemiller@rogers.com if you would like to take advantage of this extension and make an abstract submission.

In addition to the poster competition, Professional Development Sub-committee #1 has also finalized the presenter line-up for the pre-conference workshop to be held on April 30, 2015. Again this year, a full day session entitled "REB Basics" will be offered. This is a perennial favourite and would be of particular value to our colleagues who are new REB members or administrators. In addition to this stream, two other advanced streams will be offered. The first advanced stream will deal with policy and procedural issues and the second advanced stream will deal with special issues. This workshop day promises to be hands-on and practical with concrete take-aways for attendees. Sample topics from both advanced streams include topics as wide ranging as "Research Contracts 101: A Primer for REB Administrators and Chairs", "Big Data and Privacy", "Coordinated and Harmonized Ethics Reviews- Three Approaches" and "Primary Research into Terrorism, Freedom Fighters and Radicalization".

Professional Development Sub-Committee #2 has developed a set of recommendations for four webinars to be developed in the near future. One series will deal with administrative and procedural issues and the other series will deal with ethical review issues. The members are in the process of finalizing a competency framework, learning objectives, assessment criteria and sample assessment questions for the webinars. The webinars are intended to offer introductory material which will be targeted to both REB back office administrators as well as REB members and Chairs. Together with subcommittee #3, the

committee has also developed a standard operating procedure which is being used to guide the recruitment and selection of facilitators, ongoing quality assurance activities and content development activities for any CAREB webinars to ensure the webinars meet members' expectations.

Professional Development Sub-committee #3 has been eagerly awaiting the finalization of the membership survey results in order to identify a series of webinars dealing with special topics in research ethics. Survey results are in and they will soon be finalizing their recommendations to the Board.

PDC Subcommittee #3 Call Out

Subcommittee 3 of the CAREB Professional Development Committee is actively seeking additional volunteer members with social science and/or humanities backgrounds to serve on the subcommittee. Subcommittee 3 is working on developing and implementing a webinar series on special/emerging topics in research ethics that appeal to the interests of the broader CAREB membership community. In an effort to ensure representative membership and a diverse perspective is incorporated into the work undertaken by this subcommittee, we are seeking additional members with social science and/or humanities backgrounds that have prior experience with designing and/or developing webinars and learning objectives.

INTERESTED MEMBERS SHOULD
CONTACT MAUREEN NUMMELIN AT:
MNUMMELIN@UWATERLOO.CA OR
(519) 888-4567 x 36005.



CAREB 2015 National Conference and AGM



Big Data, Small World

Friday, May 1st and Saturday, May 2nd
at the Fairmont Waterfront, Vancouver, British Columbia

Agenda Highlights (subject to change)

Keynotes:

- *When Science, Consumer Rights, and Human Subjects Collide: Now What?*
Mary L. Gray, PhD, Senior Researcher at Microsoft Research and Associate Professor of the Media School, with affiliations in American Studies, Anthropology, and Gender Studies at Indiana University.
- *The Dark Side of Research Ethics Boards*
Carl Elliott, MD, PhD, Professor, Center for Bioethics, University of Minnesota
- *Is Gwyneth Really Wrong (and Why It Matters)? Celebrities, Science and Our Health*
Timothy Caulfield LL.M., FRSC, FCAHS, Canada Research Chair in Health Law & Policy, Trudeau Fellow and Professor, Faculty of Law and School of Public Health, Research Director, Health Law Institute, University of Alberta

Plenary Session Topics:

- *Ethics and Ebola*
- *Human Microbiome Research*
- *Visual and Arts-based Methodologies*

Concurrent Breakout Sessions:

Friday, May 1st

- 1 Vulnerable Subjects: Ethical Issues in Research on Gender and Sexuality
- 2 TBA
- 3 The Responsible Conduct of Research: Norms and Challenges for Research Ethics Boards
- 4 Research Ethics Boards and Data Management Plans: Conflict and Coexistence
- 5 Clinical Trials in Canada

Saturday May 2nd

- 1 CTRNet: Biobank Certification Program
- 2 a) Promoting Respectful Research Practices through an Indigenous Lens
b) Applying Chapter 9: Research with First Nations, Inuit and Metis Peoples - Balancing Academic and Community Values.
- 3 How Research Ethics Boards "Know" (or Imagine They Know) How Research Will Impact Research Participants
- 4 Protecting Confidentiality: To the Limits of the Law and Beyond?
- 5 The Return of Genetic Findings from a Participant's Family Perspective
- 6 Privacy and Risk Assessment

Registration opens soon at <https://www.careb-accer.org/>

NATIONAL HEALTH ETHICS WEEK: MARCH 2-8, 2015

Exploring Ethics from Coast to Coast to Coast

In collaboration with the Nova Scotia Health Ethics Network (NSHEN), and participating organizations across Canada, the Canadian Bioethics Society (CBS) is coordinating the 2nd annual National Health Ethics Week, taking place March 2-8, 2015.

What is National Health Ethics Week?

National Health Ethics Week is a time set aside for health and educational institutions, ethics committees, health care professionals, community organizations, businesses and members of the general public, to host and take part in educational events that explore health ethics issues.

How Do I Participate?

All organizations, groups, and individuals who are interested in health ethics issues are invited to participate. By participating in National Health Ethics Week, you will show a commitment to ethical discussion and decision-making and will open lines of communication with others in your community. Involvement in Health Ethics Week is encouraged at a level relevant to and comfortable for you and your organization or group.

Registration

To participate please download and complete the registration form found on the CBS website: <http://www.bioethics.ca/ethicsweek> , or contact CBS at ethicsweek@bioethics.ca for more information.

ABOUT CAREB NEWSLETTER

CAREB Pre and Post is not a refereed journal and does not publish full length articles. The opinions expressed are those of the writers, and do not necessarily represent the views of CAREB. CAREB Pre and Post will be distributed via the CAREB listserv and can be read on the CAREB website: <https://www.careb-accer.org/> .

Contributions are welcome. If you have a suggestion for upcoming editions of the newsletter or if you would like to contribute an article, please email: post@careb-accer.org .

CAREB CONTACT INFORMATION

Questions? Contact us!

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