



CONFERENCE SUMMARY REPORT

Plus ça change?

CAREB/ACCER 2014 National Conference and
Annual General Meeting

Fairmont Queen Elizabeth, Montreal

April 23 - 26, 2014

INTRODUCTION

The title of this year's conference, *Plus ça change*, is ripe with meaning. Derived from the popular French expression, *plus ça change, plus c'est la même chose* or the more things change the more they stay the same, can have a pessimistic connotation; however, we presented it as a question. The more things change, the more they stay the same. Or do they? It was the Greek philosopher Heraclitus (535-475 BC) who said the only thing that is constant is change. Heraclitus also said: No man ever steps in the same river twice, for it's not the same river and he's not the same man. Over the course of the two day conference, respected international speakers revisited events of historical significance juxtaposed with current events with the overarching goal of examining lessons learned, changes advancing the ethical conduct of human participant research, and constant principles that should be carefully protected.

HIGHLIGHTS

Keynote Speakers

Joseph J. Fins, E. William Davis, Jr. M.D. Professor of Medical Ethics and Chief of the Division of Medical Ethics, Weill Cornell Medical College, New York, spoke about his work: A Critique of the Bucharest Early Intervention Project Romanian Orphan Study. Dr. Fins' presentation pointed out the dangers of looking at research isolated from social context and illustrated that an emphasis on regulatory compliance alone can cloud judgment on the moral and ethical implications of a research study – reminding researchers and REBs alike to ask not only can this be done but should this be done. Questioning the equipoise of the 1999 Orphan Study and the way in which it was contextualized in light of existing standards of treatment, Dr. Fins considered whether, under ancillary-care obligation, researchers have a duty to not utilize (and thereby perpetuate) a toxic environment in pursuit of data regardless of the sanctity of study design.

Jonathan Kimmelman, Associate Professor Biomedical Ethics, Department of Human Genetics, Experimental Medicine, McGill University, Quebec, addressed How to Think (Ethically) about Clinical Translation. In this keynote, Dr. Kimmelman examined some of the ethical, social, and policy challenges in moving from animal testing to testing novel medical technologies in human beings ("translational clinical research") The presentation focused specifically on risk, prediction, validity and knowledge value across the trajectory of drug development and alternative frameworks and understandings concerning the role and content of clinical research ethics.

Charles W. Lidz, Research Professor of Psychiatry, University of Massachusetts Medical School delivered a presentation entitled: Therapeutic Misconception: What Difference Does it Make? Therapeutic misconception (TM) is widely thought of as a major problem for consent to clinical trials. Research participants often fail to grasp the distinction between clinical research and ordinary treatment, despite researchers' attempts to inform. Dr. Lidz provided empirical

data suggesting that TM is a serious impediment to participants' ability to appreciate the issues involved in participating in clinical trials. Examples included participants' belief that treatment in a clinical trial would be individualized and participants' unreasonable assessment of the benefits of clinical trials (i.e. precluded by the design of the study). Dr Lidz presented a theory of the origins therapeutic misconception based on socially structured, cognitive frameworks – misconceptions arise when participants' personal frameworks conflict with researchers' scientific frameworks; suggestions for how this might be remedied; and a new validated measure that can be used as screen for TM.

Ian Mosby, Adjunct Professor, History Department, University of Guelph, Ontario delivered a keynote address on the Aboriginal Nutritional Health Study, Nutrition Research and Human Biomedical Experimentation in Aboriginal Communities and Residential Schools, 1942–1952. Dr. Mosby's academic work and accounts of these experiments has provided a narrative record of a largely unexamined episode of Aboriginal exploitation and neglect by the Canadian government while situating the studies within the context of broader federal policies governing the lives of Aboriginal peoples; a shifting Canadian consensus concerning the science of nutrition; and changing attitudes towards the ethics of biomedical experimentation on human beings.

Ted Palys, Professor in the School of Criminology, Simon Fraser University, British Columbia, in his presentation, Who do you Trust?: Protecting Research Confidentiality "Within the Extent Permitted by Ethical Principles and/or Law" addressed January, 2014 Quebec Superior Court decision, and surrounding principles that upheld researchers' rights to protect confidential information needed for their academic work. After his keynote talk, Dr. Palys was joined by two key members of the case who provided their personal perspectives, Researcher and Professor, Department of Criminology, University of Ottawa, Christine Bruckert; and Professor, Faculty of Education and Chair, Social Sciences and Humanities Research Ethics Board, University of Ottawa, Barbara Graves. Drs. Bruckert and Gaves also presented a session on the Ottawa University case at the CAREB Professional Development Workshop day that preceded the conference.

Concurrent breakout sessions

In addition to the keynote sessions, conference delegates were able to choose between 8 concurrent, theme-based, breakout sessions over the course of two days.

1. Chapter 9 in Practice

Aboriginal Research remains a strong topic with CAREB members as researchers, REBs and Research Ethics Administrative Professionals strive to respect Indigenous Peoples and understand and implement TCPS2 Chapter 9

- Session A - Aboriginal Health Research and the Academy: Navigating the Tensions from the TCPS2 to the REB to the Community
- Session B - Developing Codes of Practice for Indigenous Research

2. Brave New World

In keeping with our theme of change, these sessions focused on the struggle to stay abreast of the fast changing environments of privacy and technology

- Session A - Striking The Balance in this Brave New World of Mega Data
- Session B - Consent, governance, and privacy arising from use of internet and communication technologies within longitudinal cohort/population based observational studies.

3. Revisiting Foundations

Recognizing that it is important to know where you come from in order to see where you are going, two presentations revisited the foundational documents of our field to both assess change and be reminded of the guiding principles at the core of human participant research ethics that remain immutable

- Session A - The 50-year History of the Declaration of Helsinki: Changes and controversies of research ethics thinking (delivered in French).
- Session B - The 40th Anniversary of the (National Research Act and subsequent) Belmont Report .

4. Emerging Topics: Poster presentations

In order to further support and highlight scholarly activity in the field of human participant research ethics, a breakout option was reserved for poster presentations. This session, comprised of three independently submitted posters chosen because, when assembled, the theme of Pediatric Research emerged. The three poster titles were as follows:

- Session A - Who should communicate IFs to research participants? When? How? How parents' experiences and expectations can inform practices at the intersection of pediatric research and clinical care
- Session B - Parent perspectives on sharing non-biological data from longitudinal birth cohorts
- Session C - Understanding Parents' Willingness to Know Incidental Findings in the Context of Pediatric Genetic Research

5. Genetic Research and the Return of Research Results and Incidental Findings: Roundtable discussion

This session, presented in French, was back by popular demand after it was first delivered as a professional development pre-conference workshop in 2013.

6. Managing Conflicts of Interest in Research Ethics Review: Exploring Ethical Tools and Guidelines for Canadian Research Ethics Boards

Drawing attention to the importance of conducting research on research ethics – governance and practice – this session focused on the results of an empirical bioethics project to advance REBs' understanding and management of conflicts of interest in their ethics review of research projects

7. Meeting the Needs of REBs: Struggles and strategies

This practical session highlighted tools for institutional REBs including ways in which to promote REB membership and training, and an overview of REB administrative workflow models.

- Session A - Smart Marketing for Raising Research Ethics Awareness
- Session B - Results of the CORE Tutorial evaluation
- Session C - A Survey of REB Systems in Canada

8. Proposed Changes to TCPS2 and other PRE Initiatives

For this session, members of the Secretariat on Responsible Conduct of Research provided an update on the ongoing evolution of the TCPS2 and were on hand to answer questions about the interpretation and implementation of federal guidelines.

Organizational updates

In order to keep our members apprised of changes in the field, we reserve space for annual updates at our conferences. The following organizations provided brief reports this year:

- Association for the Accreditation of Human Research Protection Programs (AAHRPP)
- Canadian Clinical Trials Coordinating Centre
- Canadian Institutes of Health Research (CIHR)
- Quebec Ministry of Health and Social Services
- Office for Human Research Protections (OHRP)
- The Secretariat on Responsible Conduct of Research (SRCR)

SUMMARY

The CAREB National Conference and AGM has become Canada's primary research ethics event and we are grateful for the ongoing generous support and involvement of our colleagues the Secretariat on Responsible Conduct of Research (SRCR), the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC).

In recognition of the financial constraints that organizations face, this year we opened the conference up to non-CAREB members (membership fee was separate from the conference fee) and the final number in attendance was 315. As has become standard for CAREB, the 2014 conference was preceded by a day of professional development workshops, from introductory to advanced, for REB members and administrators. Over 125 attendees participated in these workshops. These sessions continue to be very well received and represent quality training for REB administrators and members.

We once again held a Poster Session which has become an effective means of integrating research, innovation and best practices in research ethics. Each year, the poster session continues to grow in the number of submissions and range of topics, providing an additional tool by which CAREB can facilitate networking and knowledge exchange among participants.

This year, for the first time, CAREB partnered with the Canadian Animal Ethics Coordinators (CAEC), hosting a one-day meeting (the day before the professional development workshops) for a group of 30 people. CAREB engaged **Jonathan Kimmelman**, Associate Professor Biomedical Ethics, Department of Human Genetics, Experimental Medicine, McGill University, to deliver a talk on clinical translation. The meeting was a success and plans are underway to see how we can further collaborate in the future. Collaboration on educational endeavors could be advantageous to both CAREB and CAEC given that there are a number of Research Ethics Administrators cross appointed (so to speak) and also responsible for Animal Care in their institution.

Comments from delegates:

"I loved the collaboration with the animal care coordinators. It was very beneficial for me to be able to get information on both topics at the same conference. I would love to see this continue and even expand going forward."

CAREB has been criticized in the past with underserving our members in social sciences and humanities as well as not offering enough sessions in French. The Conference Planning Committee (CPC) worked particularly hard this year to include sessions of primary relevance to the social sciences and humanities as well as to French-speaking researchers and REBs, in addition to sessions that were predominantly focused on issues in health research. Combined sessions were, as much as possible, designed to address issues relevant to all REBs and

we appear to have struck the right balance as there were no comments received this year in terms of lack of social science topics . The Secretariat's support contributed, of course, to simultaneous translation which benefitted both English and French speaking participants.

- Conference evaluations indicate that 88% of the respondents rated the conference as excellent.

Comments from delegates:

- *This was a very strong program this year. I don't go to the CAREB AGM every year but I was very impressed with this one.*
 - *I appreciate that this year the program was applicable to academics of research ethics as well as REB administrators.*
 - *The conference has improved tremendously compared to previous years.*
 - *My best conference of the year. Very interesting topics. Thanks!*
 - *Keynotes were wonderful.*
 - *The conference is getting stronger with each year.*
- Ninety-three percent of the respondents considered the program both relevant and stimulating.

Comments from delegates:

- *Stimulating and excellent discussion.*
- *We have been talking about this topic and this all just came together perfectly.*
- *Great for building relationships/collegiality.*
- *Excellent selection of topics accompanied by the appropriate experts.*
- *[The speaker's] expertise in raising awareness about an important issue was most appreciated.*
- *I appreciated that this year the program was applicable to academics of research ethics as well as REB administrators.*
- *Very timely.... thanks!*

We look forward to providing an equally strong program in Vancouver in May 2015.

APPENDIX A: EXPENDITURE REPORT

CAREB 2014 Conference and AGM
SRCR Grant Reporting

Revenue

SRCR	\$ 35,000.00
Total	<u>\$ 35,000.00</u>

Expenses

AV	\$ 19,723.39
Translation	\$ 10,227.31
Poster Boards	\$ 1,286.66
Speaker Honorariums	\$ 2,500.00
Speaker Travel	\$ 2,679.56
Total	\$ 36,416.92

Surplus(Deficit)*	<u><u>\$ (1,416.92)</u></u>
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* deficit funded through CAREB Conference Revenues