

# *Examining and Understanding the Need for Canadian Research Ethics Board (REB) Member Standardized Education: Governance Views from the Field*

**Heather Sampson, Susan Cox, Raphael Saginur & Michael Owen**

## **Introduction**

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), was rolled out in 1998. This unique Canadian research guidance document is updated regularly and posts the following instructions: “Notice: Effective 2003, the electronic version of the TCPS constitutes the official version of the policy document.”<sup>1</sup> This dynamic document was joined, in 2004, by the Panel for Research Ethics (PRE) Tutorial that includes the following statement: “The Tutorial for the TCPS helps to educate the research community about the TCPS. It also facilitates the use, interpretation and implementation of the TCPS.”<sup>2</sup> In our view, the Tutorial relates more to principles than the practice covered in the first five chapters of the TCPS. As of October 31<sup>st</sup> 2008, 35,399 individuals had completed the tutorial since its introduction.<sup>3</sup> These two living documents frame and inform the Research Ethics Board (REB) decision-making process. However, given that there is no formal governance or monitoring of Canadian REBs, one can hypothesize that variable standards of what constitutes human research ethics review may exist.<sup>4</sup> Since there is no accreditation or formal national oversight system,

it is not surprising that there is also no standardized or national REB member orientation or continuing education program.

This paper offers some background and examples of challenges to Canadian REB members’ baseline knowledge and education in an attempt to shed light on various learning needs. Recommendations made in another national socialized health care system that may contribute to governance in Canadian research ethics are then examined.

## **Ethics Review**

REB membership responsibility is evolving, and clinical research is a dynamic process that is becoming more elaborate. The protocol approval process and monitoring responsibilities take on greater complexity as, for example, we are faced with the advent of vaccine and stem cell research, gene transfer protocols, and social science research that investigates such matters as the need for and barriers to teen sex education. These protocols are examples of the complex human



research projects that are presented to REB members who may not have the necessary innate or experiential knowledge to review appropriately and/or may have inherent conflicts of interest. Although we may have learned some prudent behaviour from Jesse Gelsinger, who tragically died as a direct result of participating in a gene transfer study, nothing yet has transformed the guidelines to regulations. While Canadian research organizations have formal conflicts of interest guidelines and the TCPS provides guidance on conflicts of interest among REB members, Canadian REB members do not have clear instructions for dealing with perceived or real conflicts of interest in clinical research.<sup>5</sup>

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For REB members charged with decision-making aimed ultimately at safeguarding participants in clinical research, there are three main documents that drive the Canadian perspective of REB review in addition to the Declaration of Helsinki and International Committee on Harmonization (ICH) guidelines: the TCPS; the Therapeutic Products Directorate Guidelines (which utilize the ICH Guidelines, per Health Canada); and the Division 5 Regulations of the *Food and Drugs Act*. The only ones having any force of law are the Canadian *Food and Drugs Act* Regulations.<sup>6</sup> Within these guidelines, including Division 5, there are few guiding principles as to the criteria that REBs should follow in evaluating research protocols, other than broad ethical guidelines, and they are really aimed at the institution conducting the research versus the REB review process. This is somewhat confounding when sorting through REB responsibilities.

The TCPS and ICH guideline policies have commonalities<sup>7</sup> as well as areas of disparity, such as the appropriate use of placebos in the conduct of placebo-controlled trials.<sup>8</sup> The ICH guideline is more specific than the TCPS

with respect to the responsibilities and procedures to be undertaken by the REB; however, these are not ethical guidelines. A list of documents to be obtained for review, the requirement that the qualifications of the investigator be reviewed, the frequency of ongoing review, the needs of non-therapeutic participants, and elements to be included in the informed consent form are all specifically addressed in the ICH guidelines. Despite the clearer set of rules, the impact of the ICH guidelines in Canada is somewhat tempered; provincial or regional policies and laws may supersede them. In addition, the guidelines only apply to data generation that will ultimately be submitted for regulatory approval, leaving a wide area of clinical research exposed.

The tension between the TCPS and Health Canada ICH guideline regulations formed the backdrop of a debate in the *CMAJ* in 2002 sparked by a commentary entitled "Placebo Trials and Tribulations."<sup>9</sup> Some of those concerns set the stage for the joint sponsored Health Canada/CIHR Placebo Initiative report submitted to CIHR and Health Canada in July 2004 that has yet to be implemented.<sup>10</sup> The Fall 2004 CIHR Ethics Live Journal in fact references the report and recommendations.<sup>11</sup> The Fall 2006 CIHR Ethics Live Journal underscores the importance of the placebo issue, once again, and of ongoing ethical concerns about the use of placebos in clinical trials, but without any reference to the Placebo Initiative report: it appears that CIHR officials may have difficulty assimilating and understanding the challenges of the appropriate use of placebos in clinical trials with conflicting policies in place.<sup>12</sup> If senior CIHR research ethics officials continue to be confounded by the placebo conundrum, one wonders if Canadian REB members, mostly unpaid volunteers of various backgrounds, are adequately equipped to discern these, and other, policy differences. Are Canadian REB members able to make reasonable, informed situational-based decisions regarding the placebo or sham-based clinical research submitted for their review?

### **Conflict of Interests**

The strongly worded direction in the TCPS regarding avoiding conflict of interest between REB members, investigators and host institutions is somewhat vitiated, as there is presently in Canada no clear definition declared between research hosts and sponsors.<sup>13</sup> The potential for at least perceived conflict of interest on university REBs reviewing protocols funded by major academic donors



remains controversial; the lessons from Nancy Olivieri linger on.<sup>14</sup> Concerns have been raised about conflicts of interest within commercial research review boards from a legal (versus ethical) perspective, with no resultant resolution.<sup>15</sup> This problem is not peculiar to Canada; the relationship between medical school faculty members serving on U.S. institutional review boards and serving as pharmaceutical industry consultants is almost 50%.<sup>16</sup>

The fact that conflict of interest may be present at many levels again raises the issue: where there is no governance, there will be no consequences. Guidelines are just that, guidelines. The healthy volunteers and patient participants in clinical trials may not be adequately protected from either real or perceived conflicts of interest in the conduct of clinical research. It must also be noted that although the members of the REB may have presumably relinquished their own self-interest, they may be acting for the institution, the investigator(s) and the research subjects; presently there is no clear process for REB members to learn these distinctions. There is no clearly defined mutual understanding between the REB and the research subjects that the REB will act on their behalf. This topic is difficult to comprehend for many human research subjects who have great trust in the clinical research system but who are not aware that REB's exist, leading to limited if any understanding of REB roles and responsibilities.<sup>17</sup> These are examples of oversights that could be addressed in a national standardized orientation and education REB program.

## **REB Membership**

An REB that is reviewing research that is supported by any of the three funding councils or that is associated with a Tri-Council funded institution must include: two members with knowledge in the appropriate research field; a member with knowledge of ethics; a community member serviced by the institution; and – for biomedical research – at least one member who is knowledgeable in the relevant law. This last is advisable but not mandatory for other areas of research.<sup>18</sup> These unique members do not have access to any specialized or standardized orientation or education. The publicly funded REBs obtain their authority through the governance of the institution they serve, which in turn must ensure the boards have sufficient financial and administrative independence to fulfil their primary duties. It is the institutions, not the action of the Tri-Council, that must ensure that the REB membership has the authority to approve, reject,

propose modifications to or terminate any proposed or ongoing clinical research.<sup>19</sup> An enforceable element associated with TCPS noncompliance is a Memorandum of Understanding allowing the Agencies to withhold funding; this does not take the place of governance.

The REB membership structure, as outlined by Article 1.3 of the TCPS, is accepted and adhered to as a practical guideline by numerous Canadian REBs. (Health Canada utilizes the ICH–GCP Guidelines that do not refer to ethics or legal expertise in their stipulations, furthering the lack of clarity).<sup>20</sup> Despite this broad acknowledgement, the interpretation of this Article's stipulation which requires

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that REB membership reflect knowledge in ethics and the relevant law varies widely. No professional designation exists to define "ethics expertise," and the education and experience brought to the REB vary tremendously. For example, interpretations of the clause mandating knowledge in relevant law can range from the understandings of institution risk management staff, to those of REB community members practicing law that may not be health research oriented. The REB is charged with the dual responsibility of protecting both potential research subjects (from poor or unethical research) and the research institution (by ensuring that legal obligations have been met).<sup>21</sup> There is a need for standardization in education, a standardization that presently does not exist, to enable all members to review protocols and consents consistently.

In 2006, an interesting dialogue transpired on the National Council on Ethics in Human Research list serve between lawyers and legal representative REB members regarding the definition of exactly what ought to be REB legal members' roles and responsibilities. This led to the formation of the Research Ethics Board Legal Society, or



REB-LS. Pursuant to those discussions, the REB-LS PB-Wiki site was formed “for those dealing with legal issues while undertaking their REB responsibilities.”<sup>22</sup> The REB orientation and education to adequately support the REB-LS was not available; consequently, colleagues rely upon each other for support and answers. The REB-LS is an interesting example of a resourceful initiative in the absence of national materials or standards to guide REB members in their roles and responsibilities.

These illustrations support the view that standardized REB orientation and annual, on going education that is accessible to all publicly funded Canadian REBs ought to be mandatory at a minimum.

### **REB Education**

The UK National Health Service, a system that bears many similarities to our own health care system, has recently moved the highly organized National Research Ethics Service (NRES) into a very interesting partnership with the National Patient Safety Agency, an Agency that “leads and contributes to improved, safe patient care by informing, supporting and influencing the health sector.”<sup>23</sup> There are many resources, such as the research ethics manual developed by Sue Eckstein at King’s College, London, that could serve as an ideal model reference for Canadian REBs, if we were to adopt a national approach.<sup>24</sup> Keele University offers standardized research ethics courses with pre- and post-testing for the U.K. research ethics community; as research ethics accreditation and governance exist in the UK, there may be more assurance that this standardized orientation and on going training are reproducible and generalizable – important features in REB education.<sup>25</sup> NRES recently commissioned the University of Leicester to assess and analyze the decisions made by UK research ethics committees, based on their education and training, to enable continued program quality improvement; these results are presently being shared nationally.<sup>26</sup>

Canadian REB orientation and education that are dynamic, creative, interactive and responsive – and nationally driven and supported, preferably – is intuitive; further investigation and inquiry are required to develop such an initiative. It is fascinating that even as we demand, support and promote innovation, knowledge translation and knowledge mobilization as standards in medical science and healthcare delivery (frequently driven by national funding bodies such as the Tri-

Councils), the equivalent has fallen to the responsibility of volunteer organizations such as the Canadian Association of Research Ethics Boards (CAREB) or the National Council on Ethics in Human Research (NCEHR). For example, both organizations admirably but independently offer REB 101 courses, and NCEHR offers a REB 201 program; this is yet another confusing element of educational standards and opportunities for REB administrators and members. Currently, we have no national pre- and post-testing methods to apply to either of the REB 101 courses, we have no program evaluation methods, and we have no central repository

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to gather the attendance or certification, as again there is no central body to regulate or apply adult education standards to the material being presented. There are local initiatives driven by large academic institutions such as McMaster University (for biomedical and social science research ethics) and small community-based teaching hospitals such as the Toronto East General Hospital, but there is no national benchmark or national evaluation tool to measure the efficacy of these initiatives.<sup>27</sup> Canadian REB accreditation could be usefully initiated by evaluating such educational offerings and programmes. Cataloguing, assessing and analyzing present educational efforts, utilizing appropriate needs assessments, identifying barriers to accessing education and implementing program evaluation tools would contribute to consolidating Canadian efforts. Until there is a Canadian national research ethics governance and oversight system, one may suggest that we continue to work in silos searching for solutions. Technology affords us opportunities to deliver education in multiple ways, from small groups in person to web-based standardized



courses. However we deliver, we must affect expertise not only in knowledge but in ethical reasoning and functionality. Whatever we do must be evaluable, and the individual who undergoes educational interventions must also be evaluable if we are to contribute to national REB governance.

## Research in the Social Sciences

Another REB education area that demands investigation and support is in research being led in the social sciences. Community-based participatory research continues to grow; the time is right to replicate such participation in the REB environment.<sup>28</sup> Just as such research engages and includes participants in the research design, participants in it might be encouraged to educate and work with REB members, to expand on conventional understandings of the REB community or lay member, and even to educate so-called scientific members. Human research has evolved dramatically since the TCPS was introduced. Do the expectations for and pressures exerted on community members to represent the community the REB serves remain realistic or reasonable? Is this the time to invite research participants to the REB table to increase capacity and understanding for all stakeholders? Without nationally supported REB governance, this new area of inquiry may either go under recognized or inadequately supported.

Finally, paradoxically, we ask many of the people who wear their symbolic disease-specific coloured ribbons as badges of statement and courage to take risks in clinical research that frequently may result in no discernible benefit to them. For example, we invite them to take part in a clinical trial; the benefit clause in the consent is limited to: "If you agree to take part in this study, there may or may not be any direct benefit to you. We hope the information learned from this study will benefit other patients with (fill in the blank) cancer/illness in the future." The daunting possible risks cited in taking part in the trial can go on for pages, finishing with: "While on the study, you are at risk for these (listed) side effects. You should discuss these with your doctor. There also may be other side effects that we cannot predict." We ask patients to take on risks that may or may not be temporary, with no apparent benefits. If they are in a placebo-controlled study, there is rarely an opportunity for them to discover which arm of the study they participated in. Further, we do not routinely tell patient-participants the actual outcomes of the

studies that they sign up for. We do not recognize the committed partnership that we ask of these people in signing the consent to participate in a clinical trial, and then we wonder why trial enrolment is so low.

We face many ethical challenges; however, more importantly, as members of the scientific community, we bear major responsibilities: to explore further, to engage the community, and to commit to addressing the educational needs of REB members appropriately with a standardized, centralized and dynamic education package that incorporates suitable performance and utility indicators – an education package that is an integral part of Canadian REB accreditation and governance.

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## Endnotes

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- 2 Interagency Advisory Panel on Research Ethics, "About the Tutorial for the TCPS," online:



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  - 16 Eric G. Campbell *et al.*, "Characteristics of Medical School Faculty Members Serving on Institutional Review Boards: Results of a National Survey" (2003) 78 *Academic Medicine* 831; Trudo Lemmens & Alison Thompson, "Noninstitutional Commercial Review Boards in North America: A Critical Appraisal and Comparison with IRBs" (2001) 23:2 *IRB: Ethics & Human Research* 1.
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## UPCOMING EVENTS

### **Critical Issues in Health Law: A National Summit**

Vancouver, BC, May 21-22, 2009

Canadian Bar Association. Information: email [sheilam@cba.org](mailto:sheilam@cba.org)

### **5th International Conference on DNA Sampling: The Age of Personalized Genomics**

Rimrock Hotel, Banff, AB, September 16-18, 2009

Information and registration [www.genomealberta.ca/APG](http://www.genomealberta.ca/APG)

### **National Health Law Conference 2009: Grand Challenges in Health Law and Policy**

Montreal, QC October 2-3, 2009

For more information visit:

<http://www.health-conference-sante-droitsherbrooke2009.ca/>

### **European Association of Health Law Conference. Learning Lessons and Making Differences: Improving the Future of Health Law in Europe.**

Edinburgh, Scotland, October 15-16, 2009

For more information visit:

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