



February 9th, 2010

Dr. Morris Rosenberg
Deputy Minister, Health Canada

Dr. Alain Beaudet
President, Canadian Institutes of Health Research (CIHR)

Dr. Suzanne Fortier
President, Natural Sciences and Engineering Research Council (NSERC)

Dr. Chad Gaffield
President, Social Sciences and Humanities Research Council of Canada (SSHRC)

Dear Drs. Rosenberg, Beaudet, Fortier and Gaffield,

I am writing on behalf of the Board of Directors of the Canadian Association of Research Ethics Boards (CAREB) in relation to two concurrent pan-Canadian projects: one being undertaken by the Interagency Advisory Panel on Research Ethics (PRE) to revise the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) and the other by Health Canada and the Canadian General Standards Board (CGSB) to develop a National Standard of Canada for Research Ethics Boards Reviewing Biomedical Clinical Trials (CGSB Reference number C**/CGSB-191.1 - draft standard). I am writing to you at this time, because we believe that we are now at a critical juncture in the development processes associated with each of these concurrent projects which, to date, seem to have operated independently and with different accountabilities. For reasons outlined below, CAREB is asking that CIHR, SSHRC, NSERC and Health Canada work closely to continue development of the draft standard and to ensure that it is harmonized with the upcoming revision of the TCPS.

CAREB is a national organization of Research Ethics Board (REB) chairs, members, administrators and professionals who are dedicated to improving the effectiveness and efficiency of ethics review of research involving humans. CAREB is supportive of both of these important initiatives, and appreciates and welcomes the openness and transparency of both processes. However, we believe that the CGSB standards development process, which is conceptually limited to ethics review of clinical trials, will inevitably impact more broadly on social sciences research and on non-clinical trial projects.



As you may be aware, in 2007, Health Canada commissioned the CGSB to develop a National Standard of Canada for Research Ethics Boards Reviewing Biomedical Clinical Trials. The CGSB established a Standards Committee, comprising many different stakeholders charged with development of the draft standard. A version of the proposed final draft has been distributed to the CGSB committee members for approval, with voting terminating February 11th, 2010. CAREB is represented on the CGSB Standard Committee as a voting member. The Panel on Research Ethics is also represented, although without voting status.

In parallel, the Panel on Research Ethics has undertaken a much needed project to revise the TCPS and a revised second draft was made public on December 18th, 2009. The comment period expires on March 1st, 2010.

Our concerns are twofold. First, in our view, the current version of the draft CGSB standard is simply not yet “final” and not ready to be voted on for adoption. Much important work remains to be done. Second, the draft standard fails to harmonize with the emerging revision of the TCPS. Acceptance, as currently written, will further fragment the Canadian ethics regulatory review framework, at a time when our neighbors to the south are actively working to harmonize theirs. Canada’s REBs would then need to comply with even more divergent Canadian laws, guidelines and standards in addition to a variety of international laws, regulations and guidances that apply to biomedical clinical trials and, more generally, to other types of research. This is likely to exacerbate an already very challenging situation.

As such, CAREB will vote against the adoption of the current draft standard. We will provide our detailed comments to the CGSB and would be pleased to provide you with a copy if that would be helpful.

If the CGSB Standards Committee votes in favor of adopting the standard, we believe that Health Canada and the Tri-Council agencies should intervene to ensure that the substantive issues being raised by CAREB are reviewed and dealt with, in particular those relating to harmonization with the new version of the TCPS, before the draft standard goes any further in the adoption process. If the CGSB Standards Committee votes against adoption of the Standard, we ask that the process of developing it be continued.

CAREB recognizes that a substantial effort has been made by the CGSB, Health Canada, and the members of the CGSB’s Standards Committee to develop the current version of the draft standard and that very significant progress has been made. We believe that getting the CGSB draft standard “right” is of pivotal importance in ensuring and sustaining Canada’s position as an international biomedical research leader. We are convinced that a viable and robust national



standard, harmonized with the TCPS, is now achievable. CAREB stands prepared to contribute to this effort.

In our view, the next step in the development of this standard should be done by a relatively small group of persons who are expert and experienced in conducting and managing ethics review processes and offices, presumably drawn from the CGSB Standards Committee, but possibly including input from the PRE representative(s) and others. The outcomes of this work would be reviewed by all stakeholders prior to the next vote. This will help to ensure that the draft standard becomes a viable and valuable tool for use by REBs, and that is harmonized with both the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) and with the Canadian legislative framework.

CAREB believes that, building on the work done to date and with the application of focused expertise on the next steps of developing a standard, we now have a special opportunity to create a standard which harmonizes with the TCPS. This will strengthen Canada's national ethics review system, protect our research participants, promote Canada as country of choice for biomedical research and foster rapid access of Canadians to new medical treatments.

We hope we can count on your support to assure that this will indeed happen and, on a broader note, to ensure coordination of initiatives which relate to Canada's national framework for the governance of ethics review.

Sincerely,

Alex Karabanow
CAREB President (2009)
Research Integrity and Planning, Ryerson University

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