

Government of Canada

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Interagency Advisory Panel on Research Ethics Groupe consultatif interagences en éthique de la recherche

Ottawa, Canada K1A 1H5

December 2005

Dear Colleagues:

Re: A Season of Consultations: Engaging Your Voice in the Evolution of the TCPS

The Interagency Advisory Panel on Research Ethics (PRE) and Secretariat on Research Ethics are pleased to announce a call for comments on the first of three documents on which we seek community input for potential amendments to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS).

This letter reproduces key information from PRE's website about its Season of Consultations http://www.pre.ethics.gc.ca/english/consultations.cfm .

- *What:* PRE invites you to help shape the future of the TCPS by taking part in a Season of Consultations. The consultations feature analysis, proposals and questions from PRE's interdisciplinary Working Committees on three documents concerning potential changes to the TCPS.
- *When:* Though other PRE consultations will follow, the consultations on these documents run from late 2005 through the spring of 2006. PRE is sequencing input on the three documents to afford the community an opportunity to participate in each or all of the consultation periods. Target dates are noted below, including a consultation that has just opened.
- *Who:* This is an open public consultation. Research ethics boards members, universities and research institutions, administrators, researchers, research participants, ethicists, analysts, policy makers, TCPS users and other colleagues are all encouraged to participate.
- *How:* Each consultation includes:
 - \checkmark a call for the submission of written comments on
 - \checkmark a 30 page consultation document during
 - \checkmark a 60-90 day period for commentary, and
 - \checkmark instructions on how to forward comments.
- *Why:* The Canadian Institutes for Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, have created PRE to provide them with independent and interdisciplinary advice on the evolution of the TCPS. PRE and the TCPS need the diverse expertise, experience, views, and voices of the TCPS user community. PRE committed itself early in its existence to a set of First Principles—implemented by public process mechanisms—to develop its advice based on inclusive, interactive, multidisciplinary, consultative and transparent process.



Engaging voices of a diverse community will not always ensure consensus on leading challenges to the TCPS. Democracy makes no such guarantees. Still, PRE is convinced that such engagement affords TCPS users an important opportunity to contribute—by analysis, debate and written commentary—to issues and answers for strengthening the TCPS.

Consultation Documents and Periods: Current and Forthcoming

PRE has asked its Working Committees to explore leading TCPS issues through community consultations, as part of the process of developing and refining recommendations for PRE's advice to the Agencies.

Refining the Proportionate Approach to Research Ethics Review in the TCPS: Calling for comments, from 22 December 2005 – 6 March 2006, on a discussion document for shaping working recommendations for potential changes related to definitional and procedural issues in the TCPS. Conducted by PRE's Working Committee on Procedural Issues for the TCPS (ProGroup). http://www.pre.ethics.gc.ca/english/workgroups/progroup/Consultation_instructions.cfm

Privacy and Confidentiality in TCPS Social Sciences and Humanities Research: Beginning in the winter of 2006, a 60-day consultation to seek community input on a consultation document that will shape working recommendations for potential changes to the TCPS. Conducted by PRE's Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC).

The Duty to Share Information in Clinical Trials: Working Recommendations for the TCPS: Beginning in the winter of 2006, a 90-day consultation on draft recommendations for textual changes to the TCPS. Conducted by PRE's Clinical Trial Information Working Committee (CTI).

Contact: For questions on the consultation process or to order copies of a consultation document, please contact PRE's supporting Secretariat on Research Ethics: <u>secretariat@pre.ethics.gc.ca</u>; 613.996.0072; visit PRE on the web at <u>www.pre.ethics.gc.ca</u>.

To subscribe to information on consultations, publications, TCPS amendments, etc., visit our updated <u>subscription</u> page, and ensure that we have your name and contact information.

We thank you in advance for considering this opportunity to comment, and look forward to receiving your feedback over the next months. In the meantime, we wish you the best for the upcoming season.

Cordially,

Bruce P. Clayman

Bruce P. Clayman Chair Interagency Advisory Panel on Research Ethics

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Derek J. Jones Executive Director Interagency Secretariat on Research Ethics