

**Management Response to
the Conclusions of the Summative Evaluation of
the Interagency Advisory Panel and Secretariat on Research Ethics**

In 2008, the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), collectively referred to as the “Agencies”, commissioned a summative evaluation of the Interagency Advisory Panel on Research Ethics (PRE) and the Secretariat on Research Ethics (SRE). The evaluation was to examine and assess:

- Success of PRE-SRE in achieving its mandate to promote high ethical standards of conduct in research involving humans through the evolution, interpretation, implementation of, and education about, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)
- Success of PRE-SRE in achieving Agency objectives
- Roles of PRE-SRE in the current and evolving environment of human subjects research ethics policies, services, and governance
- Ongoing relevance of PRE-SRE, and
- Effectiveness of the functions of SRE that support the Agencies.

The Presidents of the three Agencies and the Interagency Management Committee for the Secretariat on Research Ethics (IMC) have considered the evaluation report. The report has acknowledged limitations: it is primarily descriptive, the response rate for interviews was lower than expected, and the timing preceded the December 2008 launch of the draft 2nd edition of the TCPS – a major undertaking of PRE-SRE. Furthermore, the evaluation was conducted at a time of uncertainty concerning the direction of research ethics governance in Canada. Despite these limitations, the report contained much valuable information from a broad range of stakeholders. Its findings were also useful in informing the Agencies’ decision on the renewal of the PRE-SRE term.

The Agencies note that there has been a strategic shift in the Panel and Secretariat’s work plan and activities. The Panel and Secretariat have proactively addressed many issues identified in the evaluation report. These actions have resulted in notable progress and significant improvements in the evolution and interpretation of the TCPS.

In light of these significant changes, the Presidents of the Agencies have decided to extend the term of the Panel and Secretariat on Research Ethics to November 2011. The following highlights some of the key conclusions of the report and decisions/actions taken in response.

Conclusion	Management Response	Decision/Action
1. PRE-SRE Mandate : Mitigated support for PRE-SRE as a structure, but strong support for the relevance of its mandates: evolution, interpretation, and education; less so for governance.	Maintain the current mandate of PRE-SRE.	The Agencies recently announced the renewal of the term of mandate of PRE-SRE up to 2011.
2. Evolution: Evolution of the TCPS generated highest expectations in the research ethics community, but progress	Support PRE-SRE’s re-focus in timelines and strategy to complete its revisions to the TCPS 2 nd edition.	The Panel released the draft TCPS 2 nd edition on December 3, 2008 for public consultation, with a work plan to submit a final version in

has been slow.		winter 2010 for the Agencies' consideration and decision.
3. Interpretation: While useful for the requesters themselves, interpretation responses could be more timely, broader in applicability, raising awareness of its existence and clarifying its link to TCPS evolution.	PRE-SRE to respond in a timely fashion to interpretation requests and to make its interpretative services more known to the community, and more broadly applied.	PRE-SRE has streamlined its response process to shorten the response period, and have incorporated many of the current interpretations in the draft TCPS 2 nd edition. In the interim, Q&As for common questions are posted on the website for the TCPS 1 st edition.
4. Education: The on-line tutorial appears to be meeting needs at several levels as well as producing positive impacts. The role of PRE-SRE vis-à-vis other players in ethics education remains unclear.	PRE-SRE to take a more active role in education on the TCPS, collaborating with other players in ethics education.	One of PRE/SRE's next strategic priorities is to coordinate and facilitate, in collaboration with other players, a national education strategy on the TCPS following the release of the TCPS 2 nd edition in 2010.
5. Governance: PRE-SRE's consistent and thoughtful contributions to the governance dialogue have not always been afforded legitimacy within the conversations. This is partly attributed to concerns about possible conflict of interest due to nature of PRE-SRE relationship with the Agencies.	The Agencies to clarify the role of PRE-SRE in contributing to the governance dialogue. The Agencies to manage the issue of possible conflict of interest.	Over 2009, the Agencies continue their participation in the Sponsors' Table, and will consult the Panel and Secretariat to advance viable alternatives for an effective model for the governance of research ethics in Canada.
6. Awareness: The TCPS appears to be well-entrenched in Canadian research communities, but there is a relatively low level of awareness of PRE-SRE's role and mandate and its activities.	PRE-SRE to put more effort into targeted communication and outreach on the TCPS and the role of PRE-SRE and its mandate. The Agencies to support PRE-SRE's communication efforts with their own communities, and use tools such as linking to, and making more prominent, the work of PRE-SRE on their websites.	The public consultation on the draft 2 nd edition of the TCPS has been effective in raising awareness of the PRE-SRE's role in TCPS stewardship. Future consultation and implementation activities will continue to serve as opportunities to raise awareness of PRE-SRE's activities and mandate. PRE-SRE have developed and are currently implementing a new communication strategy including the launch of a "compass" e-newsletter and a new website in Feb, 2009.
7. Support for Agencies: SRE's role in enhancing the Agencies' capacity to ensure that the research they fund is carried out	The Agencies to continue to support the positive work of SRE in the review of institutional policies.	SRE continues to review the ethics policies of institutions for adherence to the TCPS, and to develop plans for review following

with the highest ethical standards has generally been positive.		the release of the TCPS 2 nd edition.
8. PRE-SRE contributes indirectly through the TCPS for the balance of risks and benefits. The TCPS is an important tool for protecting participants but the way it is applied constrains some types of research.	Put focus in the TCPS on the proportionate approach to research ethics review.	The TCPS draft 2 nd edition clearly emphasizes the proportionate approach to research ethics review.