Summative Evaluation of the Interagency Advisory Panel and Secretariat on Research Ethics (PRE-SRE)

Submitted to:

Susan Morris
Chief, Evaluation
NSERC
(613) 995-1818

Submitted by :

Natalie Kishchuk Research and Evaluation Inc.
26 Oriole Drive
Kirkland (Québec) H9H 3X3
(514) 694-8995
nkishchuk@sympatico.ca

and

Benoît Gauthier
Circum Network inc.
74, rue du Val-Perché
Gatineau (Québec) J8Z 2A6
(819) 770-2423
gauthier@circum.com

V4 : February 16, 2009

TABLE OF CONTENTS

Executive summary 5

1. CONTEXT 11
   1.1 Background to the PRE-SRE and the summative evaluation 11
   1.2 Program description 12
   1.3 Evaluation aims and overall approach 18

2. EVALUATION STRATEGY 20
   2.1 Evaluation questions 20
   2.2 Indicators, data sources and respondent characteristics 24
   2.3 Methodological assessment 36
   2.4 Ethics approval and practices 36

3. FINDINGS 38
   3.1 Reach and support to the research community 38
   3.2 Impacts of PRE-SRE on evolution of the TCPS 40
   3.3 Impacts of PRE-SRE on interpretation of the TPS 52
   3.4 Impacts of PRE-SRE on education of the research community 60
   3.5 Contribution to increased assurance that research participants are adequately protected 66
   3.6 Success of PRE-SRE in meeting Agency objectives and expectations 71
   3.7 Effectiveness of SRE activities in support of the Agencies 73
   3.8 PRE-SRE in the broader ethics environment 77
   3.9 Ongoing relevance of PRE-SRE 83

4. CONCLUSIONS 88
   4.1 Limitations on interpretation 88
   4.2 Ongoing relevance of PRE-SRE and alternatives 88
   4.3 Reach and support to the research community 89
   4.4 PRE-SRE mandate elements 89
   4.5 Achievement of Agency objectives 91
   4.4 Overall conclusion 91

Appendix 1: Logic Models

LIST OF ACRONYMS

CAREB	Canadian Association of Research Ethics Boards
CIHR	Canadian Institutes of Health Research
IABED	Institute Advisory Board Ethics Designate
IAPH	Institute of Aboriginal Peoples' Health
IMC	Interagency Management Committee
NSERC	Natural Sciences and Engineering Research Council of Canada
NCEHR	National Council on Ethics in Human Research
PRE	Interagency Advisory Panel on Research Ethics
PRE-SRE	Panel and Secretariat on Research Ethics
PRE-TACAR	PRE Technical Advisory Committee on Aboriginal Research
REB	Research Ethics Board
RMAF	Results-based Management and Accountability Framework
SSHRC	Social Sciences and Humanities Research Council of Canada
SSHWC	Social Sciences and Humanities Working Committee
SRE	Secretariat on Research Ethics
TCAG	Tri-Council Advisory Group
TCPS	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
TIFF	TCPS Implementation Framework

LIST OF TABLES AND FIGURES

Table 1: PRE-SRE Allocations and Expenditures 2002-2003 to 2007-2008
Table 2: PRE and SRE Allocations and expenditures, 2002-2003 to 2007-2008, by mandate area
Table 3: Types of PRE-SRE Expenditures
Table 4: Evaluation questions
Table 5: Links of evaluation questions to PRE-SRE risk areas
Table 6: Survey of Panel and Committee members - Potential and actual respondents by group
Table 7: Web survey of Canadian REB chairs – Proportion of responses by source
Table 8: Prospective survey of tutorial users - respondent characteristics
Table 9: Response rates, researcher survey
Table 10: Respondent characteristics, researcher survey
Table 11: Data sources addressing each evaluation question
Table 12: Presentations to research communities
Table 13: REB chairs and research officers and researchers - Awareness of the TCPS and of PRE-SRE roles and responsibilities
Table 14: Researchers' views of need for more outreach
Table 15: Panel and Committee members, REB chairs and research officer - Effectiveness of the TCPS evolution mandate
Table 16: Evolution activity areas
Table 17: Response to public and targeted consultations about TCPS evolution
Table 18: Discussion document outputs available on PRE-SRE website
Table 19: Number of ongoing and pending PRE projects and Agency projects, 2005-2007
Table 20: Response to TCPS interpretation questions
Table 21: Interpretation requesters - Satisfaction with the interpretation service
Table 22: Interpretation requesters - Usefulness and impacts of TCPS interpretations
Table 23: REB chairs and university research officers - Usefulness and impacts of TCPS interpretations
Table 24: Usefulness of published interpretations according to survey respondents
Table 25: Website usage of TCPS interpretations – main page viewings
Table 26: TCPS On-line Tutorial usage
Table 27: REB chairs and university research officers: Success in the TCPS education mandate
Table 28: Tutorial compared to users' expectations
Table 29: Self-reported increase in TCPS knowledge
Table 30: Tutorial users' survey: ratings of tutorial impact
Table 31: REB chairs and research officers - Impacts of PRE-SRE on ensuring ethical practices
Table 32: REB chairs and university research officers and researchers views on contributions to balancing risks and benefits
Table 33: How the TCPS constrains research – main themes, researcher survey
Table 34: Panel and Committee members' views of effectiveness of Agency support to PRE-SRE
Table 35: Institutional research ethics policies reviewed and adherence to the TCPS
Table 36: REB and university research officers' views of SRE's roles in reviewing policies
Table 37: REB and university research officers – understanding of SRE's relationship to Agencies
Table 38: Response to calls for nominations to PRE
Table 39: Contrasting positions on institutional conflict of interest
Table 40: REB chairs and university research officers, Panel and Committee members - Ongoing relevance of PRE-SRE

Table 41: REB chairs and university research officers, Panel and Committee members - relevance of PRE-SRE mandates
Table 42: REB chairs and university research officers, Panel and Committee members - Alternatives to PRE-SRE

Figure 1: PRE allocations to mandate areas, 2002-03 to 2007-08
Figure 2: PRE expenditures on mandate areas, 2002-03 to 2007-08

EXECUTIVE SUMMARY

EVALUATION CONTEXT

The Interagency Advisory Panel on Research Ethics (PRE) and the Secretariat on Research Ethics (SRE) were created in November 2001 by the three federal research Agencies: the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC). Their creation followed the publication of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* in 1998, and reflected the Agencies' commitment to making the TCPS a "living" or evolving document in order to respond to new research developments and identified gaps in the Policy as well as to promoting research conducted with the highest ethical standards.

PRE-SRE were conceived as an interim measure for the period 2001-2006, with a review of their function and continued relevance to be conducted within five years. A mid-term evaluation was replaced by a Special Study on Roles and Responsibilities, conducted in 2004. In 2005, the term of mandate of PRE-SRE was extended by three years to November 30, 2009 and the summative evaluation rescheduled to the current fiscal year. This document presents the results of that evaluation. The evaluation addressed the following issues, developed through a consultative process in the framework phase:

- Success of the PRE-SRE in achieving its mandate to promote high ethical standards of conduct in research involving humans through the evolution, interpretation, and implementation of, and education about, the TCPS
- Success of the PRE-SRE in achieving Agency objectives
- Roles of the PRE-SRE in the current and evolving environment of human subjects research ethics policies, services, and governance
- Ongoing relevance of the PRE-SRE, and
- Effectiveness of the functions of the SRE that support the Agencies.

The major clients for the evaluation are the Presidents of the three Agencies and the Interagency Management Committee. NSERC has managed the evaluation on behalf of the Interagency Evaluation Steering Committee. An expanded Working Group has overseen the evaluation, composed of representatives from the ethics functions of SSHRC and CIHR, the evaluation function of all three Agencies, the SRE's executive director and a senior policy analyst, and the PRE chair.

This evaluation was conducted at a critical moment in the history of PRE-SRE: on the cusp of the public release of a second edition of the TCPS, 10 years after the first. The evaluation data were collected before external stakeholders and research communities had seen the new draft TCPS, which is expected in late fall 2008. The evaluation was also conducted at a time when options for the broader-based organization of research ethics governance in Canada were being considered. Views of PRE-SRE, its effectiveness, and its role may evolve quickly by the time this report is finalized.

EVALUATION STRATEGY

The evaluation design included qualitative and quantitative lines of evidence about each evaluation question, including:

- Review of PRE-SRE output production: program documents, website usage statistics, and other monitoring sources, activity logs, and financial data
- Surveys of internal and external stakeholders:
    - Qualitative/quantitative survey of current and former PRE, Standing Committee and Working Committee members (n = 25, response rate 43%)
    - Web survey of chairs of Research Ethics Boards and research offices of Agency-funded institutions (n = 103, response rates 43% and 19% respectively)
    - Prospective survey of TCPS tutorial users (n = 55, response rate 24%)
    - Retrospective web survey of interpretation service users (n = 23, response rate 29%)
    - Key informant interviews with high-level stakeholders (n= 24, response rate 63%)
    - Web survey of researchers who work involves human participants (n = 709, response rate 24%).

Qualitative and quantitative analyses of the evaluation data integrated findings from all the data sources, using the evaluation framework to structure the organization of responses to evaluation questions.

Being essentially descriptive, this evaluation does not benefit from comparisons to external objective benchmarks that could be used to assess performance. PRE-SRE performance was mainly judged by comparing results to stakeholder expectations. The research ethics community in Canada is small, and has been frequently solicited by PRE-SRE and other players in the last year; lower than expected response rates to the evaluation surveys may reflect respondent fatigue. As well, it must be said that given the current uncertainty in the environment, some potential respondents may have considered that the PRE-SRE evaluation is moot – the organization's fate will rest on the results of the Sponsors' Table's activities. The low response rates should be kept in mind in the overall interpretation of the significance of the findings.

That being said, this evaluation benefits from the input of a substantial number of individuals belonging to a vast array of interest groups vis-à-vis the issues of ethics in research: PRE, Standing Committee and Working Committee members; institutional research officers; chairs of REBs; tutorial users; interpretation requesters; researchers; CIHR, SSHRC and NSERC staff; former and current senior SRE staff; disciplinary and student associations; university representatives; REB administrators in the public and private sectors; representatives from federal and provincial government departments, and other organizations involved in research ethics. All in all, more than 1,100 individuals contributed to a better understanding of PRE-SRE performance. So, despite the lower than expected response rates, the broad variety of opinions expressed suggests that the evaluation results have captured the range of views in the community, although their exact distribution is less certain.

FINDINGS AND CONCLUSIONS

Overall relevance of PRE-SRE

Overall, above a generally low level of awareness, there is mitigated support for PRE-SRE as a structure, but strong support for the relevance of its mandates. It appears that the three Agencies remain committed to PRE-SRE as a stewardship structure for the TCPS, but there are also clear differences among and within the three Agencies and across their respective research communities in views about how TCPS stewardship should be positioned vis-à-vis the Agencies. In terms of alternatives, the evaluation found no consensus about the relative merit of the alternative structures proposed by the Experts' Committee and by the PRE. There are signs that the Agencies' position on PRE-SRE's as a structure could evolve in the medium term: two of the Agencies stated that PRE-SRE should eventually be separated from the Agencies and its function vested in a separate, national and nongovernmental organization. It now appears that in some ways the positions in some sectors of the biomedical and social sciences communities that were present in debates surrounding the relationship of PRE-SRE to the Agencies have merely been transferred to the Sponsors' Table. The overall relevance of the existing PRE-SRE thus remains an open question in the ethics community, both in the short and longer term. The evaluation data give us little reason to be optimistic about an easy resolution.

Reach and support to the research community

The TCPS appears to be becoming well-entrenched in Canadian research communities: almost all researchers whose work involves human participants have heard of it, and REB chairs and university research officers know their and the Agencies' roles and responsibilities with respect to it. This suggests that the Agencies' overarching aim of ensuring that its harmonized policy statement would become an integral part of the research landscape has been met.

The role of PRE-SRE within this landscape is not as easy for these stakeholders groups to discern, and their level of awareness is correspondingly lower. While it may not be a concern that only one-third of researchers have heard of the TCPS stewardship structure, it is of interest that only two-thirds of REB chairs and research officers are aware of PRE-SRE mandate, and only half are aware of its activities. This is somewhat surprising given the relatively large investment made by PRE-SRE in communications and partnering. This may point to the need for more effective communication efforts in these communities, for which the release of the second edition of the TCPS may afford excellent opportunity. There is support among the researchers surveyed for a more proactive role for PRE-SRE, in communicating about the TCPS and its activities.

PRE-SRE mandate elements

This evaluation provides evidence about the relevance of PRE's mandate elements of evolution, interpretation, education and contribution to the governance dialogue. According to the evaluation findings, the need for the first three is certain, although how they should be organized is less clear. In the sections below, the findings for each mandate element are summarized.

Evolution of the TCPS. The mandate accorded to PRE-SRE to evolve the TCPS and more specifically, to correct what were perceived by many to be serious flaws in the first version, was its most central and generated highest expectations in the research ethics community. At time of writing, PRE-SRE is within months of launching a very extensive revision of the TCPS, with substantial changes in 20 topic areas based on extensive community consultation and debate, including a new chapter on ethics of research with Aboriginal peoples, and another one on qualitative research. This launch is, however, occurring years later than expected. The evaluation data suggest that a combination of overambitious planning, ineffective leadership and/or capacity to adjust leadership styles as the projects' needs and timelines changed, and inefficient volunteer work processes all conspired to check TCPS evolution. Alternative and more effective ways of working and of organizing the work could be, and may have since been, identified.

Slow progress in TCPS evolution has in some areas created a vacuum of ethics guidance. PRE-SRE's approach to the evolution work, while successful in increasing acceptance of the TCPS in the social sciences and humanities community, has also resulted in alienation of at least part of the biomedical community, and caused CIHR to question the return on its investment. That a vacuum in the Aboriginal research area was partly filled by CIHR added to the perception of PRE ineffectiveness. However, possibilities for complementarity with CIHR's guidelines are now becoming apparent, as the new Aboriginal chapter of the revised TCPS builds extensively on the CIHR work, but with the advantage of having achieved national political buy-in.

These difficulties notwithstanding, the entire field is looking forward to the second edition of the TCPS. Future evolution work can profit from the lessons learned in this first decade, starting with realistic and achievable targets given the amount and type of resources available.

Interpretation of the TCPS. The various sources of data on the interpretation mandate provide an overall picture of a service that has struggled to become adequately organized, but is now showing signs of improvement. There has been dissatisfaction among interpretation requesters with the timeliness of the services; however, there has been a substantial reduction in response times to interpretation requests over 2008. There has also been a perceived lack of clarity and applicability of some responses which may point to a larger issue: while the aim of the interpretation function is to help orient TCPS evolution through interpretation of broadly applicable policy elements, the service provision is geared toward helping users with specific context- and time-bound decisions.

Overall, the level of utilization of the published interpretations is moderate, and a substantial minority of respondents in the key user group of REB chairs and research officers were not aware of the interpretation function. The download rate of published interpretations seems low when the size of the overall population of REBs (let alone the population of researchers) is considered. At the same time, many users and observers of the interpretation function are satisfied and have found the interpretations useful. The mechanisms linking TCPS evolution and interpretation may require clarification.

Education of the research community. PRE-SRE's approach to its education mandate got off to a contentious start (particularly in relation to initial plans for visits to institutions and the possible handling of

alleged breaches of ethical conduct[1]), but developed more smoothly once the proposed plan to conduct consultative visits was dropped. Although it was slower than expected in producing its main output, the TCPS on-line tutorial, despite some limitations in depth and coverage, is clearly successful in reaching the research community. Its national accessibility could, however, be examined by the Agencies more closely, in relation to institutional policies about mandatory completion. The prospective survey also provided some evidence that the tutorial is being applied in research decision-making in ways that improve ethics practices. This on-line tool thus appears to be meeting needs at several levels as well as producing positive impact. The role of PRE-SRE vis-à-vis other players in ethics education, most notably NCEHR but also universities and professional bodies, remains unclear.

Contribution to the governance dialogue. PRE-SRE has consistently and thoughtfully attempted to contribute to the governance dialogue, but has not always been afforded legitimacy within the conversations. Some of the reluctance to admit it to the debate arises from concerns about possible conflict of interest related to the nature of its relationship with the Agencies. CIHR appeared to hold this position, in contrast to the other two Agencies, in 2002. Although perceived structural conflict of interest was identified as a risk to PRE-SRE in 2003, the evaluation data do not suggest that its response has resolved the issue. In any case, PRE-SRE's response is not widely known, even among stakeholders closely involved with PRE's work.

Support in the achievement of Agency objectives

Agencies' capacity to ensure that research is carried out with highest ethical standards. PRE-SRE's role in enhancing the Agencies' capacity to ensure that the research they fund is carried out with the highest ethical standards has generally been positive, although more positive for NSERC and SSHRC and less so for CIHR. However, the recent changes within PRE-SRE have been associated with greater coordination with CIHR. Support provided by SRE to the Agencies in policy adherence review seems to be of greater salience and value to the Agencies than it is to the institutions. Tangible Agency support to PRE-SRE, in the form of financial and human resources, were likely adequate, but they were not used by PRE-SRE as effectively nor as completely as possible. Intangible support from the Agencies to PRE-SRE may not have been optimal.

Balancing risks and benefits to participants. A strong majority of both researchers and those involved in applying the TCPS in institutions agree that the ethics review process is effective in protecting research participants. Researchers are less likely to maintain that ethics review processes using the TCPS are ensuring a balance of risks and benefits for research participants. PRE-SRE's role in balancing risks and benefit is, not surprisingly, less clear. There are equally prevalent views among researchers that the TCPS is an important tool for protecting participants but that the way it is applied constrains some types of research. PRE-SRE's role in contributing to increased assurance that research participants are adequately protected and risks are balanced against the benefits of research is indirect and supportive, as direct responsibility rests with institutions and researchers.

---

[1] This was originally addressed by PRE/SRE as part of their implementation mandate. Note that, following the prioritization of questions during the development of the evaluation framework, the assessment of PRE-SRE's work on its implementation mandate was excluded from this evaluation study.

Overall conclusion

This evaluation concludes that despite the current commitment of the Agencies to the existing structure, it remains contested in some important quarters of the research ethics community.

Overall, the evaluation has shown that PRE-SRE has made much progress, but that its path and pace have not been straightforward or rapid. Internally to the Agencies, there is optimism that current and future action will redress past difficulties; externally, there is optimism but also, at the same time, some scepticism. A key lesson to be learned from the period 2001-2009 would be about the need to strike a better balance between productivity and earnest, thorough and inclusive debate. Additional and more effective supports to this type of work could be explored. Another lesson would be about the need to maintain an open and collaborative approach in working with the many other organizations that have direct and indirect roles in research ethics policy, education and governance, working together to overcome fractiousness and competition. Finally, increased awareness about the mandate and activities of PRE-SRE as well as education of research community stakeholders about the controversial issues that remain regarding PRE-SRE, would help develop more informed opinion and clarify how PRE-SRE's contributions can be more clearly framed and delivered, and how stewardship of the TCPS should best be managed.

1. CONTEXT

1.1 Background to the PRE-SRE and the summative evaluation

The Interagency Advisory Panel on Research Ethics (PRE) and the Secretariat on Research Ethics (SRE) were created in November 2001 by the three federal research Agencies: the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC). Their creation followed the publication of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) in 1998, and reflected the Agencies' commitment to making the TCPS a "living" or evolving document in order to respond to new research developments and identified gaps in the Policy as well as to promoting research conducted with the highest ethical standards. PRE and SRE replaced the Tri-Council Advisory Group (TCAG) that was created by the Agencies in 1999.

PRE-SRE were conceived as an interim measure for the period 2001-2006, with a review of their function and continued relevance to be conducted within five years. Based on input from internal and external stakeholders, a Results-based Management and Accountability Framework (RMAF) for PRE-SRE was finalized in October 2003. The RMAF proposed that a mid-term assessment be conducted in 2004. In its place, a special study to assess PRE-SRE's high risk areas was commissioned2. Early in 2005 the term of mandate of PRE-RE was extended by three years to November 30, 20093, and the summative evaluation was rescheduled to the current fiscal year. This document presents the results of that evaluation.

It must be noted at the outset that this evaluation was conducted at a critical moment in the history of PRE-SRE: on the cusp of the public release of a second edition of the TCPS, 10 years after the first. The evaluation data were collected before external stakeholders and research communities had seen the new draft TCPS, which is expected in late fall 2008. The evaluation was also conducted at a time when options for the broader-based organization of research ethics governance in Canada were being considered.4 Views of PRE-SRE, its effectiveness, and its role may evolve quickly by the time this report is finalized. Although the evaluation timing (mandated and thus immutable) was in some ways less than optimal, we have taken an approach that aims to inform the ongoing debate about the future of PRE-SRE and its mandates, by drawing lessons from the past.

---

2 Available upon request from the Agencies.

3 MEMORANDUM OF UNDERSTANDING: Administrative Support for the Interagency Advisory Panel on Research Ethics and Secretariat on Research Ethics, Extension to November 2009, signed January 26, 2005

4 In 2006, a Sponsors' Table consisting of individuals representing research ethics stakeholders and supported by Health Canada mandated an Experts Committee to develop a plan for developing a system of research ethics governance in Canada. This followed several years of uncertainty about the direction of research ethics governance, as well as tensions in the research community which were in some ways linked to the creation of the PRE and SRE. Although the Agencies are members of the Sponsors Table, PRE-SRE is not. See Section 3.5 for more details on the status of this initiative at the time of writing.

1.2 Program description

1.2.1 PRE Mandate, Terms of Reference and Composition

The Terms of Reference (2001-2009, as revised in 2005) for the PRE establish it as a governance structure for the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, in the form of a partnership between the three Agencies (CIHR, NSERC and SSHRC).

The mandate of the PRE is to5:

- promote high ethical standards of conduct in research involving humans;
- advise the Agencies on the ongoing development and evolution of the TCPS;
- establish or commission ad hoc expert groups to address specific issues;
- provide interpretations of the TCPS for its implementation and use;
- learn from and respond to evolutions in research ethics issues and practices, in a national and international context;
- promote and support the implementation of the TCPS;
- identify educational activities and mandate the Secretariat to promote and coordinate them;
- participate in the ongoing national discussion regarding the development of an oversight system for the ethics review processes;
- recognize the diversity of approaches used in research involving humans;
- report annually on its activities to the Presidents of the Agencies.

The Agencies' objectives for this governance structure are[6]:

- to manage, coherently and consistently, the development, evolution, interpretation and implementation of the TCPS;
- to support and assist researchers, research institutions, and REBs;
- to rationalize and consolidate human resources, program expenses, and operational costs devoted to all matters related to the TCPS.

The PRE-SRE are "intended to contribute to a better governance of research ethics policies and practices in Canada and to enhance public trust in research involving humans undertaken under the auspices of Canadian institutions receiving funding from the Agencies"[7]. This structure "responds to Treasury Board's requirements for result-oriented management of public monies, accountability to the Canadian public, and valuing of Canadian citizens"[8].

PRE is composed of 12 external volunteer members with a range of expertise and experience in the ethics of human research. Its membership also includes a lay perspective. Following a rotation cycle established by the Agencies, the term of membership is three years, renewable for another three. To date, PRE has had a total of 21 members. There are also several official observer positions on the Panel, for

5 http://pre.ethics.gc.ca/english/aboutus/termsofreference.cfm#intermandate
6 http://pre.ethics.gc.ca/english/aboutus/termsofreference.cfm#objectives
7 http://pre.ethics.gc.ca/english/aboutus/termsofreference.cfm#activities
8 http://pre.ethics.gc.ca/english/aboutus/termsofreference.cfm#activities

representatives of: CIHR's Standing Committee on Ethics; the SSHRC Standing Committee on Ethics and Integrity; National Council on Ethics in Human Research (NCEHR); Canadian Association of Research Ethics Boards (CAREB); and Health Canada.

PRE has established 14 Standing Committees and Working Committees with responsibilities for specific priority areas. These are:

- Standing Committee on Evolution
- Standing Committee on Education
- Standing Committee on Interpretation
- Standing Committee on Implementation
- ProGroup: Sub-group on procedural issues for the TCPS
- Pre-Technical Advisory Committee on Aboriginal Research
- Guiding Consortium on Aboriginal Research
- Social Sciences and Humanities Working Committee
- Stem Cells Committee
- Clinical Trials Initiative
- Public Emergencies Working Committee
- Conflict of Interest Working Committee
- Planning and Priorities Committee
- PRE Working Committee on Evaluation

In addition, other individuals have been invited to participate, on a project-specific basis, in the committees and working groups, based on their specialized expertise and experience.

1.2.2 SRE Mandate and roles

The mandate of the Secretariat is to[9]:

- promote high ethical standards of conduct in research involving humans;
- learn from and respond to evolutions in research ethics issues and practices, in a national and international context;
- provide interpretations, as requested, of the existing TCPS for its implementation and use;
- recognize the diversity of approaches used in research involving humans;
- foster awareness and understanding of research ethics issues among researchers, research institutions, members of REBs, and the public;
- participate in the ongoing national discussion regarding the development of an oversight system for ethics review practices;
- promote and coordinate educational activities related to the implementation of the TCPS; identify concerns or issues that may arise as part of these activities and inform the Interagency Advisory Panel on Research Ethics should these issues warrant any modification or clarification of the TCPS;

[9] http://pre.ethics.gc.ca/english/aboutus/termsofreference.cfm#secretariat

- provide administrative, substantive and communication support to PRE by:
    a. managing incoming requests for interpretation of the TCPS;
    b. arranging for expert advice on substantive questions of interpretation, as needed, for PRE;
    c. issuing and disseminating official interpretations that PRE develops of the existing TCPS; developing a publicly accessible bank of precedents;
    d. monitoring requests for interpretation over time to identify trends, gaps or difficulties in the TCPS and communicating these to PRE for action;
    e. communicating PRE's decisions, as well as highlights of their meetings, to the broader community in an open and transparent manner;
- establish and sustain collaborative relationships with other organizations.

In practice, the Secretariat staff support PRE and its Committees by helping to prepare, by participating in, and by following up on all meetings, by preparing draft of all education, interpretation, evolution and other policy materials, and by responding to inquiries and requests from the Agencies and the ethics community.

Apart from its role in support of PRE, the Secretariat has an additional role described as follows:

The Secretariat provides technical assistance and advice to the Agencies as outlined below:

1. coordinates the institutional research ethics policy review process in the context of the eligibility process defined under the Memorandum of Understanding on Roles and Responsibilities in the Management of Federal Grants and Awards1 (MOU);
2. assesses adherence of written institutional research ethics policies submitted to the Agencies and reports exclusively to the Agencies on TCPS adherence; the Agencies alone determine the eligibility of institutions;
3. works in a collaborative and formative manner with institutions to ensure that institutional written research ethics policies meet the Agencies' expectations;
4. provides technical and policy advice to the Agencies related to the implementation and application of the TCPS in institutions or organizations eligible to receive or administer federal research funds;
5. coordinates and supports the meetings of the Interagency Management Committee and the Steering Committee.

As a condition of funding, all institutions that receive funds through the Agencies are required to adopt institutional policies for the ethics of research involving humans that are consistent with the TCPS. These policies are part of those outlined in Memoranda of Understanding (MOUs) between institutions and the Agencies, defining all roles and responsibilities and administrative requirements in the management of federal grants and awards.[10] While the implementation and monitoring of the ethics review process remain the responsibility of the institutions, the Agencies have adopted an ongoing formative review process to assess institutional adherence to the TCPS. This review process was put into place in 1999, once the TCPS had been adopted but prior to the existence of the SRE. It became formally part of SRE's role when the SRE was created in 2001. The SRE provides technical advice to all three Agencies on the acceptability of institutional policies for the ethics of research involving humans regarding implementation of the TCPS, in the context of the MOU. The SRE's institutional policy review role is firewalled from the PRE: the PRE is

[10] See "Memorandum of Understanding (MOU) on the Roles and Responsibilities in the Management of Federal Grants and Awards" at http://nserc.gc.ca/institution/mou_e.htm.

not informed of either the overall review process or the review status of any individual institution, in order to ensure that the PRE's actions are understood to be at a policy rather than an implementation level.

More detailed program description may be found in the Evaluation Framework. Logic models for PRE and SRE and for SRE functions in supports of the Agencies are shown in Appendix 1.

1.2.3 PRE-SRE resources

The main inputs to the PRE-SRE are the direct contributions from the three Agencies' operational and grant appropriations. The initial budget was about 1.2M$ per year for five years, this amount remained the same when PRE-SRE's existence was extended to 2008-09. The yearly total and operational–to-grant ratio are based on yearly work plans submitted by the Executive Director of the Secretariat on behalf of PRE[11] and the capacity of the Agencies to provide support through the two funding mechanisms. The three Agencies' contributions are intended to be roughly proportional to the amount of funds disbursed to the research population conducting research with human participants, as well as to the number of projects funded. CIHR contributes 55% of PRE-SRE funds; SSHRC contributes 25%, and NSERC contributes 20%. (According to Agency data, human participants are involved in the research of 67% of CIHR applicants, approximately 50% of SSHRC applicants, and approximately 6% of NSERC applicants.)

Table 1 shows the budget allocations and actual approved expenditures for the years 2002-.2003 to 2007-2008, with the differences. PRE-SRE has under-spent its allocations in all years, although the proportion under-spent has declined over time.

Table 1: PRE-SRE Allocations and Expenditures, 2002-2003 to 2007-2008

	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08
Initial allocation	1,150,171	1,255,200	1,094,928	1,210,581	1, 219,028	1,219,183
Total expenditures	752,958	951,579	951,901	976,560	1,103,377	1,095,401
% difference	34.5%	24.2%	13.1%	19.3%	9.5%	10.0%

Summarized from data prepared by SRE based on data provided by CIHR.

Resources allocated and expended by PRE-SRE for the years 2002-2003 to 2007-2008 by mandate area are shown in Table 2, and illustrated in Figures 1 and 2. It is not possible to attribute SRE staff time to specific PRE-SRE mandates. However, SRE estimates that about 25% of staff time is spent on institutional policy adherence, i.e. in its support role to the Agencies, meaning that about 75% of SRE resources are used to support PRE's activities. The data in Table 2 show that under-spending is mainly attributable to PRE, rather than the relatively fixed costs of SRE: over the six years of data, PRE's budget was under-spent by about one-third (65% of its allocated budget was expended), while SRE's was under-spent by only 5%.

Figure 1 shows the proportion of PRE resources, out of those allocated to the five mandate areas and communications and partnering (i.e., not including PRE meetings or evaluation, nor the SRE's resources),

[11] Memorandum of Understanding re : the Interagency Advisory Panel on Research Ethics (PRE) and Secretariat on Research Ethics (SRE), between the Canadian Institutes of Health Research (CIHR), Social Sciences and Humanities Research Council (SSHRC), Natural Sciences and Engineering Research Council (NSERC). June 2002.

allocated to each. Figure 2 shows the expended amounts by mandate area. Comparison of these two figures shows that PRE spent less on TCPS evolution than had been planned (42% versus the budgeted 51%), and relatively more on communications and partnering (36% versus the planned 26%) and on TCPS education (17% versus the planned 13%). Overall, TCPS evolution and communications and partnering accounted for 78% of PRE mandate-related expenditures. (These figures likely underestimate the proportion of overall resources spent on the interpretation mandate because they do not count SRE staff's significant involvement in receiving and preparing interpretations. As well, some of the expenditures in communications and partnering are likely related to the governance dialogue mandate.)

Figure 1
PRE Allocations to Mandate Areas, 2002-03 to 2007-08

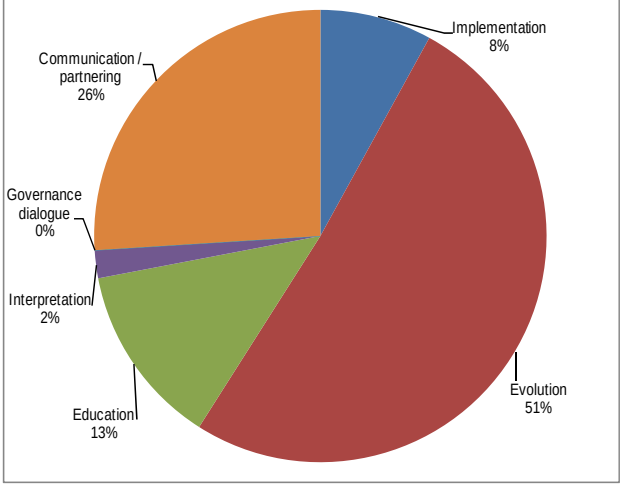
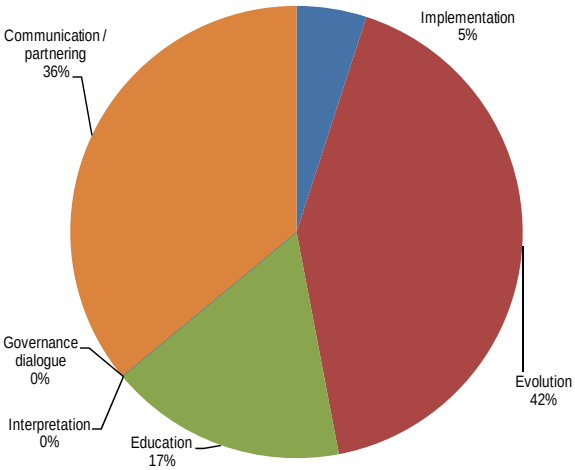


Figure 2
PRE Expenditures on Mandate Areas, 2002-03 to 2007-08



Summarized from data prepared by SRE based on data provided by CIHR.

Table 2: PRE and SRE Allocations and expenditures, 2002-2003 to 2007-2008, by mandate area

	2002-03		2003-04		2004-05		2005-06		2006-07		2007-08	
	Alloc.	Expend.	Alloc.	Expend.	Alloc.	Expend.	Alloc.	Expend.	Alloc.	Expend.	Alloc.	Expend.
PRE												
PRE Meetings	36,000	30,242	30,600	28,312	30,000	27,624	35,000	41,956	49,000	41,836	48,000	41,777
Implementation	94,300	8,778	73,000	50,919	26,500	11,820	14,560	4,683	6,000	4,567	7,500	7,883
Evolution	102,000	44,251	317,900	146,939	297,500	192,507	269,500	89,896	271,000	118,761	149,600	122,831
Education	74,500	59,665	44,500	28,450	24,550	22,671	108,750	76,938	110,000	108,022	1,000	0
Interpretation	15,000	152	24,000	0	4,000	0	3,500	550	2,000	807	1,000	0
Governance dialogue	9,500	1,204	0	0	0	0	3,000	0	1,000	5	0	0
Communication and partnering	109,500	51,096	128,500	126,106	89,500	82,948	109,780	114,698	70,785	66,639	205,700	182,409
Evaluation	25,000	23,043	6,000	0	0	0	0	0	20,000	0	40,000	37,766
Total for PRE	465,800	218,431	624,500	380,726	472,050	337,570	544,090	328,721	529,785	340,637	452,800	392,666
SRE												
Salaries and benefits, including IT support	479,571	394,918	452,500	419,446	454,378	449,598	520,491	501,453	528,443	572,143	601,500	567,174
Indirect general support and costs, including rent	95,600	80,392	72,500	80,026	80,500	80,748	72,500	72,500	72,500	72,500	72,500	72,500
Operational costs	109,200	59,217	102,700	71,381	88,000	83,985	73,500	73,887	88,300	118,098	92,383	63,063
Total for SRE	684,371	534,527	627,700	570,853	622,878	614,331	666,491	647,840	689,243	762,741	766,383	702,737
PRE and SRE												
Total PRE and SRE	1,145,871	752,958	1,255,200	951,579	1,094,928	951,901	1,210,581	976,561	1,219,028	1,103,337	1,219,183	1,095,402

Summarized from data prepared by SRE based on data provided by CIHR.

Finally, Table 3 shows that overall, about 85% of expenditures were operational, and 15% were for grants (this breakdown was not available for 2002-03 and 2003-04). Over and above staff and administrative costs, operational expenditures included mainly the costs of meetings of the Standing and Working Committees, PRE on-site representation, consultation costs, and translation, communications and website costs. For PRE, grant expenditures included research services for preparation of background papers, scoping documents, and literature reviews; review of institutional policies, and contracted consultations and workshops. It also included a budget line called "TCPS educational programs" where educational services were contracted from and conference support provided to CAREB and NCEHR. These latter grants totalled $253,000 over 2002-03 through 2007-08, about 86% of the education mandate expenditures. For SRE, grant expenditures included those for contracted expertise and a few small research contracts.

Table 3: Types of PRE-SRE Expenditures

	2004-05	2005-06	2006-07	2007-08
Grants	164,770	129,397	168,755	188,732
Operations	787,131 (83%)	847,163 (87%)	934,722 (85%)	906,669 (83%)

Summarized from data prepared by SRE based on data provided by CIHR.

SRE's staff includes its Executive Director, two senior policy analysts and two junior policy analysts (increased from one initially, and then back down to one as of June, 2008); a communications officer position was approved in 2007, briefly staffed then and filled in the summer of 2008; and an administrative officer. Each of the Agencies transferred one full-time professional who had had responsibility for the ethics dossier within the agency, to the Secretariat when it was created. For NSERC and SSHRC, this contribution represents the transfer of the agency's total resource allocation to human participants' research ethics. It also includes support previously administered by SSHRC to its Standing Committee on Ethics and Integrity. In addition to the staff positions it provides to SRE, CIHR maintains additional internal resources devoted to ethics, through an Ethics Office, reporting to the President and Governing Council and linking to the ethics designate in each of the 13 Institutes of Health Research.

The Executive Director of SRE reports to PRE through its Chair primarily on policy matters, and to an Interagency Management Committee (IMC), composed of the Executive Vice President of CIHR, the Corporate Secretary of NSERC, and the Executive Vice-President of SSHRC, primarily on interagency administrative and operational matters.[12]

1.3 Evaluation aims and overall approach

The conduct of the PRE-SRE summative evaluation has involved an in-depth study of PRE and the Secretariat addressing the evaluation issues and questions outlined in the Evaluation Framework. Specifically, the evaluation addressed the following issues:

[12] < http://www.pre.ethics.gc.ca/english/aboutus/termsofreference.cfm#secreporting>

- Success of the PRE-SRE in achieving its mandate to promote high ethical standards of conduct in research involving humans through the evolution, interpretation, and implementation of, and education about, the TCPS
- Success of the PRE-SRE in achieving Agency objectives
- Roles of the PRE-SRE in the current and evolving environment of human subjects research ethics policies, services, and governance
- Ongoing relevance of the PRE-SRE, and
- Effectiveness of the functions of the SRE that support the Agencies.

The evaluation also examined the management of risks associated with the PRE-SRE, as identified in the 2002 Performance Measurement and Evaluation Framework.

The PRE-SRE's environment and thus that of this evaluation is complex. The evaluation design aimed to provide information from multiple lines of evidence about all of the evaluation questions, taking into account the challenges to be expected from the sometimes parallel, sometimes converging and sometimes competing interests of stakeholders.

The key clients for the evaluation are the Presidents of the three Agencies and the Interagency Management Committee. NSERC has managed the evaluation on behalf of the Interagency Evaluation Steering Committee[13]. An expanded Working Group has overseen the evaluation, composed of representatives from the ethics functions of SSHRC and CIHR, the evaluation function of all three Agencies, the SRE's Executive Director and a Senior Policy Analyst, and the PRE Chair.

[13] The Interagency Evaluation Steering Committee is composed of the heads of Evaluation in the three Agencies and is charged with overseeing evaluation of joint Agency programs.

2. EVALUATION STRATEGY

2.1 Evaluation questions

The evaluation questions were developed through a consultative process in the framework phase and approved by the Inter-Agency Management Committee in September 2007. They are presented in Table 4[14].

Table 4: Evaluation questions

A. QUESTIONS ABOUT THE PRE AND THE FUNCTIONS OF THE SRE THAT SUPPORT THE PRE	
ISSUE 1: Success of the PRE-SRE in achieving its mandate to promote high ethical standards of conduct in research involving humans through the evolution, interpretation, and implementation of, and education about, the TCPS	1.1 To what extent has the PRE-SRE's work succeeded in reaching and supporting the research community? - To what extent are REBs, research administrators and researchers aware of, satisfied with, and supportive of the PRE-SRE activities and services? - To what extent are the roles and responsibilities of the PRE-SRE clear to REBs, research administrators and researchers? - To what extent has the PRE-SRE contributed to the capacity of institutions/REBs to assure improved ethical research policies and practices in all research disciplines and settings? - What factors have facilitated and hindered PRE's success in reaching and supporting the research community?
	1.2 a) What have been the impacts of the PRE-SRE on evolution of the TCPS? Specifically, to what extent has the PRE-SRE produced: - Effective mechanisms to receive and solicit evolution-related input? - TCPS revisions, especially in areas identified as priorities e.g., Aboriginal research? - An evolved, more inclusive TCPS meeting more research community needs than the original policy? b) How appropriate, effective and efficient are the PRE-SRE's evolution mechanisms and processes?
	1.3 a) What have been the impacts of the PRE-SRE on interpretation of the TCPS? Specifically, to what extent has the PRE-SRE produced: - Mechanisms to respond effectively and in timely fashion to TCPS interpretation needs? Would alternate mechanisms be more effective or more timely? - A corpus of interpretations? b) How have the interpretations affected practice at the institutional level? Specifically, to what extent have: - Requesters of interpretations successfully applied them? - Interpretations been used by a broader community, resulting in facilitated ethics management? c) How has the interpretation function facilitated evolution of the TCPS?

[14] Note that the evaluation questions do not include an assessment of PRE-SRE's work on its implementation mandate. This was due to the prioritization of questions in the framework phase. Less than 1% of PRE resources were allocated to implementation; these were used to produce a TCPS Implementation Feedback Framework (TIFF) and conduct of a census of REBs of research offices of institutions that are funded by the Agencies and subject to the TCPS.

	1.4 What have been the impacts of the PRE-SRE on education of the research community? Specifically, to what extent has the PRE-SRE produced: - Mechanisms for identifying and monitoring educational needs? - Needed educational tools and resources? - Collaboration with others involved in ethics education? - Utilization by the research community of educational tools and resources? - Improved knowledge of ethical issues and practices among users?
	1.5 To what extent has the PRE-SRE contributed to increased assurance that risks to research participants are balanced against the benefits of the research?
	1.6 What operational improvements can be identified to increase PRE-SRE effectiveness, in terms of: - PRE-SRE linkages to the Agencies and their respective ethics-related entities (CIHR Ethics Office, Institute Ethics Designates, Standing Committee, SSHRC Ethics and Integrity Committee)? - PRE, Standing and Working Committee memberships and rotations? - Standing and Working Committee structures and functioning?
ISSUE 2: Success of the PRE-SRE in achieving Agency objectives and meeting Agency expectations	2.1 To what extent has the PRE-SRE increased CIHR's, NSERC's and SSHRC's capacity to ensure that research conducted through their support is carried out with the highest possible ethical standards for research involving humans? - How effectively has the PRE-SRE carried out its advisory function to the Agencies?
	2.2 To what extent has the PRE-SRE achieved the Agencies' objectives of: - managing, coherently and consistently, the development, evolution, interpretation and implementation of the TCPS? - How effectively has the PRE-SRE managed its performance? In particular: - were performance measurement systems implemented and used? - were resources used efficiently and in line with priorities? - supporting and assisting researchers, research institutions, and REBs? - rationalizing and consolidating human resources, program expenses, and operational costs devoted to all matters related to the TCPS?
	2.3 How effectively have the Agencies, through the IMC and the Steering Committee supported the PRE-SRE towards achievement of their objectives, through: - adequate resources? (sufficient or insufficient?) - effective management? - communication and assurance to the public?
	2.4 To what extent are each of the three Agencies continuing to endorse the PRE-SRE's role and mandate, seeing it as the most appropriate and best use of their ethics-related resources and the most appropriate location for ethics policy development?
ISSUE 3: Roles of the PRE-SRE in the current and evolving environment of the governance of human subjects research ethics policies and services	3.1 Through and following the special study conducted in 2005, to what extent have the high-risk areas identified in the 2002 RMAF of perceived structural conflict of interest and relationship-building issues around PRE been effectively addressed and resolved?
	3.2 What has the PRE-SRE contributed to the dialogue about the development of a national system of oversight for the governance of research involving humans?
ISSUE 4: Ongoing relevance of the PRE-SRE for the Agencies and their stewardship of the TCPS	4.1 Given the current and evolving situation of policies, practices and governance of human participant research ethics in Canada, does the PRE-SRE have ongoing relevance as structures and mechanisms for contributing to the long term outcomes: of better research ethics policies and practices in Canada; enhancing public trust in research involving humans undertaken in Agency-funded institution; and protecting human research participants? - How has the mandate been implemented/translated to evolve and respond appropriately with the changes in the environment? - Is the mandate of the PRE-SRE still appropriate in the new environment? - How should the role for TCPS stewardship be defined in the new environment?

	4.2 What structures and mechanisms for achieving the same long-term outcomes should or could be considered as alternatives to the PRE-SRE? - To what extent would these alternatives increase the likelihood of achieving the outcomes, at the same or lesser cost to the Agencies and the other stakeholders?
B. QUESTIONS ABOUT THE FUNCTIONS OF THE SRE IN ITS SUPPORT TO THE AGENCIES	
	1. To what extent are the roles and responsibilities of the SRE in support of the Agencies clear to REBs, research administrators and researchers? What are the impacts of this? - How clear is the firewalled structure between PRE-SRE and SRE's functions in support of the Agencies to REBs, research administrators and researchers? What are the impacts of this?
	2. How effective and timely has the SRE's support to the Agencies been in facilitating a greater proportion of institutional policies that are consistent with the TCPS?
	3. How effective and timely has the SRE's support to the Agencies been in facilitating Interaction between the Agencies and institutions about research ethics?
	4. How effective have been the other forms of support provided by SRE to the Agencies?

Links to risk management issues identified in the RMAF

The Interagency Advisory Panel and Secretariat on Research Ethics RMAF (November 2002) identified several areas of risk for the PRE-SRE. All of these except the lowest risk area are captured in the evaluation questions, as shown in the table below.

Table 5: Links of evaluation questions to PRE-SRE risk areas

Risk areas	Risk level as assessed in 2002	Addressed by evaluation question:
1a) Risk of inability to build functional, productive relationships with other key players	Medium likelihood, significant impact	A3.1Through and following the special study conducted in 2005, to what extent have the high-risk areas identified in the 2002 RMAF of perceived structural conflict of interest and relationship-building issues around PRE been effectively addressed and resolved? A3.2 What has the PRE-SRE contributed to the dialogue about the development of a national system of oversight for the governance of research involving humans?
1b) Risk of failing to clarify roles and mandates with the research community	High likelihood, significant impact	A1.1 To what extent are the roles and responsibilities of the PRE-SRE clear to REBs, research administrators and researchers? B1. To what extent are the roles and responsibilities of the SRE in support of the Agencies clear to REBs, research administrators and researchers?
1c) Risk of failing to resolve issues of structural conflict of interest	High likelihood, moderate impact	A3.1 Through and following the special study conducted in 2005, to what extent have the high-risk areas identified in the 2002 RMAF of perceived structural conflict of interest and relationship-building issues around PRE been effectively addressed and resolved?
2) Risk of failing to reach output commitments	Low likelihood, significant impact	1.2 a) What have been the impacts of the PRE-SRE on evolution of the TCPS? 1.3 a) What have been the impacts of the PRE-SRE on interpretation of the TCPS? 1.4 What have been the impacts of the PRE-SRE on education of the research community?
3) Risk of failing to obtain necessary support and legitimacy from the three Agencies	Medium likelihood, moderate impact	2.4 To what extent are each of the three Agencies continuing to endorse the PRE-SRE's role and mandate, seeing it as the most appropriate and best use of their ethics-related resources and the most appropriate location for ethics policy development?
4) Risk of failing to represent adequately and equitably the perspectives of all disciplines/Agencies	Medium likelihood, minor impact	Not addressed directly

2.2 Indicators and data sources

The evaluation design included qualitative and quantitative lines of evidence about each evaluation question, including all relevant stakeholder groups and sources of documentation among the data sources. Indicators and data sources for each of the evaluation questions were identified in a detailed evaluation matrix. Existing data sources were limited to material available at SRE, exclusive of material only available at Agency level. The data collection methodologies are summarized below.

Note that most of the survey data sources were identified in the PRE-SRE RMAF as the source of performance management indicators to be produced at three and five years of operation. Because the mid-term review was replaced by the Special Study, these data were not collected as part of an ongoing performance management strategy. However, most ongoing data collection tools recommended in the RMAF were implemented, and information from these was used in this evaluation.

2.2.1 PRE-SRE output production

Review of program documents: project vita. To address questions about the success of the PRE-SRE especially in the evolution of the TCPS, an adaptation of the "Project vita" method was used15. This is a structured approach to documenting the chronological accomplishments of large scale, complex projects in situations where there are many aspects of project activity to be monitored and compared to goals and timelines. This involved a review of PRE-SRE documents from 2001-02 through mid-2008-09, including: meeting minutes (and teleconference records when these were available), briefing notes and reports prepared for PRE, Standing Committee and Working Committee meetings. A quantitative profile of the extent to which expected outputs were produced within expected timelines was prepared, by group.

Review of logs, website usage statistics, and other monitoring sources. In addition to relevant data gained through the project vita review, other forms of administrative data were reviewed and data relevant to the evaluation indicators extracted. These included:

- Records of presentations produced by PRE members and SRE staff were reviewed, to document the extent of communication with research organizations and researchers.
- TCPS interpretations log. SRE maintains an Excel database of all TCPS interpretation questions and responses. These data were extracted and entered into an SPSS file.
- TCPS interpretations: website usage statistics. Once completed, interpretation results are anonymized and published on the PRE-SRE website and in document form as a compendium of interpretations. Website usage statistics were used to assess the utilization of the TCPS interpretations published on the website. Note that interpretations were also published in two printed volumes and distributed at relevant events such as conferences.
- TCPS Tutorial: website usage statistics. A tutorial on the TCPS, described in more detail below, is freely available on-line. Analysis of internal website data allowed documentation of the level of uptake of the tutorial.

---

15 Smith, NL; Florini, BM (1993). The Project Vita as a Documentation and Evaluation Tool for Large-Scale Research and Development Projects. *Evaluation and Program Planning*, 16(1), 49-53.

- TCPS tutorial: existing user questionnaire. All of those completing the TCPS tutorial are asked to complete a brief online survey. Demographic questions were added to the questionnaire in 2006, so from that date, these data can provide information on users' diversity (geographic, disciplinary, institutional type, role/status). These data were compiled from existing reports.
- Financial data. The outputs review also examined PRE and SRE resource utilization through analysis of budget and financial reporting documents.
- TCPS adherence assessment. As mentioned above, one of the SRE's main outputs is review of institutional policies to assess adherence to the TCPS. SRE maintains a log of this process; data from this were extracted and entered into an SPSS file to be summarized.

2.2.2 Surveys of internal and external stakeholders

Qualitative/quantitative survey of current and former Panel, Standing Committee and Working Committee members

Sample and data collection procedures. All current and former Panel, Standing Committee and Working Group members were invited to participate in an evaluation survey. According to SRE records, a total of 88 individuals had participated in one or more of these groups. Nineteen individuals were withdrawn from the potential sample, either because they were to be included in the sample of key informant interviewees (n = 5), were deceased (n = 2) or, in the case of some members of the Guiding Consortium on Ethics in Aboriginal Research, had had minimal involvement or could no longer be reached through their sponsoring organization (n= 12). The total number of potential respondents was 69, with a total of 116 memberships (because all PRE members are also members of at least one committee, and because several individuals have been involved in multiple groups).

The SRE supplied membership lists with coordinates for all PRE, Committee and Group members. Potential respondents were invited to participate in the survey by an email letter from the three Agency Presidents, and given the choice of completing the attached Word version of the survey or responding though an interview. A reminder invitation was sent two weeks later, followed by a reminder telephone call to all potential respondents who had not completed the survey. Those who elected to participate by telephone were sent the survey in advance. The survey and interview were available in both English and French. Respondents signed and faxed a consent form prior to completing the questionnaire or interview. The survey was conducted between May 9 and July 3 2008.

Survey instrument. The instrument used for this survey combined a mix of quantitative ratings (5-point agree-disagree scales) and qualitative responses. All respondents were asked to answer questions on only those elements of the PRE-SRE's mandates with which they were familiar.

Response rate. Twenty-five responses were obtained, three through interviews and the rest as e-mailed questionnaires. Four respondents were on extended leave and considered unreachable, two had changed employers and could not be traced, and one was deceased. Four respondents declined to participate, citing insufficient involvement. When these 11 potential respondents are removed from the sample of 69, the response rate is 43%: 25 out of 58. This is much lower than expected, given that these individuals are all engaged in the organization being evaluated.

Table 6 shows the number of potential and actual respondents by group (PRE, Standing Committee or Working Committee). The respondents included members of all committees except for the Stem Cells Committee and the Public Emergences Working Group.

Table 6: Survey of Panel and Committee members - Potential and actual respondents by group

Entity	No. in retained sample	Potential respondents	Actual respondents
Panel on Research Ethics	22	20	11
ProGroup: Sub-group on procedural issues for the TCPS	13	12	6
PRE Standing Committee on Education	6	5	2
PRE Standing Committee on Interpretation	3	3	1
PRE Standing Committee on Evolution	7	7	1
PRE Standing Committee on Implementation	4	4	2
PRE Working Committee on Evaluation	2	2	1
Social Sciences and Humanities Working Committee	14	13	9
Pre-Technical Advisory Committee on Aboriginal Research	11	9	6
Guiding Consortium – Aboriginal Research	17	13	3
Stem Cells Committee	7	5	0
Clinical Trials Initiative	4	4	1
Conflict of Interest Working Committee	4	4	1
Planning and Priorities Committee	7	7	4
Public Emergencies Working Committee	3	2	0

Web survey of research ethics offices of Agency-funded institutions

A web survey was conducted of representatives of research offices in organizations eligible to receive funding from one or more of the three Agencies. This includes all institutions having signed a Memorandum of Understanding with the Agencies. These offices are responsible for overseeing the research ethics function including implementation of the TCPS, and supporting the institution's REBs.

Sample. The Tri-Agency REB Census conducted by PRE-SRE in 2007 served as the sampling frame for this survey. This census identified a total of 109 research officers (research administrators and REB chairs) in institutions eligible to receive funding from the Agencies. The Canadian Association of University Research Administrators (CAURA) was apprised of the survey and facilitated the survey administration through a presentation at its annual meeting in May 2008.

Instrument. The survey contained a total of 55 mainly closed-ended (agree-disagree) items. The invitation email and the survey stressed that the evaluation was focusing on the stewardship mechanism for the TCPS, and not the TCPS itself.

Procedures. Because SRE was not able to release the census contact information to external consultants, it was asked to send a survey invitation to the research officers identified in the census. This email invitation contained the survey URL (with embedded unique password) for each respondent. The consultants supplied a list of these to the SRE to import into the messages. The 109 survey invitations were sent from SRE on May 21 2008. Reminders were sent by SRE to the census list on May 27 and June 10.

Analyses. All data were captured in Circum's secure database and transferred to SPSS for analysis.

Response rates and responders' characteristics. Twenty-one responses were received, for a response rate of 19%. All but one response were from universities or colleges. The distribution of respondents' location shows that all regions of the country participated in the survey. However, because of the low response rate, these data were combined with those of the survey of REB chairs, described below.

Web survey of chairs of Canadian Research Ethics Boards

Sample. While there is no complete sampling frame of all Canadian REBs, the Tri-Agency REB Census conducted by PRE-SRE in 2007 served as the major component of the sampling frame for the REB survey. This census identified a total of 189 designated REB contacts. As there are additional REBs in organizations that are not eligible for Agency funding but who nevertheless make use of the TCPS (including private sector REBs, REBs in provincial and federal government departments, and REBs in practice settings such as school boards and health agencies), these were solicited through two additional sources: the National Council on Ethics in Human Research (NCEHR) and the Canadian Association of Research Ethics Boards (CAREB). NCEHR maintains a voluntary registration of REBs on its website[16], which at the time of the survey included a total of 302 REBs. CAREB also maintains a publicly available list of members, which had a total of 88 listings when the survey was conducted. Both NCEHR and CAREB posted a survey invitation on their listservs, asking REB representatives who had not already responded to the survey to complete it.

Instrument. The survey contained a total of 57 mainly close-ended (agree-disagree) items. The invitation email and the survey stressed that the evaluation was focusing on the stewardship mechanism for the TCPS, and not the TCPS itself.

Procedures. As for the previous survey, because the REB census contact information was considered to be confidential, SRE was not able to release it to external consultants. SRE was thus asked to send the survey invitation to the designated REB contacts identified in the census. This email invitation contained the survey URL (with embedded unique password) for each respondent. The consultants supplied a list of these to the SRE to import into the messages. The survey invitations were sent from SRE on May 21 2008. Invitations from the NCEHR and CAREB listservs were launched the same day. The fact that the survey invitations were launched from all three sources on the same day resulted in some overlap among the samples, so that some Agency-funded institutions' REB representatives received and responded to one of the listerv invitations before receiving their Census-based invitation. Reminders were sent by SRE to the REB census list on May 27.

The initial invitation from SRE mixed up the lists of REB chairs and university research officers, so that while respondents accessed the correct survey, their invitation referred to the other group. This problem was corrected in the reminder invitation. It may have affected the response rate.

Analyses. All data were captured in Circum's secure database and transferred to SPSS for analysis.

[16] http://ncehr-cnerh.org/forms/pdfListings.php

Response rates and responders' characteristics. Table 7 shows the number of responses received by sample source. About half of the respondents (37 out of 82, or 45%) responded using the URL sent to the REB census list. While the overall response rate for all Canadian REBs is not possible to calculate, it may be in the order of 27% if the total number of Canadian REBs is about 300 as per the NCEHR list. Less conservatively, it may be about 43% if the SRE's list of designated REB contacts is considered the denominator

Table 7: Web survey of Canadian REB chairs – Proportion of responses by source

	No. received	Total population
REB census	37	189
CAREB	31	88
NCEHR	14	302
Total	82	

About 73% of respondents were from universities or colleges, and another 20% from hospitals. Six responses came from REBs in institutions that are not likely eligible for Agency funding: community-based/volunteer agency or organizations, government agency or organizations, or private sector/industry. If these are counted as not eligible for Agency funding, the response rate for Agency-eligible REBs is 39% (76 out of 189). These respondents were included in the analyses.

Prospective survey of TCPS Tutorial users

Sample. The SRE does not maintain a database of contact information for tutorial registrants, so it was not possible to retrospectively survey tutorial participants to assess longer term outcomes. A prospective on-line survey was therefore instituted, where all tutorial registrants for the first months of the evaluation data collection period (March-May 2008) were asked through a message on the tutorial site to provide contact information, by being redirected to the consultants' secure server, for a follow-up survey, to be conducted two months later (May-August 2008).

Based on the overall tutorial utilization rate of 519 completers per month, it was expected that approximately 1,038 tutorial registrants would be solicited. Applying the same response rate as for the post-tutorial on-line evaluation survey of 23%, we expected that about 240 tutorial takers would accept to participate.

Instrument. To allow comparability, this survey was built on the existing survey questions as well as including indicators of application of the tutorial content.

Analyses. All data were captured on Circum's secure server and then transferred to SPSS for quantitative compilation. Open-ended responses were coded using an emergent coding scheme to represent the most frequent and qualitatively important response categories, and these codes were entered into SPSS.

Response rate and sample characteristics. A total of 230 individuals agreed to complete the survey two months after their tutorial, which was very close to the expected 240. However, only 24% of those who accepted (n = 55) completed the questionnaire. This is an unknown proportion of those completing the tutorial in the time period from March 11 to May 23, 2008.

Table 8 shows the breakdown of respondents by their type, in comparison to the characteristics of 7,783 respondents to the existing tutorial survey (as of July 2008). Our sample is comparable in that by far most responses were from students and researchers, working in universities and hospitals. However, it appears to contain somewhat more respondents from the biomedical and health sciences. The uneven geographical distribution mirrors that in the existing survey data, with a preponderance of responses from British Columbia and Ontario.

Retrospective web survey: Interpretation service users

Sample. The SRE maintains a database of all interpretation questions and responses, as well as of interpretation requesters. A web survey of all 89 interpretation question submitters since 2001 was conducted.

Instrument. The survey contained nine closed- and open-ended items assessing satisfaction with and the impacts of the interpretation service.

Procedures. Because SRE was not able to release the contact information for interpretation requesters to external consultants, it was asked to send the survey invitations. This email invitation contained the URL (with embedded unique password) for each respondent. The consultants supplied a list of these to the SRE to import into the messages. The 89 survey invitations were sent from SRE on May 21 2008. Reminders were sent by SRE on May 28 and June 10. Ten e-mail addresses were no longer valid.

Analyses. All data were captured in Circum's secure database and transferred to SPSS for analysis.

Response rate. A total of 23 (29%, out of 79 valid addresses) responses were received.

Table 8: Prospective survey of tutorial users - respondent characteristics

	Prospective survey respondents (no., % of 55 respondents: multiple responses allowed)	Existing survey respondents 2004-2007 (% of7,738 responses)
Role		
Graduate or undergraduate student	28 (52%)	45%
Researcher, research team member	30 (53%)	37%
REB member or research administrator	2 (4%)	7%
Research participant	2 (4%)	3%
Professor, instructor, lecturer	8 (15%)	2%
Other (health professional, research administration)	2 (4%)	(not asked)
Discipline		
Biomedical, health sciences	37 (67%)	45%
Humanities/social sciences	20 (36%)	36%
Natural sciences / engineering	--	4%
Interdisciplinary	3 (6%)	6%
Other (education, nutrition, urban planning)	3 (6%)	6%
Type of institution		
University or college	38 (69%)	67%
Hospital	24 (44%)	23%
Government department or agency	2 (4%)	3%
Private sector/industry	1 (2%)	3%
Community-based agency	3 (6%)	2%
Other	2 (2%)	1%
Province		
British Columbia	10 (18%)	25%
Alberta	1 (2%)	3%
Saskatchewan	3 (6%)	2%
Manitoba	0	2%
Ontario	35 (64%)	57%
Quebec	5 (9%)	4%
New Brunswick	0	2%
Nova Scotia	0	3%
Prince Edward Island	0	0%
Newfoundland and Labrador	0	2%
Yukon, Northwest Territories, Nunavut	0	0%
Outside Canada	1 (2%)	(not asked)

Key informant interviews with high-level stakeholders

Interviews were conducted with key stakeholders in the PRE-SRE and the research ethics community, both internal and external to the three Agencies.

Sample and data collection procedures. The Evaluation Framework had identified a series of respondent categories, and organizations within those categories. Using this framework, a first list of individuals within the stakeholder organizations was generated by the consultants and complemented by suggestions by all three Agencies and SRE. The final list of 49 potential key informants was approved by the Evaluation Steering Committee. This contained both internal key informants – management and senior staff of SRE, SSHRC, NSERC and CIHR – as well as external stakeholders. The latter included representatives of

agencies, organizations and stakeholders constituencies whose work is affected by the TCPS and by PRE-SRE.

Potential respondents were invited to participate in the survey by an email letter from the three Agency presidents, and were subsequently contacted by the consultants by e-mail and telephone to obtain agreement and to schedule an interview time. Respondents who requested it were sent the survey in advance. The interviews were conduced in English or French, those in Ottawa in person and those outside by telephone. Respondents signed and faxed a consent form prior to completing the interview. The survey was conducted between May 9 and July 31, 2008.

Survey instrument. The open-ended interview guide addressed the main evaluation questions. All respondents were asked to answer questions on only those elements of the PRE-SRE's mandates with which they were familiar. Only internal stakeholders were asked questions about the success of the PRE-SRE in achieving Agency objectives.

Response rate. Twenty-four interviews were completed. Six external respondents declined to participate, citing insufficient knowledge of PRE-SRE. No valid contact information was obtainable for three respondents and one was deceased. When these 11 potential respondents are removed from the sample, the response rate is 63%: 24 out of 38. Of these, four were individuals delegated by the original respondents because they were said to be more knowledgeable about PRE-SRE.

Internal stakeholders interviewed included two from each of CIHR, SSHRC and NSERC, and six former and current senior SRE staff (n = 12). External stakeholders (n = 12) represented a wide range of organizations, including disciplinary and student associations, university governance, research ethics board administrations working with the public and private sectors, federal and provincial government departments, and other organizations involved in research ethics. It is important to note that members of the Sponsor's Table other than from the Agencies declined to participate in these interviews due to their ongoing development of a position on governance of research ethics, and hence the PRE-SRE, at the time the interviews were being conducted.

Analyses. Interview notes were transcribed, and qualitative analyses using a matrix approach were conducted. Analyses distinguished between internal (Agency and SRE) and external responses.

Web survey of researchers

Sample. Two pretests were conducted. The first, with a questionnaire that resembled the surveys described previously, was conducted with a convenience sample of six senior researchers in various disciplines and institutions. The results suggested that knowledge levels of PRE-SRE would be low even among experienced researchers, and that they would not be able to answer most questions. A revised, shorter survey was then pretested with a random sample of 50 researchers whose research involves human participants (20 CIHR applicants, 20 from SSHRC and 10 from NSERC). Responses to this pretest survey showed that about 30% of respondents could be expected to have heard of PRE-SRE. The survey sample was then constructed so as to obtain an adequate sample size in this group, representative of all three Agencies. The sample was distributed in a non-proportional fashion among Agencies to allow for sufficient sample for analysis among NSERC researchers. About 20% of the sample was drawn from the NSERC list and about 40% were from each of CIHR and SSHRC. These proportions and the number of researchers

invited are not whole numbers (and do not add up to whole numbers) because a large incidence of e-mail address duplication was found in the file. Duplicates were eliminated during the field work and sample was added to compensate for these losses. *Ex post facto* weights were applied to re-establish natural proportions in the data processing stage. The obtained sample sizes and response rates, about 24% for all Agencies, are shown in the table below.

Table 9: Response rates, researcher survey

Researchers ...	All	CIHR	NSERC	SSHRC
In the sampling frame[1]	10,520	5,707	961	3852
Invited	2,933	1,128	632	1,173
Who completed the form	709	257	151	285
Participation rate	24%	23%	24%	24%
Margin of error at a confidence level of 95% for a proportion of 50%	+/- 3.6 points	+/- 6.0 points	+/- 7.3 points	+/- 5.6 points

[1]After deleting duplicate entries.

When asked to indicate the main disciplines of their research experience (allowing multiple responses), 58% of researchers indicated social sciences and/or humanities, 18% indicated natural sciences and/or, engineering, 60% indicated biomedical and/or health, and 22% indicated interdisciplinary research. Further respondent characteristics are shown in Table 10. Respondents seem to cover a range of types of research and involvement with human participants, as well as representing adequately the distribution of research capacity across regions of Canada and types of institutions.

Structured telephone interviews with community members of REBs

The evaluation plan called for a survey of community members of REBs, in order to provide a lay perspective on PRE-SRE results in terms of public assurance and assurance to participants[17]. Respondents to this survey were to be identified through the survey of REB chairs: each responding chair was asked to contact their members representing these constituencies and ask for permission to have the evaluation team contact them for a brief telephone interview. According to the REB survey data, a total of 35 REB chairs accepted to contact their community members and invite them to be interviewed. However, only four of these contacted the consultants. No reminders could be sent because of the contact methodology: it would have to have been sent by SRE (who had already sent two reminders to the REB census group about their own survey); and it would have to have been sent to everyone in the initial sample, even those who declined to contact their community REB members (because SRE should not have access to any of the survey data), potentially causing irritation. The Evaluation Working Group thus decided to abandon this component of the evaluation.

[17] The PRE's study of the educational needs of community REB members found that: *"Community members felt that their primary role on the REB is to ensure that the community members' voice is heard and their experiences are recognized and understood. Some did this by taking the perspective of the research participants*" (REB Community Member Educational Needs: A PRE Pilot Project, 2007. http://pre.ethics.gc.ca/english/pdf/FINAL_Community_Member_Project_EN25SEP07.pdf, p. 3)

Table 10: Respondent characteristics, researcher survey

	All	CIHR	NSERC	SSHRC
Proportion of research (including students' research) involving human participants				
Less than 75%	37%	32%	46%	36%
76% or more	63%	68%	54%	64%
Type of involvement of human participants (multiple responses allowed)				
Interview, survey respondents	77%	68%	47%	95%
Observed in behavioural, observational research	42%	35%	46%	47%
Participants in clinical studies or trials	23%	41%	23%	6%
Participants in non-clinical experiments	33%	33%	53%	22%
Testers of tools, devices, media	14%	10%	29%	9%
Donors of human physical samples	17%	31%	20%	4%
Other	9%	5%	7%	13%
No answer	1%	1%	2%	1%
Research with special populations (multiple responses allowed)				
Children	31%	27%	38%	32%
Elderly people	27%	36%	33%	15%
Aboriginal peoples	16%	14%	6%	23%
Minority of ethnocultural groups	23%	23%	6%	32%
Adults who are legally incompetent to consent	8%	12%	7%	5%
Other special populations	19%	16%	22%	21%
No answer	31%	26%	38%	31%
Expertise in research ethics				
Yes	31%	27%	30%	35%
No	61%	66%	62%	56%
Type of institution				
University	93%	87%	95%	97%
College	0	0	0	0
University-affiliated hospital	20%	42%	13%	4%
Community-based hospital	1%	2%	1%	1%
Community-based, volunteer organization or agency	3%	4%	2%	2%
Other	3%	3%	4%	2%
No answer	0	0	0	0
Province				
British Columbia	13%	9%	19%	13%
Prairies and territories	13%	13%	13%	11%
Ontario	43%	44%	42%	44%
Québec	23%	26%	17%	24%
Atlantic	7%	4%	9%	8%

In the analyses reported below, responses are compared by Agency.

Table 11 summarizes the above sections by indicating which data sources were used to address each evaluation question.

Table 11: Data sources addressing each evaluation question

Evaluation question	Review of PRE-SRE and SRE outputs	Interviews /questionnaires: Panel and Committee members	Survey of research offices and REB chairs	Survey of tutorial users	Survey of interpretation service users	Key high-level stakeholder interviews	Researcher survey
A. QUESTIONS ABOUT THE PRE AND THE FUNCTIONS OF THE SRE THAT SUPPORT THE PRE							
ISSUE 1: Success of the PRE-SRE in achieving its mandate to promote high ethical standards of conduct in research involving humans through the evolution, interpretation, and implementation of, and education about, the TCPS							
A1.1 To what extent has the PRE-SRE's work succeeded in reaching and supporting the research community?			X				X
A1.2 a) What have been the impacts of the PRE-SRE on evolution of the TCPS? b) How appropriate, effective and efficient are the PRE-SRE's evolution mechanisms and processes?	X	X	X			X	X
A1.3 a) What have been the impacts of the PRE-SRE on interpretation of the TCPS? b) How have the interpretations affected practice? c) How has the interpretation function facilitated evolution of the TCPS?	X	X	X		X	X	X
A1.4 What have been the impacts of the PRE-SRE on education of the research community?	X	X	X	X		X	X
A1.5 To what extent has the PRE-SRE contributed to increased assurance that risks to research participants are balanced against the benefits of the research?			X			X	X
A1.6 What operational improvements can be identified to increase PRE-SRE effectiveness?	X	X				X	
ISSUE 2: Success of the PRE-SRE in achieving Agency objectives and meeting Agency expectations							
A2.1 To what extent has the PRE-SRE increased CIHR's, NSERC's and SSHRC's capacity to ensure that research conducted through their support is carried out with the highest possible ethical standards?		X				X	
2.2 To what extent has the PRE-SRE achieved the Agencies' objectives? of: - managing, coherently and consistently, the development, evolution, interpretation and implementation of the TCPS? - How effectively has the PRE-SRE managed its performance? In particular: - were performance measurement systems implemented and used? - were resources used efficiently and in line with priorities? - supporting and assisting researchers, research institutions, and REBs? - rationalizing and consolidating human resources, program expenses, and operational costs devoted to all matters related to the TCPS?	X	X				X	
A2.3 How effectively have the Agencies, through the IMC and the Steering Committee supported the PRE-SRE?	X					(X)	
A2.4 To what extent are each of the three Agencies continuing to endorse the PRE-SRE's role and mandate?	X					(X)	

Evaluation question	Review of PRE-SRE and SRE outputs	Interviews /questionnaires: Panel and Committee members	Survey of research offices and REB chairs	Survey of tutorial users	Survey of interpretation service users	Key high-level stakeholder interviews	Researcher survey
ISSUE 3: Roles of the PRE-SRE in the current and evolving environment of the governance of human participant research ethics policies and services							
A3.1 Through and following the special study conducted in 2005, to what extent have the high-risk areas identified in the 2002 RMAF of perceived structural conflict of interest and relationship-building issues around PRE been effectively addressed and resolved?		X				X	
A3.2 What has the PRE-SRE contributed to the dialogue about the development of a national system of oversight for the governance of research involving humans?	X	X				X	
ISSUE 4: Ongoing relevance of the PRE-SRE for the Agencies and their stewardship of the TCPS							
A4.1 Given the current and evolving situation of policies, practices and governance of human subject research ethics in Canada, does the PRE-SRE have ongoing relevance?		X	X			X	X
A4.2 What structures and mechanisms for achieving the same long-term outcomes should or could be considered as alternatives?		X	X			X	X
B. QUESTIONS ABOUT THE FUNCTIONS OF THE SRE IN SUPPORT OF THE AGENCIES							
B1. To what extent are the roles and responsibilities of the SRE clear?		X	X			X	
B2. How effective and timely has the SRE been in facilitating institutional policies that are consistent with the TCPS?	X		X			X	
B3. How effective and timely has the SRE been in facilitating Interaction between the Agencies and institutions about research ethics?	X		X			X	

2.3 Methodological assessment

Being essentially descriptive, this evaluation does not benefit from comparisons to external objective benchmarks that could be used to assess performance. PRE-SRE performance was mainly judged by comparing results to stakeholder expectations.

This evaluation has one main limitation: its lower-than-expected response rates to all survey tools. While research ethics touches the work of a great many researchers, the size of the community directly involved in the management or shaping of research ethics policy and practice is quite small, and has been frequently solicited for input over the last several years. This may have affected response rates.

The timing of this evaluation was less than ideal. It followed a period of intense consultation on changes to the TCPS which may have exhausted the availability of some individuals consulted as part of this evaluation. It preceded the release of the second edition of the TCPS, such that respondents were unable to assess a key PRE-SRE result. The timing of the evaluation also coincides with important changes in the environment of the PRE-SRE through the work of the Expert Committee and Sponsors' Table.

That being said, this evaluation benefits from the input of a substantial number of individuals belonging to a vast array of interest groups vis-à-vis the issues of ethics in research: PRE, Standing Committee and Working Committee members; institution research officers; chairs of REBs; tutorial users; interpretation requesters; researchers; CIHR, SSHRC and NSERC staff; former and current senior SRE staff; disciplinary and student associations; university representatives; REB administrators in the public and private sectors; representatives from federal and provincial government departments, and other organizations involved in research ethics. All in all, more than 1,100 individuals contributed to a better understanding of PRE-SRE performance.

2.4 Ethical approval and practices

After discussion within the Evaluation Working Group18, the detailed evaluation design and tools were submitted to the National Research Council of Canada's Ottawa Research Ethics Board for review and guidance. A positive response was received on February 29, 2008, and comments received were incorporated into the design, consent forms and tools. Participants were assured that: their participation was voluntary and they could withdraw at any time without penalty or prejudice, that all individual responses would be stored securely and held confidential to the evaluation team, and that no individual or organization would be identified or identifiable in any report. Where relevant, respondents were informed that they could withdraw their data from the evaluation up until the time it was entered into the anonymized databases.

---

[18] PRE-SRE's official position is that program evaluations are not considered research and therefore do not fall under the purview of the TCPS, although they "*may nonetheless raise ethical issues (e.g., consent, voluntariness and confidentiality) that at least warrant an expedited research ethics review.*" (TCPS Interpretation Definition of Quality Assurance Studies, Performance Review and Research, http://www.pre.ethics.gc.ca/english/policyinitiatives/interpretations/interpretation007.cfm. However, it was felt that this particular research community might question the absence of ethical oversight, although the study itself posed no risks to participants that are not typical of federal evaluation practices.

Survey responses (written or interview notes) were transferred to electronic files for use in qualitative and quantitative data analysis. When this had been agreed to in the consent process, permission was sought to use verbatim responses to illustrate points. Original responses were then destroyed. An alphanumerical code was used to separate respondents' contact information from their responses. All datafiles will be destroyed one year after acceptance of the final evaluation report.

3. FINDINGS

In the sections that follow, the qualitative and quantitative analyses of the evaluation data have integrated findings from all the data sources, using the evaluation framework to structure the organization of responses to evaluation questions.

3.1 PRE-SRE reach and support to the research community

3.1.1 Communication of role and mandate to external audiences

As noted in Section 1.2, PRE-SRE has invested a significant portion of its resources in communication and partnering. A main activity in this area has been presentations to external audiences, aiming to communicate its role and mandate; provide opportunities to update research communities on its progress; and to gather feedback about its activities and the ethics issues under consideration in them. Table 12 provides an indicator of the level of activity, summarizing the number of presentations made by either PRE or SRE staff. These peaked at 62 in 2005-06 (more than 5 per month or one per week, on average), during the intensive phases of consultations on several of the evolution dossiers.

Table 12: Presentations to research communities

	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09 (to date)
No. of presentations	3	18	25	39	62	47	21	23

Summarized from presentations folder on SRE's shared drive. There may be inaccuracies due to multiple versions of the same presentation; an attempt was made to identify unique presentations.

The audiences for these presentations were varied. Each year, PRE-SRE has held a workshop in conjunction with the annual NCEHR conference, where several presentations were made. Other venues included the annual CAREB conference, disciplinary association meetings (e.g., Congress of Humanities and Social Sciences, Canadian Biostatistics Society, Canadian Indian and Native Studies Association), as well as institutional groups (e.g., CAURA, Quebec university rectors conference). No data are available on the size or nature of the audiences reached at these events.

The SRE has had a communications officer position since 2004-05 (approved by IMC in October 2003), but it was vacant for long periods and finally filled in August, 2008 after running two competitions. In January 2008, the SRE began developing a communications strategy in light of the completion of the first series of consultations and the upcoming release of the revised TCPS. In February 2008, a communications strategy was adopted, containing key messages and timelines up to the launch of major consultations on the 2nd edition of the TCPS (late fall 2008) and the final version (Winter 2009).

3.1.2 Awareness of the TCPS, PRE-SRE, and roles and responsibilities

Survey data showed that among responding researchers (whose work involves human participants), awareness of the TCPS is high: 87% state they have heard of it. The proportion was slightly higher among SSHRC researchers (92%) than among CIHR researchers (84%). Seventy-nine percent of responding researchers have read the TCPS, and 71% have used it. Sixty-five percent of those having used it agree or

strongly agree that it was useful to them. This confirms that the object of PRE-SRE stewardship, the TCPS, is in fact present in the environments of most of the responding researchers.

However, in all the stakeholder groups surveyed, awareness of PRE-SRE and its roles and mandates is substantially lower, even among its most direct stakeholder groups: Research Ethics Boards and university research offices. Table 13 shows data on levels of awareness and understanding for that population, as well as for researchers who responded to equivalent items in their survey. While the vast majority of REB chairs and research officers agree that the roles of the Agencies (83%), institutions (87%) and REBs (93%) with respect to the TCPS are clear to them, only about two-thirds (65%) are aware of the roles of PRE-SRE with respect to the TCPS. About the same proportion (62%) are aware of the mandate of PRE-SRE, and one-half (52%) are aware of its activities. Less than one-quarter (22%) believe that their research community is aware of PRE-SRE's activities. The researcher survey data confirm this low level of awareness: 29% have heard of PRE-SRE, and among those who have, 61% of researchers agree or strongly agree that they are aware of the mandate, and 36% of the activities of PRE-SRE. Researchers associated with CIHR were less likely to have heard of PRE-SRE (21%) than researchers from NSERC (33%) or SSHRC (35%).

Table 13: REB chairs and research officers and researchers - Awareness of the TCPS and of PRE-SRE roles and responsibilities

	REB chairs and research officers (n = 103)		Researchers (n = 709)	
	% Agree or strongly agree[1]	% Don't know	% Agree or strongly agree[1]	% Don't know
The roles and responsibilities of the Panel and Secretariat on Research Ethics with respect to the Tri-Council Policy Statement are clear to me.	65.0	4.9	36	4
The roles and responsibilities of the three Agencies (NSERC, CIHR and SSHRC) with respect to the Tri-Council Policy Statement are clear to me.	82.6	2.9	54	7
The roles and responsibilities of research institutions with respect to the Tri-Council Policy Statement are clear to me.	87.4	1.9	n/a	n/a
The roles and responsibilities of Research Ethics Boards with respect to the Tri-Council Policy Statement are clear to me.	93.2	1.0	n/a	n/a
I am aware of the mandate of the Panel and Secretariat on Research Ethics.	62.1	3.9	61	3
I am aware of the activities of the Panel and Secretariat on Research Ethics.	52.4	4.9	36	3
The research community I am concerned with is aware of the activities of the Panel and Secretariat on Research Ethics.	22.4	15.5	n/a	n/a

[1] Out of all responses, including "don't know".

The low responses rate from university research officers as well as from researchers may be another indicator of low levels of awareness or interest in PRE-SRE; indeed, the levels in the above table may represent the views of an interested minority and thus overestimate awareness in the entire populations.

When asked how effectively PRE-SRE had communicated its mandate and role, a few external ethics community stakeholders were satisfied, for example: *"They've done a fairly good job. Their communication strategies have been sound. The message about where they fit is communicated accurately and consistently over time. They didn't overstate".* However, many felt that communication could have been

more effective: *"Its not as visible as it could be" ; "Its communications could be greater"; "This is one of the areas that could be greatly enhanced. Most researchers are aware that it's out there, but are not sure whether this applies to them;" "If it's the overall mandate, I guess that it hasn't been that effective, because I don't know. I get confused between the PRE and the Secretariat*." Several noted confusion as well about the relationship between PRE and the Agencies: "*People don't understand the relationship between the Presidents of the Councils and the Panel. People might not understand that it's not the Panel's fault if the Presidents reject the Panel's recommendation"; "What's PRE's role with the Councils? This is not clear in many academic institutions"; "Researchers don't understand the relationship of the PRE with the granting Agencies, other than it is associated with the granting Agencies" .* (This issue is related to that of perceived institutional conflict of interest, discussed more fully below.)

As Table 14 shows, a majority of researchers completing the survey endorsed a more proactive role for PRE-SRE in informing the research community about the TCPS (61%) and about its activities (70%). Consistent with their levels of awareness, researchers associated with CIHR tended to agree more often (74%) and researchers from SSHRC, less often (53%).

Table 14: Researchers' views of need for more outreach (n = 709)

	% Agree or strongly agree[1]	% Don't know
The Panel and Secretariat, as stewards of the TCPS, should be doing more to inform the research community of the TCPS.	61	5
The Panel and Secretariat, as stewards of the TCPS, should be doing more to inform the research community about their activities related to the TCPS.	70	3

[1] Out of all responses, including "don't know".

3.2 Impacts on evolution of the TCPS

3.2.1 Evolution success

Evolution of the TCPS is a central function of the PRE-SRE. It is of special concern in the evaluation because its progress has been slower than originally expected: as mentioned above, at time of writing, revisions to the initial TCPS have not yet been formally adopted. External key informants generally described PRE-SRE's work in evolving the TCPS as unexpectedly slow: "*remarkably*", "*inordinately*" or "*extraordinarily*" so. Many stated that the 10 years' wait for a revised TCPS was simply too long. Internal key informants in the Agencies and SRE, as well as PRE and PRE Committee members, acknowledged that the process of producing a revised TCPS has been slow, leading to frustration in the field. However, there were some different types of qualifiers on this lack of rapidity: while some respondents, especially from the biomedical sector, found this rate of progress unacceptable, those in other sectors were often less categorical, focussing more on the movement forward than the final product: *"I guess my view is that it is a situation of ongoing success instead of having reached a final destination."* Some noted that the pace of progress reflected the sensitivity and complexity of the issues, suggesting that slowness was to have been expected.

However, some ethics community stakeholders also expect that much may be forgiven when the new TCPS will be released, despite the delays. A representative of a national stakeholder organization

highlighted the recently stimulated sense of anticipation that many stakeholders are now feeling: *"I just got an email from the Panel on Research Ethics – which has the subject line* "Important step towards the second version of the TCPS*". This was an important symbol for us that things were moving forward.*" Another key stakeholder organization's representative emphasized that it is in fact too early to evaluate the success of the evolution mandate: *"The Panel's success will only be measured in a year's time after the publication of the second version of the TCPS."*

PRE and PRE Committee members, REB' chairs, and university research officers were all asked to indicate their views on the adequacy of PRE-SRE's evolution activities. These findings, summarized in the table below, echo the dissatisfaction with the timeliness reported above, but PRE members are even more dissatisfied than REB chairs and research officers.

Table 15: Panel and PRE Committee members, REB chairs and research officer - Effectiveness of the TCPS evolution mandate

	% agree or strongly agree	
	Panel and PRE Committee members (n = 25)[1]	REB chairs and university research officers (n= 65)[1]
The processes being used to produce the modifications to the Tri-Council Policy Statement are effective.	52.0	56.0
I am satisfied with the timeliness of the production of the modifications to the TCPS.	20.0	44.0

[1] Out of all responses, including "don't know".

In the sections below, we describe the processes and activities used to evolve the TCPS, followed by discussion of some reasons evoked by the data for slow progress. This chapter closes with views of external stakeholders and client groups on the effectiveness of PRE in its evolution mandate.

3.2.2 Processes and activities used to evolve the TCPS

Most of the major TCPS revisions and additions that will appear in the second edition of the TCPS later in 2008 were known to be issues for the research community since PRE's creation. The Tri-Council Advisory Group (TCAG) on the TCPS was formed in 1999, and undertook to oversee the initial implementation of the TCPS. In a transferring letter to PRE, TCAG urged PRE to address the following gaps in the TCPS: research with Aboriginal communities and people; qualitative research including naturalistic observation; ongoing research reviews; good clinical practice harmonization; included and excluded research; and review of research conducted for course projects.

Document review showed that PRE's initial workplan, tabled at the January 2002 PRE meeting, proposed addressing a total of 51 areas, including those identified by TCAG. Several of the items identified were eventually addressed through TCPS interpretations, some were retained as Evolution activities, some were taken on by other groups, and some were not retained. The revision of the original TCPS Chapter 6 on Aboriginal research ethics was identified as the longest term result.

In the first year of the PRE's mandate, the Standing Committee on Evolution saw to the creation of new groups to further evolution of the TCPS in specific areas: procedural issues in the TCPS (ProGroup); issues arising for the social sciences and humanities communities, including the creative arts (Social Sciences and Humanities Working Committee - SSHWC), and aboriginal research[19]. While the first two were operationalized within a year of their initiation, the nomination process for the Aboriginal groups' memberships took longer (this process is discussed more fully below). Other Working Committees were subsequently created to address evolution in other areas: Stem Cells Committee; Clinical Trials Initiative; and Public Emergencies Working Committee.

As of 2008, evolution initiatives had been formally undertaken on 20 issues related to elements of the TCPS. These are shown in Table 16. Each of the groups charged with a component of TCPS evolution worked towards preparation of background documents and then position papers for consultation. Some of these involved the letting of contracts for external research: for example, a contract to identify resources on stem cells; background research on outbreaks (public emergencies); a paper on naturalistic observation; as well as several review and analysis papers in the area of Aboriginal research ethics.

Table 16: Evolution activity areas

	Element
1.	Identifying and prioritizing procedural and related definitional issues in the TCPS
2.	Proportionate Approach to Research Ethics Review in the TCPS (Was broken down into 3a-d below)
3a	Definition of research
3b.	Delegated authority framework and review
3c.	Concept of risk
3d.	Concept of Vulnerability
4.	Procedures for Continuing Ethics Review
5.	Multi-centred Ethics Review
6.	Good Clinical practice/TCPS Harmonization
7.	Operational issues for REBs / Procedures for reconsideration and appeals
8.	Procedures for identifying and managing conflict of interest
9.	TCPS Glossary
11.	Reconsidering Privacy and Confidentiality in the TCPS: A Discussion Paper
12.	Qualitative Research in the Context of the TCPS
13.	Survey of the Artist-Researchers in Fine Arts, Social Sciences & Humanities Research Community
14.	Scholarly merit
15.	Free and informed consent
16.	Internet and new media research
17	Collectivities other than Aboriginal peoples
18.	Research Involving Aboriginal Peoples
19.	The Duty to Share Information in Clinical Trials: Working Recommendations for the TCPS
20.	Stem cells research
21.	TCPS Principles for Public Emergencies Research

[1]PRE Evolution Status Chart, June 2007.

[19] PRE-Technical Advisory Group on Aboriginal Research, PRE-TACAR, preceded by an internal tri-agency Staff Working Group and Guiding Consortium.

Preliminary work was begun on some expected outputs that were not eventually retained in the PRE-SRE workplans: professional norms, nanotechnology, biobanking, and research with children. Scoping papers were contracted in these areas. Two areas remain on ProGroup's workplan: procedures for reconsideration and appeals, and procedures for managing conflicts of interest.

In 2005, the Agencies adopted a five-phase process for developing input on draft and final revisions to the TCPS. This process was crafted with a rolling amendment model in mind. The main steps of the phases were:

- Phase I: PRE-SRE internal processes for draft policy development. These took into account the results of interpretation activities, and included the following steps:
    - Issues identification and prioritization
    - Project design (identification of goals, partners and initial research)
    - Research, analysis and development of policy options
    - Draft working recommendations
    - Internal and targeted consultations
- Phase II: Public and Agency consultation: formal 30-90 day comment periods on PRE consultation documents, in a two-stage process: release of a discussion document seeking input, followed by analysis of the input received and release of recommendations for textual changes to the TCPS, and then seeking input on these.
- Phase III: Finalization of recommended changes
- Phase IV: Submission of formal recommendations to the Presidents through the IMC; and recommendations by Presidents to their Governing Councils for approval
- Phase V: Integration of the approved TCPS changes and dissemination to the wider community through the PRE.

Phases I through III were generally followed for the 20 areas listed in Table 16. Broad consultations were undertaken for the evolution areas shown in Table 17; levels of response to these consultations varied.

The process for approving TCPS revisions was amended in 2007, when it was decided to produce an entire second edition of the TCPS, incorporating all changes, and submitting this version to consultation. While in June 2007 it was noted that the three-member Evolution Standing Committee would act as 'clearing house' for all ongoing initiatives under evolution portfolio to coordinate the creation of the 2nd edition of the TCPS, this role has now been assigned to a Drafting Committee composed of PRE members with the participation a representative from each of SSHWC and ProGroup.

The Standing Committee on Evolution has also undertaken other activities relevant to evolution: a survey of the NSERC community's need with respect to ethics and the TCPS (published in 2003) and liaison with other entities such as Health Canada, CIHR and the World Health Organization.

In early 2008, PRE-SRE finalized and placed on its website a number of key discussion papers from working committees which may be incorporated into the new TCPS. These outputs are shown in the Table 18.

Table 17: Response to public and targeted consultations about TCPS evolution

	Number of responses received		Profile of respondents
Public consultations			
Refinements to the Proportionate Approach to Research Ethics Review in the TCPS	82		Agencies, associations, government departments, universities (mainly their REBs), private industry and individuals
Qualitative Research in the Context of the TCPS	97		Anthropology, Social Work, Urban Studies, Pharmacy, Library and Information Science, History, Education and Environmental Studies
Reconsidering Privacy and Confidentiality in the TCPS: A Discussion Paper	36		Institutions, organizations, associations, and individuals,
Refinements to the Continuing Research Ethics Review in the TCPS	30		Researchers, REBs, administrators, groups and associations with interest in research ethics
Targeted consultations			
	Solicited	Received	Disciplinary profile of respondents
Survey of the Artist-Researchers in Fine Arts, Social Sciences & Humanities Research Community	open	14	Unknown
Survey of NSERC Researchers	664	299	Engineering or natural sciences; Psychology/life sciences related to health and disease

Various sources: briefings to Panel meetings and reports of the Standing Committees involved.

Table 18: Discussion document outputs available on PRE-SRE website

Document	Date of publication
Feedback Regarding the Qualitative Research Document	May 2008
REB Operational Issues in the TCPS	May 2008
Ethics Review of Research in Multiple Settings and/or Involving Multiple REBs	March 2008
Public Emergencies in the TCPS	March 2008
Research Involving Aboriginal Peoples in the TCPS	February 2008
Researchers' Continuing Duty to Share New Information in Clinical Trials; Confidentiality Clauses in Ethics Review; Continuing Consent duties and REB Purpose and Functions	February 2008
Research Involving Creative Practices: A Chapter for Inclusion in the TCPS	February 2008
The TCPS and Ethical Issues in Internet Research	February 2008
SSHWC Recommendations Regarding Privacy and Confidentiality	February 2008
Qualitative Research: A Chapter for Inclusion in the TCPS	February 2008
Proposed Textual Changes for Concept of Risk in the TCPS	February 2008
Incorporating the CIHR Stem Cell Guidelines into the TCPS	February 2008
Refinements to the Continuing Research Ethics Review in the TCPS	January 2008
Concept of Vulnerability in the TCPS	January 2008
Towards a Revised Definition of Research in the TCPS	January 2008
Delegated Ethics Review	January 2008
Harmonisation of the TCPS and ICH-GCP: Conflict or Clarification?	November 2007

http://www.pre.ethics.gc.ca/english/publicationsandreports/publicationsandreports.cfm

A full draft of the second edition of the TCPS was tabled at the June 2008 PRE meeting. PRE members' comments will be integrated into the version expected to be released for public consultation in late fall 2008. The final, approved version is now expected in mid-2009.

3.2.3 Reasons for slow progress in evolution

Views of the causes of slow progress in the evolution mandate vary according to stakeholders' perspectives. Agency respondents attribute the slowness of TCPS evolution largely to ineffective leadership, which they see as having had a very academic and perfection-seeking approach. Other respondents also stated that changes within the Agencies are contributing to the positive direction, including: more attention from the Presidents; a clarification of the Agencies' expectations; and a more production-oriented approach to managing PRE-SRE. Agency respondents also noted that changes in the external environment are also contributing to increased momentum, where there is now greater awareness of ethics issues in the research milieu and greater engagement of the research community.

SRE staff pointed out that the first two years of PRE-SRE's mandate had been consumed by setting up the structure and resources, as well as garnering credibility, especially in the social sciences. This, in their view, meant that the real evolution work did not begin until 2003-04. Additionally, Agency staff emphasized that PRE had not been created in a context of consensus: its existence was openly disputed particularly in some biomedical research sectors. These issues took time to address, limiting early impetus on TCPS evolution.

In accounting for the lack of progress up until recently in the evolution mandate, external stakeholders as well as some PRE and PRE Committee members were critical of the way PRE's work had been organized and led. The following observations were made:

- Ineffective Committee work: Several individuals who had been involved with the evolution work through various steps of consultation stated that the work of Working and Standing Committees had been at times ineffectual, leaving organizations *so exhausted they could not get their members involved. They were spending hours a week discussing, with no results, just an ongoing complacency….. they were captive of a process that did not move forward."* A respondent to the survey of PRE and PRE Committee members reflected: *"It has taken far too long to reach this point, with too few PRE meetings, too little work done by Panel members between meetings, a long period with no focus."* It was pointed out by PRE and PRE Committee members that face-to-face meetings were more productive than e-mail work: *"Lack of resources forces PRE-SRE to try to do business by e-mail. But that does not work well".* A frequent suggestion for operational improvement was to increase the number of face-to-face meetings and the proportion of work to be carried out at them. Also observed in the PRE evolution mandate functioning was a lack of capacity for trenchant decision-making, that left committees sometimes mired in debate. *"PRE's working committees have been overly accommodating to vocal interests. There is fragmentation everywhere you look. We need to find a way to pull together, there are crying needs not yet fulfilled. The squabble may be continuous, but we need effective, smart compromise: some tough decisions have to be made."* Another of the issues raised was the quality of the drafts emerging from committee work: some respondents were critical of this (e.g., *"The quality of the work was not great. There were times when it was poorly presented, weakly argued, and didn't look beyond the TCPS for causes and consequences"; "The consultation was very broad, but did not seem to get to concrete ideas. It just produced other vague documents. This was discouraging."*).

- Overambitious workload: Compounding these difficulties, also recognized by external stakeholders, was the very heavy workload PRE had given itself, given its resources: *"They haven't been that successful because they took on too much work. If they had been more selective, they*

would have been more successful. They got off track probably with taking on too many areas of the TCPS at once – too many working groups that it seemed to be difficult to manage that with the resources that they had". Slowness in producing TCPS revisions were attributed by SRE staff to a view that PRE had perhaps become too spread out over numerous projects and had not established priorities for TCPS evolution early enough, which spread SRE's resources thinly across a large number of parallel priorities and initiatives.

This observation is corroborated by data from the document review. Gantt charts prepared and updated throughout 2005 - 2007 also provided information about the evolving status of PRE and Agency projects. The numbers of initiatives are summarized below (Table 19). It can be observed that the number of ongoing projects increased in each period, while the number of future and pending projects declined and the number of Agency projects remained constant. Because the PRE's and the SRE's resources were constant over this period, this means that the PRE constantly increased its workload as well as that of the Secretariat.

Table 19: Number of ongoing and pending PRE projects and Agency projects, 2005-2007

	September 2005	June 2006	November 2006	Spring 2007
Ongoing	17	23	24	*27*
Future & pending	11	8	8	3
Agency projects	5	5	5	5

Summary of Gantt charts prepared as briefing notes to Panel for meetings in 2005 and 2006.

- "Voluntary" status of Panel: Another theme raised in both internal and external stakeholder interviews, seen as contributing to slow concrete progress, was the voluntary nature of PRE work. Panel, Standing Committee and Working Committee members being "volunteers"20 has, in the view of several key informants, meant that progress on evolution documents was subject to their limited availabilities. *"Members are doing this on a volunteer basis, everyone is involved in addition to their daytime jobs. It's a huge commitment."* This, combined with a perceived lack of accountability and leadership for the committees, was seen as having undermined progress: *"its really hard to drive an agenda with a firm timeline when working with volunteers. Leadership at PRE suffered in dealing with this"*.

  There was also some question about whether supporting the work of a volunteer panel and committees would require additional human resources with levels of research ethics expertise comparable to that of the panel and committees.

- Rotation of Panel and Committee membership. Rotation in PRE and PRE Committee members may also have contributed to slowing down evolution productivity, both in terms of the rotation in of new members: *"…I have great concerns about people who come in with good concerns but who come in cold without knowing the background. A lot of time is spent getting them up to speed, especially when meetings are infrequent. And there is always so much going on."*. The rotation off committees of members who had acquired significant background in their files before the product was complete was also criticized. Concerns were expressed about the Inter-Agency management Committee's rotation policies and their application: *"It is sometimes hard for me to understand just*

[20] "Volunteers" in the sense that they perform this committee work while on salary from their employer institutions, but without necessarily having been formally delegated this role or having it recognized in release time from other duties.

how decisions on membership are made. While rotation is important, in some ways it has inhibited progress"; *"There needs to be better consultation and continuity in rotation. The Management Committee's role is not satisfactory. The cycling of memberships is disconcerting and disruptive. The assumption that new blood is good and that continuity is secondary – needs to be re-examined."* This was another area frequently identified as in need of operational improvement.

- Linkages between Committees and PRE: Another such area in need of operational improvement according to PRE and PRE Committee members was a lack of connection in memberships between the Working Committees and PRE: *"Because the working committees are not committees of PRE, and have few members (sometimes only one) at the PRE table, months of work by working committees can be devastated by PRE with minimal discussion. This does not happen with the Standing Committees, where the membership involves Panel members."*

As shown by these observations, and given very large number of files covered at any one PRE meeting, it is clear that the efficiency and effectiveness of PRE-SRE progress was challenged by a variety of factors.

3.2.4 Consultation effectiveness

Some views of PRE-SRE' consultation processes in the research ethics community were quite positive, while others were critical. On the positive side, some external key informants recognized the PRE's consultative approach as a strength, and worth the time it has taken in the gains in stakeholder buy-in. "*One of the processes has been the inclusivity of stakeholders, so that has been helpful. People can't complain about what they have constructed."* Many key informants stated that the processes had effectively engaged the research ethics community: "*Processes on the ground were effective, involved a broad consultation as well as on some more basic issues" ; "I would say that the Panel chose all the best methods for developing this type of document … it was an extensive consultation process, and requires going back and forth in terms of different drafts, and they did this correctly"; "We have deep appreciation for the work that has been done. It has engendered genuine enthusiasm among our members. Our members devoured the consultation papers."* The consultations were seen as embedding a message of legitimacy and recognition to some groups who had previously felt outside of the TCPS: "*I really appreciated being recognized and consulted. Those of us who were asked felt great respect for being recognized for looking at things differently."* Although a distinction was made by some between the opportunity to respond to consultations and the response actually obtained, the mechanisms were cited as effective. "*The mechanisms for submitting comments were all highly functional. The timeline seemed appropriate… the timelines were generous, and they were expanded."* Survey data showed that 17 out of 25 PRE and PRE Committee members (68%) and 60% of REB chairs and university research officers agreed that the consultations undertaken by PRE and Secretariat on Research Ethics about modifications to the Tri-Council Policy Statement ensured adequate input from the research community.

On the critical side, some key informants including some PRE and PRE Committee members, qualified the consultation process as overburdening: "*They didn't have a good way of organizing their work, and no vision about achieving the task, so the consultations were endless iterations" ; "It seemed like there was a fast and furious list of things to respond to."* ; *"Progress has been delayed by the many stages of consultation".".* This may in part have been, according to one respondent, because of a lack of organization in the spacing of the consultations: "*You can't go to policy experts with 3-4 policy drafts all at one time and get the feedback you want. If they had planned it better, they would have been able to phase in the*

consultations better over time:" Others felt that consultation had not always been broad or inclusive enough: *"The consultations were not as inclusive as they could have been, due to prioritization and leadership "; "Its fundamentally changing the definition of research to one that is broad and sweeping – there has not been sufficient discussion "; "they have been inclusive but have left out (respondent's) sector – the consultations are not proportional to all sectors involved in the research.".* The recent decision to scale back the consultative approach in the finalization of the Aboriginal research ethics chapter is seen by some external observers as imposing a limit on inclusivity.

An issue raised by several Working Committee members was that although the processes for ensuring input through consultation had been effective in their view, it was not clear how the consultation results would be used by PRE in the modifications. "*After two years of providing input, I am still not sure which recommendations will be implemented and when. The process to make a change to the TCPS is lengthy and involves multiple levels of review (some committee to PRE to Public Consultation, and then where?). Also, due to the existence of other parallel sub-committees assessing similar regulatory areas, some relevant recommendations were being deferred to other groups which left me wondering whether or not they were being given sufficient consideration as there was no follow-up on them to the referring committee."; " Notwithstanding their alleged commitment to "openness, transparency and accountability," PRE is none of those three. We won't really know what they are up to and whether they have actually listened to anyone until a draft is released."; "It is simply impossible to answer this question on the basis of any evidence. I am well aware of the numerous topics being addressed by the various working groups. And I am also aware of the recommendations which have been made by some of these groups. However, the process by which this work is going to be turned into modifications of TCPS is absolutely opaque. Until a revised draft is put out for public review judging the adequacy of proposed modifications will remain impossible"'.* This underscores a theme that arose in several areas of the results: that there had been a lack of communication from the PRE itself about its processes (see section 3.8.1) and (already mentioned above) a lack of connection between the work of the Working Committees and PRE.

3.2.5 Evolution in priority areas

Stakeholders' views of PRE-SRE's success in addressing TCPS evolution in the priority areas identified specifically by TCAG were varied. Respondents associated with the biomedical sector expressed disappointment and frustration at the lack of progress in some key areas, and at perceived preferential treatment of social science issues. For example, an external key informant noted: *"It was frustrating for CIHR to get PRE-SRE to address important things – it tried to be supportive, recognizing importance of the TRI-Council structure, but returns to CIHR were poor". A*nother stated: "*Some aspects were not attended to. They have always addressed social sciences first. They were reluctant to address clinical trials – this has not been done. Everyone was aware in the social sciences, the TCPS was too biomedical. My perception of PRE is that they overshot the mark, and spent an inordinate amount of time on social science issues."* On the other hand, some PRE and PRE Committee members emphasized that bringing the social sciences community back on board to collaborate with PRE-SRE, after its initial negative reaction to the TCPS, has been PRE-SRE's greatest accomplishment. This viewpoint defended the slow progress of TCPS evolution, arguing that the decision to value and prioritize appropriate, inclusive processes had paid off in this reconciliation, and that the process had been as important as the results.

Other respondents, representing broader constituencies, felt that priorities had been well-chosen and well-addressed: "*Consultation on continuing ethics review, qualitative research, confidentiality, those are the kinds of things we participated in. The questions were important, and the issues created interest among our members."* Survey data found that 17 of 25 PRE and PRE Committee members (68%) and 63% of REB chairs and university research officers agreed that TCPS modifications are adequately addressing areas identified as priorities (examples provided were: Aboriginal research, qualitative research, information sharing in clinical trials).

Aboriginal research ethics policy. One key area that was addressed specifically in the evaluation was the Aboriginal research ethics policy, given that CIHR published its own guidelines for health research with Aboriginal people in 2007.

The draft version of the TCPS circulated in 1996-97 contained a chapter on Aboriginal ethics that was withdrawn from the final publication due to negative reaction it generated. Document review showed that the negative reaction had been attributed by PRE to a lack of proper consultation and so its approach to developing a new Tri-Agency Aboriginal chapter aimed to ensure buy-in from Aboriginal communities from the beginning of the process. This was validated in interviews: *"This has been one of the more complex files, requiring a lot of background preparation to secure buy-in of key communities. The challenge was not to introduce harms; to ensure that the increasingly affirmative First Nations research community didn't feel it was imposed in a top-down approach".* Document review also showed that concrete steps toward this began to appear in PRE documentation in April 2003; PRE-SRE appears to have had mainly internal discussion in 2001-2002. The main steps in PRE-SRE's approach to producing this chapter were:

- Adoption of the idea of a national guiding body developed cooperatively by PRE and the Agencies (July 2003)
- Appointment of a PRE member of Aboriginal heritage – a prerequisite to the creation of the working group (2003)

- Creation of an Interim Technical Staff Working Group, with eight members from SSHRC, CIHR-IAPH, PRE, SRE and the National Aboriginal Health Organization (NAHO) (September 2003)
- Bilateral meetings with aboriginal organizations to gauge interest in the initiative: Assembly of First Nations, Inuit Tapiriit Kanatami , Congress of Aboriginal Peoples, Métis National Council, Native Women's Association of Canada (2004)
- Preparation of Terms of Reference for and launching of calls for membership in the Guiding Consortium (2004, revised in 2005)
    - Consortium membership included: representatives of the five core Aboriginal organizations above, representatives from each Agency, one to two representatives of nongovernmental organizations, one PRE member, and an Elder.
    - First meeting of Guiding Consortium (September 2004)
- Preparation of Terms of Reference for and launching of calls for membership in PRE-TACAR: (2004, revised in 2005)
    - PRE-TACAR members were selected by a committee chaired by SRE and composed of two PRE members (one Aboriginal), a representative of a national Aboriginal organization, and one from SSHRC's Aboriginal research Pilot Program. The call for nominations closed in January 2006, with 22 applications, 20 of whom applied and 2 were referred. Its membership includes 10 Aboriginal and non-Aboriginal scholars
    - First meeting of PRE-TACAR (June 2006), to review first draft document
- Second draft document (December 2007).
- Website release of the draft TCPS chapter (February 2008).

The initial Tri-Council workplan had the initiative being led by CIHR, who had hired a resource person. A number of background papers and discussion documents were produced in the early phase of the initiative (and some were later produced by CIHR and shared with PRE-SRE).

A change of process with CIHR occurred in April 2004. Document review showed that CIHR announced to the Interim Technical Staff Working Group (ITWG) that IAPH and CIHR's Ethics Office "*will lead an initiative for the development of health specific ethics guidelines for research involving Aboriginal peoples. This CIHR IAPH initiative stems from a concern about accountability towards its community and the need for CIHR to develop ethics guidelines as well as a secondary concern which is the 2 year timeframe in which the project has been instructed to produce guidelines*" (Minutes of ITWG, 27.04.04.). Interviews with stakeholders familiar with these exchanges noted PRE-SRE's official position vis-à-vis CIHR's initiative, despite some internal consternation, was to be supportive and to emphasize the possibilities for complementarity. A consensus workshop on policy, planned and budgeted as a joint initiative, was not held as such due to the change in process.

CIHR's separate process generated questions among external stakeholders*: "It was expected that the Panel would work on this issue, and it would seem that this was one of the first priority areas, but that was not done. …. CIHR did the work for them on this issue – CIHR said that they couldn't wait. So then you had a competing process. Individuals were confused about who is doing what. Why was CIHR able to do this when SRE-PRE wasn't?"* However, among PRE, PRE-TACAR and Guiding Consortium members, PRE-SRE's approach to the evolution of the Aboriginal chapter generally elicited supportive opinions. Some respondents noted that given the evolution in the Aboriginal research field more broadly, the PRE process and response are appropriate and timely. "*The Aboriginal component is timely – being produced at a good time, and could not have been done earlier". There is a lot of development in Aboriginal ethics (for example*

around the Health Survey) that is happening at the same time". It was also pointed out that CIHR sought and allocated additional resources, including a full-time staff person, to its Aboriginal ethics initiative.

The engagement of Aboriginal political organizations directly in the process took time for both capacity building and consultation. As part of the process, grants were awarded to the five main national Aboriginal organizations (a total of $111,000, spent mainly in 2006-07 and 2007-08) who submitted an application to allow them to consult within their communities and build their positions for input into the PRE-SRE initiative. Indeed, two respondents representing Aboriginal constituencies in the Guiding Consortium felt that the consultation process could have been more in-depth: *"Aboriginal communities may not agree that all has been done that could be done"; " Not quite as good as it could have been because there could have been deeper consultation."*

According to key informants familiar with the parallel processes, possibilities for complementarity of PRE-SRE's work and CIHR's guidelines are now becoming apparent, as the new Aboriginal chapter of the revised TCPS builds extensively on the CIHR work, while having secured participation of the national Aboriginal organizations.

3.2.6 Consequences of slow evolution progress

A consequence of the general lack of advancement in evolving the TCPS in key areas was, in the view of many stakeholders, that it has created a vacuum of guidance: *"We are frustrated with the lack of progress. They have inadvertently created a vacuum; there are questions that could have been answered, and we would have been farther ahead."* According to some key informants, this void has been especially problematic in the Aboriginal research ethics area, as it leaves the door open to inconsistent interpretations and differential treatment of research projects and hence research participants across the country: "*we would have liked to see Aboriginal research ethics promulgated for all three Agencies at the same time. … It has created a mixed playing field: CIHR has one set of requirements, SSHRC another. For the same project, there are not the same guidelines on ethics. It should not be allowed to remain that way, it will create conflicts"* . Respondents expect this situation to be resolved with the release of the new TCPS with its Aboriginal chapter.

Some specific issues were raised with respect to CIHR and its decision-making in areas related to PRE-SRE. In CIHR informants' view, PRE-SRE's processes were inefficient and untimely. While in principle, CIHR's Ethics Office states that it leaves the leadership to PRE-SRE wherever the three Agencies are affected, their views that PRE-SRE processes were unsatisfactory has led to some exceptions. First was the production of Aboriginal research guidelines, described above. PRE-SRE's consultation on stem cells research ethics, which has led to its adoption of the proposal initially made by CIHR five years previously, was cited as another example. PRE-SRE's actions in the file were described as slow, ineffective and costly. There is a view within CIHR that it is subsidizing the research ethics development in Canada, echoing the external view cited above that returns to CIHR from PRE-SRE have been poor.

Several respondents pointed out that it was hard to comment on the success of the evolution mandate prior to the release of the revised TCPS, e.g., *"I am still unsure which changes will be formally adopted and implemented so I am unable to take position at this time "; "Nothing can be seen at this point. Given the protracted gestation of a revised Statement, one can only assume the worst:" (vs. "I'm still optimistic!").* Survey data show, however, that most stakeholders are optimistic about the final results of the evolution

work: 68% of PRE and PRE Committee members, and 74% of REB chairs and university research officers agreed that the modifications being produced of the Tri-Council Policy Statement will be helpful to the research community they are concerned with.

3.3 Impacts of PRE-SRE on interpretation of the TCPS

3.3.1 Response to interpretation needs

The PRE-SRE Interpretation function provides interpretive guidance for users of the TCPS. Users are invited to submit questions about interpreting the TCPS to the Secretariat. PRE-SRE retains for interpretation TCPS issues that have "broad, national application, or ones that present challenges at the institutional level"21, (i.e., uses the interpretation function as a user-driven means of providing policy-level clarification to the TCPS). Some questions that are submitted are therefore referred back to the users' institution or to other more relevant organizations, or receive a general response that is not considered an interpretation.

Questions that are retained for interpretation follow a defined process; this process has however evolved in the last year. Up until 2007, depending on the complexity of the interpretation and its novelty and impact, responses were formulated by the Secretariat or by PRE. The Secretariat conducted any necessary research and consulted with experts; and then prepared draft interpretations on which PRE was asked to provide input. Interpretations were approved by a quorum of at least seven PRE members. The final interpretation response was then prepared by the Secretariat, along with records of implications for changes to the TCPS. As there were often links between incoming questions and completed interpretations, the interpretation work aimed to be integrative and build on all existing interpretations.

Table 20 summarizes the SRE database of all interpretation questions and responses. As of July 2008, a total of 119 interpretation requests, 101 general requests and 17 "other" requests had been logged. Responses to 102 interpretation requests had been completed, while seven were ongoing.

The initial interpretation process proved to be quite slow. The PRE-SRE website initially promised to produce interpretations within 21 days; this was modified in November 2004. For requests made in 2004-05, the average time to produce a response was almost two years, at 98 weeks (see Table 20), due to time required for PRE to reach consensus on and approve the responses. By 2006, response to interpretation requests had cumulated a considerable backlog. Review of SRE files showed that prioritization criteria and processes to clear the backlog were discussed by PRE in June 2005. A revised internal SRE process for assigning and developing interpretations was approved in December 2007, where SRE staff handle most requests, preparing responses for PRE approval, and PRE's Standing Committee on Interpretation works directly only on requests raising novel and/or major points. In dealing with the backlog, SRE staff also contacted requesters and asked whether the response was still required: four of these were dropped. Six other requests were not processed. Overall, the time lapsed between the submission of the question and

---

21 http://pre.ethics.gc.ca/english/policyinitiatives/interpretation.cfm; see also "A collection of official responses form the Interagency Advisory Panel and Secretariat on Research Ethics, prepared in 2003, to community requests for interpretations of the TCPS (December 2004), which contains nine interpretations; and "Interpreting the TCPS, Volume II" (December 2006), which contains 10 interpretations .

the response has varied between one day and 4.1 years, but as Table 20 shows, has been reduced considerably since 2007/08.

Table 20: Response to TCPS interpretation questions

	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09
Number of questions received	26	19	20	8	15	20	11
Number of interpretations completed[1]	22	8	10	6	11	26	5
Mean (range) of weeks from request to output[2]	9.9 (1- 98)	56.7 (2 – 197)	97.9 (1 – 194)	35.2 (1 – 106)	27.4 (1 – 103)	7.6 (1 – 41)	2.0 (1 – 9)

[1]Completion dates were not recorded for 4 interpretations logged as be complete.
[2]Responses taking less than a week were coded as one week.

Satisfaction with the interpretation service. The survey of interpretation requesters' found that 12 of 23 respondents, about 50%, were satisfied with the service (see Table 21). Reasons given for satisfaction were related to clarity of the response: "*I asked a very simple and specific question, in return I received a very clear response.", "The answer was thorough, apt, and it was the one I was hoping for"; "The explanation was clear and succinct".* There are two sources of dissatisfaction: timeliness of the response (not surprising given the data in Table 19), and lack of clarity in the answer: "*The response did not address a crucial element of my question, rendering the response less than helpful"; "The answers from PRE have been unhelpfully vague and general when I have needed specific guidance"* . Ten out of 23 respondents (44%) were satisfied with the timeliness of the response, i.e., most were dissatisfied: "*It took several months (yes, months!) to get a response. It was completely useless to me, because the issue I was trying to solve was long decided by the time I got the response".* Open-ended responses suggested that requesters seemed to have expected a personalized, specific response to aid a particular decision, and thus within a timeframe structured by their internal processes, for example: "*I believe the response came nearly 10 months after I submitted my query. Far too long - decisions on applications cannot wait that long at my institution."*

Table 21: Interpretation requesters - Satisfaction with the interpretation service (n = 23)

	No. agree or strongly agree
The TCPS interpretation I received provided a satisfactory answer to my question.	12 (52%)
I received the TCPS interpretation within a satisfactory time delay.	10 (44%)

Data from the other surveys support those on interpretations requesters' experiences. In the survey of PRE and PRE Committee members, it was noted that while in the early years, the rapidity of responses had been quite unsatisfactory, there had been improvements more recently, e g., "*At the beginning, there was a long delay, but turnaround time has been reduced. In many cases, people have had to deal with the situation that led to the request well before they got the answer."* Similarly, Agency and SRE staff noted that while up until 2007, the interpretation function had suffered from untimely delivery and burdensome processes, the current management's implementation of systems and standards have now reduced the backlog and increased responsiveness. The initial approach to dealing with interpretation requests caused delays because replies aimed for maximum thoroughness, because interpretation competed with other mandates for scarce SRE resources, and because PRE approved all responses. According to informants, a

tension between becoming paralyzed in dealing fully with the complexity of the issues and the risks of responding too rapidly has been resolved in favour of a judicious balance. It should also be noted that the recently instituted practice of clarifying the question with the requesters may help ensure clarity of the response to them.

Internal respondents believe that demand for interpretations is decreasing as the research community becomes more familiar with the TCPS. However, some Agency respondents believe that awareness of the service is low because awareness of PRE-SRE is low: *"it would not be a reflex to go to PRE-SRE for interpretation"*. The interpretation service is seen as important, but, according to an Agency respondent, *"it needs to be more robust and effective. There is also a need for more education on it and more points of access to the service."*

3.3.2 Impacts on practice

A key question for the evaluation of PRE-SRE's interpretation mandate is whether the interpretations it has provided have made any difference to research ethics practice: whether users have been able to apply the interpretations in their research design and conduct, and whether this has resulted in more effective protection of human participants. Three populations of interpretation stakeholders were queried about interpretation impacts: the individuals who requested the interpretations in the first place, TCPS users to whom the interpretation were made publicly available, and internal and external PRE-SRE stakeholders.

Usefulness of interpretations provided to requesters

Table 22 shows the responses to questions about the utility and impacts of the interpretations of the TCPS provided by PRE-SRE directly to interpretation requesters. These responses are quite mixed, and suggest that the quality of responses as well as the delays in receiving them did not always allow them to be applied to research decisions, for example: "*Decision had already been made before the interpretation was received.": "The response was of no use because it did not address the issue I had raised."* Some respondents noted that part of the impact of the interpretations was to stimulate reflection on the issues, which could be seen as both helpful and unhelpful: *"The TCPS interpretations I have received seem designed to provoke thought, not provide clear guidance. Practical, not theoretical, issues should be more clearly addressed."; "The opinion is complex as is the issue, I think it would be unrealistic to expect its application to be easy as well. In fact, I think if it had been a simple matter, I would not have been motivated to request clarification."* In some cases, the interpretations confirmed existing practice: "*It confirmed what we had already put in place"; "It has supported our committee's decision making policies".* However, a few requesters reported that the interpretation had resulted in changes to their practice or their organization: *"The response was used to make governance decisions regarding research ethics approval process within our hospital".*

Table 22: Interpretation requesters - Usefulness and impacts of TCPS interpretations (n = 23)

	No. (%) agree or strongly agree
The TCPS interpretation I received was useful to me.	12 (52%)
The TCPS interpretation I received was used to make decisions related to conducting research.	7(30%)
It was easy to apply the TCPS interpretation I received.	11 (48%)

Utilization and usefulness of published interpretations

Once completed, interpretation results are anonymized and published on the PRE-SRE website and in document form as a compendium of interpretations. Currently the website contains 30 interpretation documents[22]. About three-quarters of the respondents to the survey of REB chairs and university research officers (76%) stated their REB was aware of the TCPS interpretations, while 62% had used them. More than three-quarters, about 78%, had found them useful (Table 23). Sixteen of 23 PRE and PRE Committee members (70%) agreed or strongly agreed that the TCPS interpretations had been useful.

Table 23: REB chairs and university research officers - Usefulness of TCPS interpretation mandate (n= 63)

	% Agree or strongly agree[1]	% Don't know
My REB is aware of the interpretations of the TCPS that have been published by the Panel and Secretariat on Research Ethics.	76.2	4.1
My REB has used some of the interpretations of the TCPS that have been published.	61.9	8.1
Overall, the interpretations of the TCPS have been useful.	77.6	6.1

[1] Out of all responses, including "don't know".

Survey respondents were also asked to rate the usefulness of the specific published interpretations. These data are summarized in Table 24.

[22] http://pre.ethics.gc.ca/english/policyinitiatives/interpretations/index.cfm. See also: Interpreting the TCPS (2004), which contains 9 interpretations, and Interpreting the TCPS, Volume II (2006), which contains 10 interpretations.

Table 24: Usefulness of published interpretations according to survey respondents

	REB chairs & Research Officers: % of REBs having referred to the interpretation (rank) (n= 47)	% of Panel and Committee members stating interpretation made using TCPS easier (rank) (n = 19)
Academic Freedom and the Role of the REB	45 (rank = 9)	47 (5)
Applicability of the TCPS to Agency-funded Organizations as well as those not Funded by the Agencies	36 (12)	42 (6)
Consent Procedures for Research in Schools, and Complaints About Research Projects	49 (8)	47 (5)
Data withdrawal in emergency health Research Situations	23 (15)	47 (5)
Definition of Quality Assurance Studies, Performance Review and Research	74 (1)	37 (7)
Ethical Considerations Related to Life Models in the Fine Arts	19 (16)	67 (1)
Institutional Permission to Conduct Research	55 (7)	42 (6)
Inter-University Ethics Approval, Naturalistic Observation and Privacy	6 (29)	37 (7)
Member Knowledgeable in Law and REB Membership	57 (6)	42 (6)
Occasional Videoconference Meetings for REBs	32 (13)	53 (3)
Proposed Establishment of Extra-Jurisdictional REB Subcommittee	28 (14)	47 (5)
Quorum for Research Ethics Boards	69 (3)	58 (3)
Reasonably Designed Inclusion and Exclusion Criteria and Applicable Human Rights Legislation	32 (13)	49 (5)
Record Retention: Departmental Reviews of Student Projects	38 (11)	47 (5)
REB Jurisdiction and Research Involving Humans Requiring Ethics Review	66 (4)	53 (3)
REB Legal Disclaimers and Inter-University Research Ethics Responsibilities	28 (14)	42 (6)
REB Membership and Decision Making: TCPS Articles 1.3 and 1.7	62 (5)	58 (3)
REB Membership—Individuals Knowledgeable in Ethics	70 (2)	58 (3)
REB Review of Previously Reviewed Administrative Research and Secondary Data Use	55 (7)	47 (5)
REB Role in Reviewing the Safety of Researchers	36 (12)	63 (2)
Requirement for an REB Review of a Technical Service	9 (17)	0 (8)
Research Involving Minimal Risk with Children and Inclusion of Vulnerable People in Research	66 (4)	53 (3)
Research or Art? Video Documentation of Reactions to Performing Arts	23 (15)	47 (5)
Retention of Research Data	55 (7)	53 (3)
Status of REB Decisions in the Absence of an REB Quorum	28 (14)	53 (3)
Survey Research by University Administrators: Requirement of REB Review	45 (9)	47 (5)
Third-party interviews or secondary use of data	49 (8)	58 (3)
US Ethics Committee Review of Clinical Trials in Canada	28 (14)	42 (6)
Use of Student Subject/Participant Pools in Research	43 (10)	42 (6)

Website usage statistics – number of page views and of downloading of the PDF documents – provide another indicator of the utilization of the published TCPS interpretations. The data for main page viewings are summarized in Table 25. Because the total number of viewings would be expected to vary with the length of time that the interpretation has been posted on the website (with perhaps a flurry of initial interest), both the total number of viewings and the mean viewings for each month that the interpretation was available are shown. The interpretations having received the highest total number of viewings are:

"Definition of Quality Assurance Studies, Performance Review and Research", "Reasonably Designed Inclusion and Exclusion Criteria and Applicable Human Rights Legislation" and *"US Ethics Committee Review of Clinical Trials in Canada".* The first of these has also been the most frequently viewed interpretation in the months that has been available, followed by *"Member Knowledgeable in Law and REB Membership"* .

Table 25: Website usage of TCPS interpretations – main page viewings

Interpretation	Total viewings	Mean viewings per month available
Definition of Quality Assurance Studies, Performance Review and Research	4294	68.2
Reasonably Designed Inclusion and Exclusion Criteria and Applicable Human Rights Legislation	2519	38.2
US Ethics Committee Review of Clinical Trials in Canada	2466	42.6
Inter-University Ethics Approval, Naturalistic Observation and Privacy	2461	42.4
Research or Art? Video Documentation of Reactions to Performing Arts	2376	42.4
REB Legal Disclaimers and Inter-University Research Ethics Responsibilities	2254	36.4
Quorum for Research Ethics Boards	2110	32.5
REB Membership and Decision Making: TCPS Articles 1.3 and 1.7	2036	33.9
Record Retention: Departmental Reviews of Student Projects	1974	37.3
Academic Freedom and the Role of the REB	1961	32.7
Consent Procedures for Research in Schools, and Complaints About Research Projects	1796	38.2
REB Membership—Individuals Knowledgeable in Ethics	1775	41.3
Ethical Considerations Related to Life Models in the Fine Arts	1598	17.6
Applicability of the TCPS to Agency-funded Organizations as well as those not Funded by the Agencies	1572	32.8
Institutional Permission to Conduct Research	1514	34.4
Retention of Research Data	1282	32.9
Third-party interviews or secondary use of data	1164	35.3
REB Review of Previously Reviewed Administrative Research and Secondary Data Use	1143	27.2
Proposed Establishment of Extra-Jurisdictional REB Subcommittee	1116	27.9
Occasional Videoconference Meetings for REBs	1048	55.2
REB Jurisdiction and Research Involving Humans Requiring Ethics Review	1047	31.7
Survey Research by University Administrators: Requirement of REB Review	846	27.3
Use of Student Subject/Participant Pools in Research	589	24.5
Status of REB Decisions in the Absence of an REB Quorum	468	18.7
Member Knowledgeable in Law and REB Membership	465	66.4
Requirement for an REB Review of a Technical Service	450	64.3
Data withdrawal in emergency health research situations	420	60.0
REB Role in Reviewing the Safety of Researchers	420	60.0
Minimal Risk with Children and Inclusion of Vulnerable Persons in Research	376	53.7
Researchers and the Duty to Warn: Limits on the 'Continuum of Confidentiality?'	116	7.7

Interestingly, when the usefulness of specific interpretations as rated by survey respondents is compared to the website statistics, there is only some convergence. Respondents to the survey of REB chairs and research officers rated *"Definition of Quality Assurance Studies, Performance Review and Research"* as the TCPS interpretation that had been most often referred to; while PRE and PRE Committee members rated "*Ethical Considerations Related to Life Models in the Fine Arts"* as the interpretation most helpful to applying the TCPS. This contrasts with the data in Table 25 showing that *"Member Knowledgeable in Law*

and REB Membership" and "*Definition of Quality Assurance Studies, Performance Review and Research'* have received the highest overall attention through the website.

Overall impacts of the interpretation mandate

Among some key informants who were familiar with PRE-SRE's interpretation mandate and its outputs, the interpretation service was seen as moderately successful. "They have done this a lot better. ….The questions that they have resolved are important ones." The interpretations were seen as important in increasing consistency of TCPS application and in developing a common understanding at the level of research institutions: "because there does need to be some common language at an institution level". Echoing data from the survey of interpretation requesters, a main value of the interpretation was seen not in providing strict rules-based guidance, but rather in informing discussion within institutions: "If it does inform discussion, then it has been successful, and that is where the TCPS has had its greatest utility." A key informant noted that in his experience, interpretations had been wise, appropriately analyzing roles and responsibilities and providing a useful response when multiple parties had multiple interpretations. However, it was also noted that existing interpretations have not produced guidance for all sections of the TCPS: "guidance documents on various sections are still needed, and these should be produced as quickly as possible, not languish." PRE-SRE's capacity to produce these with its current staff resources was questioned. It was noted that the interpretation function is seen as responding to the perspective of REBs, but that this was too narrow: "REBs are not hands-on in terms of research design and conduct. More responsibility should be given to other stakeholders: researchers, individual, community and participants."

Some external key informants were sceptical of the value of the interpretation function: "It has not had a huge impact"; "No one has told me the interpretations have been useful and in some cases they are disputed". One specific interpretation said to be problematic was that regarding minimal risk under the issue of proportionate review which remains, according to some respondents' observations of their communities, controversial. Other external key informants expressed a concern that relates to a more general issue of TCPS application: that it is not known to what extent and how the interpretations are being applied: "We don't have any idea of what we are actually doing to protect human subjects" ; "How do users make use of the TCPS in the field?"

SRE staff noted that the interpretation function has aided more consistent TCPS application across institutions, and has helped to educate people new to the ethics debate and review process. However, in terms of the utility of the interpretation function to TCPS users, an internal respondent noted that *"interpretation is a difficult challenge, because PRE-SRE are constrained by the mandates of the three Agencies. They cannot act as a decision maker or an arbitrator…. Therefore, the opinions given are general in nature".*

3.3.4 Impacts on evolution of the TCPS

One of the key functions of the TCPS interpretation service is to help identify emerging issues that can inform evolution of the TCPS. Overall, the data suggest that while interpretations have borne fruit for TCPS evolution, the mechanisms linking TCPS evolution and interpretation may also require clarification. In the survey of PRE and PRE Committee members, sixteen of 23 respondents (70%) agreed or strongly agreed that the interpretation function had been useful to evolution of the TCPS. But, concerns were voiced by two

respondents about the link between the interpretation and evolution functions: *"There is not enough co-ordination between those doing the interpreting, and those planning TCPS changes"; "It is not clear how the interpretations will be worked into the revised statement".* Two respondents questioned the value of providing interpretations of a policy that will be rendered obsolete with the new edition, arguing that the changes should have been made directly in the TCPS rather than as a separate corpus*: "Having compendia of interpretations means that one must continuously jump from TCPS to interpretations. One wonders why PRE-SRE has not taken the baby step of referencing the interpretations in the TCPS itself.*

According to SRE staff respondents, the interpretation function has been useful to TCPS evolution, providing opportunities to review areas of the TCPS that may contain gaps in the policy. An example provided here is data retention policy, which had not been addressed in the original TCPS.

3.4 Impacts of PRE-SRE on education of the research community

3.4.1 Overall approach and success

The mandate of PRE's Standing Committee on Education is: "To advance policy initiatives on educational dimensions of the TCPS". PRE's Standing Committee on Education has produced three main outputs: the TCPS on-line tutorial, collaboration on a National Research Ethics Education Strategy, and a study of education needs of community REB members. In addition, PRE has collaborated with other organizations involved in ethics education, primarily NCEHR.

Overall, external key informants' views of PRE-SRE's contribution in ethics education were quite positive*: "They have been more successful here"; "It's succeeding. I see this as an ongoing thing. It's not achieving universal education, but the effort continues".* However, it was noted that ethics education should be seen primarily as a responsibility of the universities, with PRE-SRE having a limited role: *"The mandate to educate is at the university level. …. It would be difficult for the Panel to influence the education process."* Several respondents were not aware of PRE-SRE activities in ethics education, stating for example that they believed education is being conducted only by NCEHR. .

PRE-SRE's approach to its education mandate has evolved over time. Its initial plan for the education mandate included educational visits, accompanying NCEHR in its existing educational visits program. The document review shows that in initial meetings, PRE saw itself as playing a supportive role in ensuring effective implementation at the institutional level through these visits. PRE's 2002 workplan included setting up a consultative visit system, which PRE explored throughout 2003/04. It was then proposed that SRE staff accompany NCEHR. Among external stakeholders who had followed PRE-SRE's education activities, this initial education plan was seen as both too ambitious (e.g., "*it was grandiose in terms of what they wanted to do in education. The role was overreaching, and they had no resources"*) and encroaching on work already done by NCEHR. The proposal to conduct such institutional visits was not well-received; and as one observer (external to both NCEHR and PRE) noted, it "*created a petty conflict with NCEHR*". PRE noted at its June 2004 meeting that NCEHR was not willing to partner in these visits. At that date, the minutes show that the PRE Implementation Committee recommended that PRE reconsider its position on visits, to focus on public consultation, and to develop an agreement with NCEHR to obtain summary information of any policy-relevant implications of the results of NCEHR's visits. Part of the budget under-spending in 2002-03 and 2003-04, can be attributed to the fact that these visits did not take place – they

were allocated budgets of $75,000 and $50,000 in those two years respectively, accounting for 22% and 16% of the amounts not spent, respectively (see Table 2).

3.4.2 Collaboration with other organizations involved in ethics education

With respect to effectiveness of collaboration with other organizations, concerns were raised about overlap among mandates in ethics education mandates and some related tensions. Most external stakeholders who were familiar with this element of PRE-SRE's mandate spoke about its relationship with NCEHR, noting some confusion or overlap in their mandates, for example: *"Sometimes I get all the Agencies confused as to who is doing what and why. We had a visit from NCEHR, and thought it was the PRE, and I still don't understand who NCEHR is."* A similar confusion was noted among some PRE and PRE Committee members, for example: *"PRE-SRE has collaborated extensively with NCEHR, but the biomedical roots of NCEHR have at times undermined the possibilities for broader educational initiatives that could be undertaken by PRE-SRE if NCEHR were not presenting itself as the main player. Despite years of involvement, I still don't fully understand NCEHR's role and feel that PRE-SRE has not done a good job in helping the community disentangle PRE-SRE from NCEHR leaving considerable confusion."*

Survey responses documented that following the initial dissension over the educational visits, the relationship between PRE and NCEHR was characterized by tension and lack of trust. This was exacerbated when, through CIHR intervention, funding that the SRE would have lapsed was used to contract NCEHR's services for educational activities (see section 1.2: 85% of the education mandate budget was expended on contracts with ethics education organizations, including NCEHR). It was noted in the survey of PRE and PRE Committee members that the use of PRE-SRE funds in contracts to NCEHR had been awkward and that it used resources that PRE would have be able to dedicate to its own purposes. And, according to external stakeholders, although the relationships are more collegial, the inter-organizational tension has not been resolved, and an issue persists as to how PRE-SRE perceives its role in ethics education versus policy-making. A consequence of this is, according to some key informants, is that PRE-SRE has missed opportunities: to understand better how the TCPS is being interpreted, and to play constructive roles nationally, provincially or locally. In terms of collaboration, the Agency respondents noted there is need for PRE-SRE to work in a decentralized way, sharing responsibility with universities as well as other ethics organizations including but not limited to NCEHR, and also conducting more outreach. Agency respondents also described the conflict with NCEHR, but believe that more recent collaboration has been effective. SRE staff noted that there have been collaborations with NCEHR, CAREB, Health Canada, CAURA, and the CIHR Ethics Office, and these enjoy excellent relationships at the level of individuals.

3.4.3 TCPS tutorial

The PRE Standing Committee on Education was responsible for developing an online tutorial for the TCPS. A request for proposals for development of the tutorial was announced in May 2002. The initial timeline saw the tutorial being launched in January 2003, but it was not launched until April 2004. The tutorial's overall aims are: "*to educate the research community about the TCPS; and to facilitate the use, interpretation and implementation of the TCPS*". It includes the following topics: ethics review; free and informed consent; privacy and confidentiality in research; conflict of interest and inclusion in research. It includes three case studies that are integrated into all the sections. In collaboration with the Social Sciences and Humanities

Working Committee, the Education Committee added a fourth case to the tutorial in early 2008, in the social sciences and humanities area.

Tutorial usage

The TCPS tutorial has enjoyed very high usage: as of July 2008, a total of 43,045 registrations had been recorded, and 31,721 individuals had completed the tutorial. As Table 26 shows, usage levels – both registration and completions -- have been increasing gradually over time.

Table 26: TCPS On-line Tutorial usage

	Average no. of users per month		
	2004-2006	2006-2007	2007-2008
Users	1,083	1,096	1,130
Completers	737	822	882

Responses to the SRE's tutorial evaluation questionnaire show that its completion is mandatory for about 68% of those who take the tutorial. Some key informants noted that the tutorial is mandatory at many institutions, and being proposed for this status at others, albeit sometimes more to promote the TCPS than to effect ethics education. *"At many institutions it is mandatory, so it is effective as a communication tool."* However, the data shown in Table 8 indicate that despite this high level of usage, it is uneven across the country: 57% of those who completed the questionnaire are in Ontario, 25% are in British Columbia, and there are very few tutorial takers in the Atlantic provinces. These data are to some extent consistent with those found in the researcher survey, where researchers located in British Columbia were significantly more likely to indicate that their students are required to take the tutorial (41%) and researchers in the Prairie provinces and territories significantly less likely (11%). This suggests that some jurisdictions have gone further in making the tutorial a mandatory part of research training and/or practice. Some unsolicited comments from the researcher survey also suggest there is room for more promotion: "*We are intrigued to learn that there is a tutorial on the TCPS - which we have now discovered by doing this survey. Clearly there is room for improved communication."; "I did not realize there was an on-line tutorial. I will now pursue it and use it in my teaching."*

Data from the surveys of REB chairs and university research officers are shown in Table 27. Fifty-six (56%) of REB and university research office respondents had used the TCPS tutorial. For these, PRE-SRE educational tools are most useful to REBs, and to a lesser extent to researchers and students. One half of REB and research office respondents agreed that the tools are being used by those who can benefit from them.

Table 27: REB chairs and university research officers:
Success in the TCPS education mandate (n= 103)

	% Agree or strongly agree[1]	% Don't know
The educational tools developed by the Panel and Secretariat on Research Ethics are being used by those who can benefit from them.	50.0	19.7
The educational tools developed by the Panel and Secretariat on Research Ethics are useful to researchers.	68.8	16.7
The educational tools developed by the Panel and Secretariat on Research Ethics are useful to students.	60.6	19.7
The educational tools developed by the Panel and Secretariat on Research Ethics are useful to Research Ethics Boards.	83.3	7.6

[1] Out of all responses, including "don't know".

Twenty percent of researchers had used the tutorial, and 15% said that their students are required to take the tutorial. This proportion was higher among researchers associated with NSERC (21%). A strong majority of those who had used the tutorial, 81%, agreed or strongly agreed that the tutorial had been useful to them – a stronger endorsement of the utility of PRE-SRE's educational tools than that proffered by the REB chairs and research officers, of whom 69% agreed that those tools had been useful to them (Table 27). Researchers associated with NSERC were less likely to indicate that they strongly agreed with the usefulness of the tutorial compared to CIHR and SSHRC researchers (3% vs. 22% and 22% strongly agreed, respectively).

Tutorial users' views

Data from the prospective survey as well as the existing tutorial survey showed that for most users, the tutorial met or exceeded expectations (Table 28).

Table 28: Tutorial compared to users' expectations

	Prospective survey (n = 55)	Existing survey (n = 7,783)
It exceeded my expectations.	22%	21%
It met my expectations.	64%	56%
It barely met my expectations.	7%	1%
It failed to meet my expectations.	0%	1%
I had no expectations about the TCPS Tutorial.	7%	10%
No answer		10%

Open-ended responses asking for explanation of the responses given in Table 29 show that the satisfied users found the tutorial to be informative and comprehensive, answering their questions and providing a good overview of research ethics with humans: "*It was a good review of research ethics, and I learned more than I expected*"; " *It was very detailed and in depth. I felt that it was a very comprehensive study of the topic.*"; *"Plenty of information, great scenarios*". Those whose expectations were not met had comments such as: *"It was very informative but at the same time, the material did not feel very user-friendly. It became a struggle to continuously work on it; personally I needed to take a few breaks in between, which is quite*

unusual for me"; " I found the course very theoretical and examples and cases did not help me very much to understand the material in a practical way."

According to respondents to the prospective survey as well as the existing survey, the on-line tutorial increased their knowledge of the TCPS significantly or moderately (84% in both surveys, although the distribution varies).

Table 29: Self-reported increase in TCPS knowledge

	Prospective survey (n = 55)	Existing survey (n = 7,783)
My knowledge of the TCPS increased significantly	22%	48%
My knowledge of the TCPS increased moderately.	64%	36%
There was no increase in my knowledge of the TCPS	0	1%
There was no increase in my knowledge because I was already familiar with the TCPS.	2%	3%
No answer		12%

Those who stated there had been no increase in their knowledge provided two types of explanations: first, that they had already encountered the material: "*I had already learned about the TCPS in school. I took the course as a refresher for a licensing exam"; "La matière enseignée dans les cours de méthodologie en psychologie comprennent pratiquement tous les points abordés"* and second, that they weren't sure of their long-term retention of it: "*I found that my knowledge of the material increased, but I am not sure of the long term effects. Looking back I'm trying to remember if I retained much of the new information that I learned*; "*mes connaissances ont quelque peu augmenté. Malheureusement, peu des informations me sont restées en mémoire, peut-être y aurait-il eu moyen de synthétiser l'information afin qu'elle soit plus facile à mémoriser ».*

Tutorial Impacts on practice

Table 30 summarizes the quantitative ratings of the tutorial impact. The vast majority of respondents stated that the tutorial was useful, and about half of the users stated that the tutorial had helped them make research decisions, apply the TCPS, or improved the ethics of their research.

Table 30: Tutorial users' survey: ratings of tutorial impact (n = 55)

	No. (%)Agree or strongly agree[1]	No. Don't know
The TCPS tutorial was useful to me.	49 (89%)	1
The TCPS tutorial helped me make decisions about my research.	26 (47%)	4
After taking the tutorial, it was easier to apply the TCPS.	32 (58%)	3
Taking the TCPS tutorial resulted in improvements to ethical research practice involving humans.	32 (58%)	6

[1] Out of all responses, including "don't know".

A content analysis of the responses provided as explanations for all of the ratings in Table 34 identified various ways that the tutorial content met users' needs:

- Preparation for future research: e.g., "*I am yet not involved in research where I can apply the TCPS knowledge"; " Avant de me lancer dans la recherche pour la première fois le didacticiel m'avait aidé à réfléchir sur les conséquences possibles".*
- Reconfirmation or review of prior knowledge: e.g., "*Taking the tutorial confirmed that I was already doing ethical research prior to the tutorial." ; "Knowing about TCPS did and the tutorial was an efficient and easy way to recap the core principles that I had previously learned."*
- Improved understanding/questioning of knowledge or principles, e.g., ":*It was an education for it provided unknown information and introduced me to issues that I did not consider";" It made me question or think differently about some aspects of my own research and methodological approach."*
- Impact related to research role, e.g.: "*I have little influence on my researchers' decisions, however, it has allowed me to be stronger in presenting the ethics issues when I have a chance to do so."; "It is easier to push back against poor ideas because I have better language now that I have completed the tutorial."*
- Increased accessibility of information, e.g., "*It provides important information in a manner that is useable by the health care professional new to research"; "I can't honestly say if the tutorial made it easier to apply the principles than just consulting the guide would have been. I think the effect is equivalent. Having multiple ways of making the information available is, however, important in order to reach everyone"*
- Class assignment, e.g. "*I did the survey as part of a course. I intend to go into clinical trials/research but am not in that field yet"; " I had to do the tutorial for a class assignment."*

Twelve out of 55 respondents (22%) provided examples of how they had applied the tutorial material. These included:

- *I became more alerted about ethics on human research - for example not even roughly seeing patients charts (those who I cared for) for research purpose before ethics clearance.*
- *Formulaire de consentement auprès d'une population qui ne comprend pas très bien l'anglais ou le français*
- *I did not know the guidelines about non-participant observation. The TCPS helped me to clear what I should do for ethics review in such data collection methods.*
- *Recently I submitted an IRB proposal and doing this tutorial helped me a lot to complete the proposal.*
- *I am new to research ethics and the tutorial helped me with the job that I do everyday.*

For these tutorial takers, the tool is contributing to its intended aims of improving research ethics practice.

The SRE has also conducted some content analyses of the comments received to its questionnaire, identifying whether comments received are editorial, technical or substantive[23]. This has enabled resolution of some early technical problems with printing, password or similar issues, as well as some substantive issues that have also received attention (for example, preparation of the fourth case study, mentioned above).

Stakeholders' views of the tutorial

The tutorial is seen by all internal stakeholders as a key success of the PRE-SRE, because of its high level of use. The inclusion of the new case study in the social sciences is also a positive step. External key informants interviewed were aware of the tutorial, and based their remarks on their own assessment as well as their assessment of its success within their constituencies. The tutorial was applauded by many of these informants as a key output of the PRE-SRE, filling an important niche particularly for educators. .*"The tutorial has played a useful role"; "I like the tutorial, its very well done."*

Both Agency and SRE respondents noted that the tutorial is seen as having some limitations in terms of depth and coverage. External key informants had also been made aware of criticisms and concerns about the tutorial, and some had their own. These centred on its incomplete coverage of the TCPS, and its basic level. "*It could be more sophisticated, but they have done something. It has limited coverage of the TCPS, and is not up to what's going on in other countries."; "Our analysis of the tutorial was that it was not very efficient. It gives people some information…. It's not good for education: the content isn't great in terms of how much you learn".* According to some key informants, there is a need for tools that provide more comprehensive and more advanced ethics education. Québec's online tutorial was mentioned several times as such a tool; indeed it appears that one major university health research network outside Québec will be adopting mandatory completion of the Québec tutorial rather than the TCPS.

3.4.3 Other education initiatives.

In addition to the above, other education related initiatives include a focus group-based study of the education needs of community members sitting on REBs.[24]

PRE, in conjunction with the Standing Committee on Education, has also prepared a position calling for the development of a National Research Ethics Education Strategy[25]. As this strategy would extend beyond the PRE-SRE mandate of TCPS education, it would be supported, but not led by, the PRE. PRE-SRE's contribution to the development of a national education strategy was praised by an external stakeholder, who said: "*Toward the development of a national strategy, PRE has been an important ally. It has helped- no question – it would not have been possible without PRE and others";* but also noted "*But there is more*

---

[23] Sample TCPS Tutorial On-Line Feedback from User Community (June- November 2005), by nature of comments.

[24] REB Community Member Education Needs: A PRE Pilot Project Summary Report. http://www.pre.ethics.gc.ca/english/policyinitiatives/EducNeedsPilotProjSep07.cfm

[25] Education is Key to a New Culture of Research Ethics: Update on PRE's Call for a National Research Ethics Educational Strategy Briefing note to Panel, September 2006.

that could, needs to be done". Indeed, several external stakeholders emphasized the urgent need for effective ethics education. Agency stakeholders concurred that there is a great need for research ethics education, with some maintaining that it is the most strategically important of PRE-SRE's mandates. Although PRE-SRE's education activities to date are seen by some internal and external stakeholders to have been limited: *"There is not enough done in the area of education. Up to now, and understandably, the effort was spent on evolution - more could be done";* it is also seen as the mandate area that should come to occupy most of PRE-SRE's energies once the second edition of the TCPS is published.

3.5 Contribution to increased assurance that research participants are adequately protected

PRE-SRE's role in contributing to the most important outcome of the entire human participants research ethics enterprise -- increased assurance that research participants are adequately protected and risks are balanced against the benefits of research --- is indirect and supportive, as direct responsibility rests with institutions and researchers. The evaluation nonetheless examined PRE-SRE's contribution from their perspectives.

3.5.1 Impacts at the institutional level

Table 31 shows data from the REB chairs and research officer surveys on the impacts PRE-SRE is perceived to have on the capacity of institutions and REBs to ensure improved ethical policies and practices. About one-half of the responding REB chairs and research officers state that PRE-SRE is helping to ensure that policies are in place (51%) and that ethics practices are adequate (51%). This proportion is higher among those who are aware of PRE-SRE's mandate (data not shown in table below): about two-thirds agree that its contribution is positive to the research community (65%) and to institutional ethics policies (63%) and practices (69%).

Table 31: REB chairs and research officers - Impacts of PRE-SRE on ensuring ethical practices (n = 103)

	% Agree or strongly agree[1]	% Don't know
The activities of the Panel and Secretariat on Research Ethics are helpful to the research community I am concerned with.	45.6	10.7
The activities of the Panel and Secretariat on Research Ethics are helping to ensure that policies for the ethics of research with human participants are in place in my institution.	51.4	11.7
The activities of the Panel and Secretariat on Research Ethics are helping to ensure that human research ethics practices in my institution are adequate.	50.5	11.7

[1] Out of all responses, including "don't know".

Open-ended comments from REB chairs illustrative of varied points of view were*: "The ongoing efforts of PRE to involve members of the research community in working papers on emerging ethical issues is evidence that they are working to address these issues. Their presence as a central authority on research ethics is now taken as given." ; "'I am aware of the Panel but not certain of how it works or how recommendations have influenced practices within my institution."*

3.5.2 Impacts on research participants

All respondents to the survey REB chairs and university research officers and researchers who had heard of PRE-SRE were asked to indicate their views on the balance of risks to research participants against the benefits of research. Among REB chairs and university research officers, there was almost unanimous support for the (somewhat self-serving) statement that REB review at the respondent's institution ensures an appropriate balance. Almost half of respondents agreed that PRE-SRE was contributing to this balance; while 18% didn't know and 23% gave a neutral response. Among researchers, 78% agreed that REB review ensures a balance between risks and benefits. Researchers associated with CIHR were more likely to agree strongly (55%) while NSERC and SSHRC researchers were less likely (25% and 29%, respectively). Overall, 42% agreed that PRE-SRE is contributing to this. Nineteen percent of researchers gave a "don't know' response to this last question.

Table 32: REB chairs and university research officers and researchers views on contributions to balancing risks and benefits

	% Agree or strongly agree	
	REB chairs and research officers (n = 103)	Researchers (n = 195)
In general, review by an REB at my institution ensures that the risks to research participants of participating in research are appropriately balanced against the potential benefits of the research.	95.2	78
The Panel and Secretariat on Research Ethics have contributed to ensuring that risks to research participants at my institution are appropriately balanced.	47.6	42

3.5.3 The TCPS and constraints on research

One of the criticisms made of the TCPS in the research community has been that it overreaches on the side of participant protection and in so doing, limits or constrains the possibility of conducting some types of research. This is seen by some as an untenable restriction on academic freedom and the advancement of knowledge. The evaluation collected some information on this question, as it is relevant to the overall acceptance of the TCPS.

Of researchers who have heard of PRE-SRE, 68% agree or strongly agree that the TCPS is an important guideline to increase protection of research participants. At the same time, 66% agree that the way the TCPS is applied constrains some types of research. Perception of constraint did not differ by discipline, although natural sciences and engineering researchers were more likely to state 'don't know". A summary of content analysis of qualitative responses to this question is shown in Table 33. It is interesting to note that many of these concerns are intended to be addressed in the revised TCPS.

Table 33: How the TCPS constrains research – main themes, researcher survey

Response theme	Examples, by Agency the researchers is associated with
Greater difficulty in recruitment of participants	CIHR (from 43 responses) - *My biggest problem concerns access to potential subjects. Though I totally agree with the need to protect subjects, researchers are being so limited in their ability to have the opportunity to even propose the research project to potential participants, that it gets totally discouraging to even think about doing large scale projects. The greater problem with this, is that some centers seem to have much greater access than others…..* - *The way TCPS is currently applied by the REBs significantly impacts certain minimal risk, participatory action research. Specifically, the consent processes that are being required makes this kind of research very difficult, with long, legalese consent forms that overstate the risk of the study, which can deter potential participants from participating in the research* NSERC (from 44 responses) - *Length of recruitment or justification of recruitment for research with children even if they have been followed-up since birth by research teams - justification for any change (even minor) in recruitment, for example, in the exclusion criteria..... ...all these changes or requirements depending on the meeting dates of ethics committees which are not so often (even if regular).* SSHRC (from 119 responses) - *L'obtention d'un consentement éclairé auprès de certains publics (notamment des personnes délinquantes non encore arrêtées par des services de police par exemple) empêche la collecte de certaines données pourtant nécessaires à l'avancement de nos connaissances*
Inapplicability to all research paradigms	CIHR - *Community based action research does not fit readily within the strictures of the existing informed consent paradigm. Research with Aboriginal collaborators is constrained by the usage and signage of bureaucratic forms* - *The increasing requirements for individual patient consent for collection of epidemiologic data, medical chart review, record linkage and acquisition and the usage of biological specimens can be restrictive. The forms should be different for epidemiologic trials and for clinical research interventions.* NSERC - *I and the graduate students that I advise work with farmers and Aboriginal communities in participatory and people-centered ways that act to affirm their knowledge systems and livelihoods. To that end, assumptions of anonymity and confidentiality ironically often act to (literally) invisibilize their roles in this research. Similarly, the prescriptive research process that the REBs demand arguably undermines the iterative and open-ended research that the communities we work with desire and, in some cases, demand.* - *I believe the TCPS is overly constraining with respect to conducting qualitative studies of human-computer interfaces. Early stage research in this area often requires in-depth study of people using interfaces with limited ethical concerns, yet the TCPS guidelines if strictly interpreted can make it onerous to express how exploratory qualitative studies do not violate such guidelines.* - *Observational studies in natural environments can be hampered if there is a requirement to force all people the researcher comes in contact with to sign the kind of legal document that is in the front of this questionnaire. - Overly formal procedures can impair the researcher-participant relationship.* SSHRC - *We often run into problems with our REB because the TCPS has been interpreted through the medicalised approach to research ethics. This forms a bureaucratic framework that is problematic for social science researchers. I would like to see the Panel and Secretariat work to assist REBs to develop protocols that meet the needs of all researchers and protect the interest of all communities, whilst avoiding a tendency to rely on the medical model as the primary model for REB approvals.* - *The ethics principles appear to be driven by the medical research model. This is inappropriate for most social science work. There should be a fundamental rethinking of the role of the consent process. It seems to be a legal "fig leaf" rather than a serious concern for ethics.* - *I think a separate panel should exist for people in the arts. The criteria related to research ethics are not the same as those for people in the social sciences.*
Application by REBs, unevenness in application	CIHR - *I don't think its necessarily the TCPS but the way it is interpreted by ethics boards etc. that might get in the way of research. For example I think in observational research, such as linkages of large patient registries with vital stats registries, one could interpret the TCPS as suggesting that specific informed consent for the linkage might be waived, on the basis of little or no potential for harm, infeasibility of obtaining consent on all individuals, etc. However, I am not sure all ethics boards interpret the TCPS the same way.* - *Review of research protocols in every jurisdiction where there is a co-investigator requires filling out different forms, different time-lines for submission, different times to review etc., and more importantly, different expectations and questions from different committees around methodological issues. A proposal passed by six committees can be held up because someone on the 7th committee has a personal opinion about the 'vulnerability' of subjects - etc.*

	- *The biggest issue is the non-standard approach by REBs in interpreting and administrating the guidelines. Multicenter research is a nightmare as the application process is vastly different site to site, as is what is allowed or not.* NSERC - *Ce n'est pas tant l'EPTC comme les délais locaux, et les lois provinciales, entre autre pour les sujets mineurs, dans l'évaluation des demandes qui sont soumises à l'obligation de se conformer à l'EPTC.* - *It's not necessarily the principles in the TCPS that are sometimes constraining to research, but rather the interpretation of these principles by our local ethics board, or sometimes the ignorance or misapplication of these principles, that can lead to problems.* SSHRC - *The university research panels do not interpret the guidelines in the same way. This affects the application of projects that involve teams from a range of universities. It would be helpful to have some way to adjudicate collaborative projects by a single source instead of each researcher having to submit to their own institution and being asked to make changes that are inconsistent with the national project research design.* - *Je suis étonnée que les universités ne reconnaissent pas les certificats obtenus auprès du CER de l'institution d'attache du chercheur principal dans le cadre d'un projet en équipe multi-université. Le processus de passer à l'évaluation auprès de multiples CER (pourtant liés par l'EPTC) est un facteur d'inefficacité qui génère des retards importants dans le réalisation d'un projet de recherche.*
Complexity, bureaucratic procedures	CIHR - *Should not underestimate the benefit to applied clinical research, nor the amount of delay imposed by extensive ethical evaluation and the increasing amount of time devoted to filling out redundant forms. Why the need for annual review. I routinely warn young investigators to reconsider clinical research as a potential career because the constraints are simply too great and the rewards too few. This is becoming an enormous problem in Canada and should not be ignored. However, not too late to fix.* - *I have found the TCPS to be a largely bureaucratic enterprise that if anything interferes with ethical consideration of research proposals. I believe more patients have been harmed by the TCPS than have been helped* NSERC - *Annual renewal is an unnecessary bureaucratic requirement. Reporting on studies (in addition to publications) is an unnecessary bureaucratic requirement. REB panel members often require petty minor changes that really have nothing to do with protecting participants* - *Les exigences de l'EPTC ralentissent le processus de recherche en induisant des contrôles abusifs à toute étape de la recherche. L'université applique à la lettre ces recommandations ce qui paralyse la recherche indûment.* SSHRC - *There HAS to be a guideline that requires the ethics process to be run in a timely fashion. Otherwise, it's punitive.* - *I think it is a waste of time and should be dissolved. There is enough bureaucracy already.*
Added costs	CIHR - *It has made if more difficult to track participants for longitudinal studies. Also, institutions interpret guidelines differently so it makes multi-site studies increasingly more difficult and more cumbersome. Research budgets may not necessarily cover all the additional expenses.* - *D'une manière générale, les démarches et formulaires que le chercheur doit effectuer ou remplir sont trop nombreuses et trop compliquées. Les chercheurs n'ont pas les ressources pour supporter les démarches et contraintes qui se multiplient d'année en année autant au niveau fédéral que provincial pour l'approbation des projets chez l'humain. Dans mon laboratoire, je consacre une 50% de salaire uniquement pour les procédures de comité d'éthique. Il est urgent de simplifier toutes ces procédures et d'assurer un support aux chercheurs pour assumer cette tâche qui devient démesurée. Sans quoi beaucoup de chercheurs vont abandonner la réalisation des projets de recherche chez l'humain.* NSERC - *Well, I disagree with the first statement, that "ALL research that involves living human subjects requires review and approval by REB ..." There is a vast array of research 'involving' human subjects that has no potential for damage, harm, etc. Subjecting these projects to excess scrutiny costs money and time, and more often that many would admit there is a lost opportunity due to temporal overhead.*

3.6 Success of PRE-SRE in meeting Agency objectives and expectations

3.6.1 Capacity to ensure that research is carried out with the highest ethical standards

Data on PRE-SRE's success in enhancing the Agencies' capacity to ensure that the research they fund is carried out with the highest ethical standards come from two sources: the survey of PRE and PRE Committee members, and interviews with internal stakeholders (Agency and SRE staff). The majority of the former either viewed PRE-SRE's contribution positively or couldn't provide a rating. Fifteen of 24 (63%) respondents agreed or strongly agreed that PRE-SRE have helped each of the Agencies ensure that the human research they fund is carried out with the highest possible ethical standards, while six didn't know. Twelve out of 24 (50%) agreed that creating PRE-SRE has helped the Agencies make the best use of the resources they have dedicated to research ethics (two didn't know).

Internal stakeholders were asked to assess the extent to which PRE-SRE has helped each of the Agencies ensure that the human research they fund is carried out with the highest possible ethical standards. Many of the Agency representatives' responses centred on SRE's role in reviewing institutional policies (see below). One Agency noted that the PRE-SRE had allowed the Agencies to be more effective in that it created a critical mass and allowed greater commitment to ethics issue, as officers do not get sidetracked into other files. Some Agency respondents also mentioned PRE-SRE's support to the Agencies in preparing responses to the Sponsors' Table documents, again citing this positively, as well as more general support by keeping the Agencies informed of developments in the ethics field.

Capacity of each Agency

NSERC. According to internal key informants, PRE-SRE's roles have been especially useful to NSERC, who has no other ethics resources. SRE's review of institutional policies has benefited NSERC as it has expanded its funding programs to include colleges.

SSHRC. SSHRC has also benefited from PRE-SRE's role, but internal key informants acknowledged that it had not always been seen as important. *It was noted that there had been: "a paradigm shift from low priority at SSHRC in 1996 to center stage in 2008". A majo*r issue for SSHRC's community was the perception that the TCPS was geared toward biomedical research, and in particular research that poses higher risks to participants. High-risk research is believed to be not as prevalent in the social sciences, and it is felt within SSHRC that there could be a different path for low-risk research, possibly one that does not involve accreditation systems. SSHRC has benefited until 2007 from the support of SSHRC staff assigned to SRE for its own ethics needs at the corporate level.

CIHR. Because CIHR maintains its own Ethics office, its representatives view this office as mainly responsible for achieving CIHR ethics objectives. Until recently, this Office worked on its own, noting that the absence of output from PRE-SRE meant that CIHR itself had to do all the work it required in the area of ethics. SRE staff observed that this has resulted in confusion in the community, because it is difficult for outsiders to distinguish the work of the CIHR ethics group and of the PRE-SRE.

When asked about areas for potential operational improvements, relationships with CIHR were one of two issues most frequently signalled by PRE and PRE Committee members, mainly because of the latter's independent ethics initiatives: *"At some point CIHR, probably frustrated with PRE's slow pace, just went its*

own way and starting doing things that are really in PRE's mandate. I don't blame CIHR, but this should have been ironed out differently."; "CIHR must improve its coordination/cooperation with the PRE-SRE. Unilateral action and frequent lack of effective communication and consultation by CIHR – despite best efforts by PRE-SRE - have hampered the effectiveness of both organizations"; "Little communication with CIHR Ethics Office and no communication with IABEDs (Institute Advisory Board Ethics Designates)." However, the recent changes within PRE-SRE have been associated with greater coordination and the elimination of redundancy.

3.6.2 Effectiveness of Agency support to PRE-SRE

Internal stakeholders were asked whether the Agencies have provided effective support to PRE-SRE. Responses here were somewhat mixed: some Agency respondents were critical of their own lack of oversight and follow-up, to which was attributed delays in some of PRE-SRE's outputs (e.g. stem cells). As Table 34 shows, there is also comparatively high level of dissatisfaction among PRE and PRE Committee members with the support provided by the Agencies, in overall terms, in resource levels, and in terms of inter-agency management (although there is again a relatively high proportion of "don't know" responses).

Table 34: Panel and Committee members' views of effectiveness of Agency support to PRE-SRE (n = 24)

	Agree or strongly agree	Don't know
In general, the three Agencies have supported the PRE-SRE effectively.	10	6
The three Agencies have provided effective inter-agency management of the PRE-SRE.	6	9
The three Agencies have supported the PRE-SRE in their communications to external stakeholders about the nature of their relationship with PRE-SRE.	10	8
The three Agencies have supported the PRE-SRE in their communications to the public.	9	8

Particular concerns that emerged about Agency support were:

- inconsistency among the Agencies in their degree of support;
- perceived failure of the Agencies to adopt research ethics as a strategic priority, and
- perceived high level of bureaucratic/political control (exemplified for several respondents by the process of changing the SRE's Executive Director, about which PRE was not consulted).

From SRE's point of view, support from the Agencies has improved: some periods of tension were experienced, but SRE staff maintain that the Agencies have now recommitted their full support.

3.6.3 Resource adequacy

With respect to the adequacy of PRE-SRE resources, the responses from PRE and PRE Committee members were quite mixed. Seven out of 24 respondents agreed or strongly agreed that PRE-SRE's resources were adequate. Resources were described qualitatively by several respondents to be at least adequate, if not well-used: "*From my perspective there has been money for programs and to get together for meetings. I've heard rumblings of complaint but nothing concrete"; "They have far too much and keep on getting more as the bureaucracy bloats even further. Is all this at the cost of research funds? If so, Canadian society is the loser"; " I have not seen that the [...] Working Group was ever been stymied by lack of funds, and the group had too much time on its hands. The factors which did hamper its deliberations were a lack of clear mandate and guidance from PRE-SRE, and any sense of urgency or discipline*".

A problem was noted by some PRE and PRE Committee members in the resource allocation structure: *"The ongoing re-jigging of administrative vs. grant resources is a problem: the budget is adequate but the division is not. The granting process to outside academics – RFP's leading to grants – means we lose control and this is not effective for time or processes. A policy development function needs to be nimble."*

For other PRE and PRE Committee members, the resources available to PRE-SRE are outstripped by the breadth of its mandate and activities: *"Obviously the present resources are not adequate! For one thing, there should be more meetings of the Panel and probably there should have been more face-to-face meetings of PRE's working committees to get the job done."; "If the mandate was reduced they have enough. However, their mandate requires them to do several things. So, PRE has prioritized their activities."*

Among Agency and SRE staff, views were also mixed on whether PRE-SRE's resources were adequate, and it was pointed out that they will have to be re-examined in the post-second edition context. It was also stated that the PRE-SRE had not always availed itself adequately of the administrative support resources offered by the Agencies, although this is now changing. Views within SRE about the adequacy of its resources were also varied.

3.6.4 Effectiveness of PRE-SRE performance management

When asked for their views on how effectively PRE-SRE has managed its performance, Agency representatives again made a clear demarcation between the previous regime and the current one, stating that up until the change, PRE-SRE had not managed its performance well, in terms of planning, timeliness, and spending. This is corroborated by the previous document review and interview data, as well as by the financial data already presented, which showed that PRE-SRE under-spending is largely attributable to PRE lapsing about of 30% of its budget overall. Now, however, Agency representatives concur that PRE management is excellent, leading to clear progress against plans and high-quality deliverables. It is felt that at this point, the Agencies need to exercise much less oversight of PRE-SRE. Some concerns remain about performance monitoring, which is said to be lacking some quantitative metrics of results.

3.7 Effectiveness of SRE activities in support of the Agencies

As mentioned above, some SRE staff time is dedicated to supporting the Agencies in ensuring that the research they fund is carried out with the highest possible ethical standards for research involving humans. These are discussed below.

3.7.1 Institutional ethics policy review

A key task performed by SRE is providing technical advice to the Agencies on the acceptability of institutional policies regarding implementation of the TCPS, in the context of the MOU between Agencies and institutions that establish the latter's eligibility to administer grant funds. This is a staged process, where the first level of review is conducted by an external expert, followed by review by the SRE. Review of SRE's log of the steps in the review processes provided the data summarized in Table 35. A total of 166 policies had undergone review up to July 2008. Of those, 139 (84%) had been deemed in compliance. The review process often required multiple exchanges with the institutions, ranging from 1 to 83, over a period of months. The average elapsed time between the start of the review and the judgement of adherence was 26.7 months (just over two years).

Table 35: Institutional research ethics policies reviewed and adherence to the TCPS[1]

	2000-01	2001-02	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09
No. of policies received for review	73	0	7	6	23	15	9	16	14
No. of policies deemed in compliance	71	0	7	6	20	11	9	15	0
Mean elapsed months from start to adherence[2]	34.4	--	24.5	17.6	24.4	18.9	9.6	5.5	--
Mean and range of no. of interactions required with the institution	6.1 (1-83)	--	5.8 (2-13)	5.5 (3-10)	7.3 (1-19)	8.3 (2-16)	10.0 (6-14)	7.2 (2-17)	5.0 (1-13)

[1] Log of Status of TCPS Adherence, July 2008. Note that reviews conducted in 2000-01 were prior to the creation of the SRE: this information is provided as background.
[2] Based on 98 cases. End-dates were missing for 68 cases, including 23 whose status was marked 'in compliance'.

Interviews with Agency respondents suggest that this role is seen as having been helpful: *"SRE does the reviews of institutional policies very well"; "The review of material for MOUs is a key service".*

However, as Table 37 shows, only about one-third of surveyed REB chairs and university research administrators agreed that the SRE's role in institutional policy review was clear. About the same proportion stated that the review had been helpful and had improved their ethics practices; however, about one-third of respondents did not know whether or not it had been helpful. Only 16% of these respondents agreed or strongly agreed that the SRE had facilitated their institution's interactions with the Agencies, whereas almost three times as many were not able to answer the question. While it is important to keep in mind that most of this sample is composed of REB chairs, the pattern of responses for university research officers is

quite similar. However, a somewhat higher proportion of research officers (9 out of 21, or 43% -- not a majority) agreed that the policy review had been helpful to their institution and it had improved their ethics policies. Although according to SRE staff, SRE's role in reviewing institutional ethics policies has been helpful in facilitating communication, overall, the data in Table 36 data suggest that the policy adherence review process is of greater salience and value to the Agencies than it is to the institutions.

Table 36: REB and university research officers views of SRE's roles in reviewing policies (n = 103)

	% Agree or strongly agree[1]	% Don't know
The Secretariat on Research Ethics' role in reviewing institutional polices for adherence to the TCPS is clear to me.	33.0	20.4
The Secretariat on Research Ethics' role in reviewing institutional polices for adherence to the TCPS has been helpful to my institution.	33.0	34.0
The Secretariat on Research Ethics' role in reviewing institutional polices for adherence to the TCPS has improved our institutional research ethics policies.	31.1	32.0
The Secretariat on Research Ethics has facilitated my institution's interactions with the Agencies about research ethics.	15.6	42.7

[1] Out of all responses, including 'don't know".

Although SRE's role in institutional policy review is viewed positively from the Agencies' perspective, there had been some difficulties in having SRE accept this role, as it was seen as outside of their core mandate as expressed in SRE terms of reference. SRE terms of reference have since been amended to include this role in a transparent way. Questions remain in the eyes of one Agency about SRE's role in TCPS compliance, which feels that there is a need for a body with an oversight function.

3.7.2 Understanding of the relationships between PRE, SRE and the Agencies

Initially, the SRE reported to PRE on its review of institutional research ethics policies. (For example, at the November 2002 PRE meeting, SRE reported on the numbers of institutions who were in compliance). Universities were informed that their funds would be frozen for 2002-2003 unless their ethics policies were deemed in compliance with the TCPS. However, the PRE's role in this aspect of TCPS implementation was under discussion from the outset. The Minutes from the first PRE meeting (November 10-11 2001) on discussion about the submission from SSHRC's Standing Committee on Ethics And Integrity for a Public Assurance system[26] raised among other issues, approaches to sites visits (discussed above) and reporting to the Agencies in the context of the MOU. In a note tabled at the November 2002 PRE meeting, the SRE Executive Director reported that some universities were confused about to whom they were to submit their policies – NCEHR or the Agencies – given their contacts with NCEHR in their educational visits. In their June 2003 meeting, PRE members indicated the need to carefully manage any misinterpretation about the role of PRE in the review of institutional policies *"to avoid misguidance on roles and confusion within the community*" (section 6.2.1).In a briefing note from the Executive Director to PRE in November 2003[27] it was reported: *"To avoid confusion of roles and to minimize any perception of conflict of interest in compliance*

[26] < http://www.sshrc-crsh.gc.ca/site/about-crsh/policy-politiques/statements-enonces/PAS_e.pdf > This is a document that was produced by SSHRC in the context of the accreditation debate that took place at that time.

[27] "Towards a basic framework for analyzing and managing perceived institutional conflicts of interest (Draft for discussion) Nov 2003.

*issues, the Secretariat and IMC have agreed to firewall functions regarding the evaluation of revised ethics policies of institutions that have agreed to apply the TCPS. The clarity and discharge of the separate roles also insulate PRE from agency compliance matters."(*p. 3). In practice, this meant that the PRE would not be privy to any information about the adherence status of individual institutions. SRE continued its review role in support of the Agencies, and was charged with bringing policy-relevant information emerging from an overview of the review results to PRE's attention.

Some evaluation data suggest that the firewalled relationship with respect to TCPS adherence among PRE, SRE and the Agencies is poorly understood within the institutions and across the ethics community. Responses to the survey of REB chairs and university research officers are shown in the table below. The findings that only 19% of respondents feel confident that the two roles are separated and that 45% of respondents do not know, suggest that the firewall is imperceptible to REB chairs and university research officers. On the other hand, there does not appear to be evidence of any negative effects of this lack of clarity: only seven respondents out of 103 (7%) agreed that lack of clarity has had a negative effect, and none agreed strongly.

Table 37: REB and university research officers – understanding of SRE's relationship to Agencies (n = 103)

	% Agree or strongly agree[1]	% Don't know
The distinction between the role of the Secretariat on Research Ethics in supporting the Agencies and in supporting the Panel on Research Ethics is clear to me.	23.3	23.3
I understand why the role of the Secretariat on Research Ethics in supporting the Agencies and in supporting the Panel on Research Ethics are kept separate.	33.0	26.2
I am confident that the roles of the Secretariat on Research Ethics in supporting the Agencies and in supporting the Panel on Research Ethics are kept separate.	18.5	44.7
Lack of clarity about the distinction between the role of the Secretariat on Research Ethics in supporting the Agencies and in supporting the Panel on Research Ethics has had negative effects in my institution.	6.8	36.9

[1] Out of all responses, including 'don't know".

Key informant interviews with SRE staff showed that some felt that more could have been done within the Agencies to communicate PRE-SRE's roles and responsibilities.

At its April 2008 meeting, the Steering committee reviewed and approved revised terms of reference for the SRE, to be renamed the Interagency Secretariat on Research Ethics, that clarified the role of the SRE in relation to the review of institutional policies and restated its mandates regarding the promotion of research ethics. This involved the addition of a new section outlining the exclusive technical assistance and advice role delegated to the secretariat by the Agencies for the purposes of the eligibility processes and the MOU, as well as additional clarification about SRE's administrative support of IMC and Steering Committee meetings. While this change was supported by all Agencies, one Agency respondent has questioned the extent of separation of mandates: *"PRE-SRE should be attached to the Agencies. I am concerned with overstatements about the firewall."*

3.7.3 Management of calls for Panel and Committee membership

Another SRE role in support of the Agencies is managing the calls for nominations on PRE and some of its Standing Committees. Document review showed that with support from the SRE, public calls are developed

and published. SRE then develops a scoring grid based on qualities identified by PRE and IMC as lacking in current membership as a function of expected rotations and then analyses nominated persons' applications using the grid. They then develop a shortlist to be presented to IMC, with a précis of their analysis. The Interagency Management Committee makes selections, and recommends them to the Presidents of the three Agencies, who make the appointments. Table 38 summarizes the response to the call for PRE nominations, as an indicator of effort required in this role.[28]

Table 38: Response to calls for nominations to PRE

Date of call	# of applicants	Gender		Region				
		Male	Female	West	Ont.	QC	East	Other
2001	72	41	31	20	35	6	9	2
2003	46	19	27	16	22	5	3	
2004	46	20	22	17	17	3	4	1
2005	24	10	14	9	5	5	4	1
2007	33	9	24	14	12	2	5	0

Although it appears that this workload has declined over time, it is important to keep in mind that public calls and similar review process were also used to populate SSHWC in 2002 and PRE-TACAR in 2005/2006. In addition, PRE-TACAR's selection process involved a Selection Committee chaired by SRE (see section 3.2). It is PRE, not IMC that approves the membership of PRE working groups.

3.7.4 Other forms of SRE support to the Agencies

SRE also provides other forms of support to the Agencies in the fulfillment of their mandates regarding research ethics. In their interviews, SRE staff noted additional ways in which they have supported the Agencies:

- engaging in dialogue with research communities and driving reflection about ethics, to the benefit of the Agencies; for example through presentations and attendance at relevant meeting and conferences;
- presenting a unified, cross-Agency policy to researchers. This is seen as facilitating the conduct of increasingly prevalent interdisciplinary research;
- providing harmonized "one-stop shopping" to institutions on ethics matters, so that their ethics-related questions are addressed by a common agency on behalf of all three Agencies;
- answering ethics-related questions raised by Agency program officers.

The latter two forms of support are provided on as-needed basis, when Agency staff refer institutions and researchers to SRE, or when the latter seek out guidance directly from SRE. In some cases, questions directed to SRE are not part of its mandate, in which case SRE refers questioners to the appropriate resources.

[28] IMC Meeting Briefing notes, June 2007.

3.8 PRE-SRE in the broader ethics environment

3.8.1 Contribution to the governance dialogue

Context

What is now termed the "national dialogue on a governance system for human subject research protection" has been evolving incrementally over several years. Between 1999 and 2002, NCEHR led an initiative aiming to develop a system for accreditation of REBs. A mandate to develop and implement a governance system, including accreditation and monitoring of REBs, was taken up by Health Canada in 2002, who along with leadership from the medical research community, collaborated with NCEHR in the establishment of a NCEHR Accreditation Task Force. PRE participated as an observer to the NCEHR Task Force and provided public commentary[29]. In 2002, the PRE published *Process and Principles for Developing a Canadian Governance System for the Ethical Conduct of Research Involving Humans*[30]. In 2004 and 2005, NCEHR undertook work on an accreditation options paper through a task force. The NCEHR Task Force published its report in July 2006[31], recommending the creation of Programs for Ensuring Ethical Research with Humans and an accreditation entity located within NCEHR, at arms' length from government. In 2006, leadership of the governance dialogue was then again taken up by Health Canada, with the creation of the Sponsors' Table for Human Research Participants Protection in Canada. This group operates as "a group of organizations that shares a common interest in promoting research involving humans that meets the highest standards in excellence and ethics"[32], i.e., is not as a delegated authority of any agency. The Sponsors' Table mandated a 14-member Experts Committee in 2006 to recommend a system for research participant protection. PRE is not a member of the Experts' Committee or Sponsors' Table, as all three Agencies are represented at the Sponsors' Table. In 2007, PRE issued a 2007 update to its 2002 Governance position paper[33] as well as a presentation to the Experts' Committee of the Sponsors' Table. The Experts' Committee report, dated July 2008, calls for stewardship and evolution of the TCPS, as well as the resources of PRE-SRE, to be transferred to a proposed independent *Canadian Council for the Protection of Human Research Participants*[34]. PRE produced a response[35] to the Experts' Committee report and made it publicly available. In response to the Experts' Committee report, the Sponsors' Table has identified four priorities: policy, education, accreditation and proportionate review, for which strategies and pilot initiatives are expected to be in place by June 2009.[36] The outcome of this process, in particular the Sponsor's Table final recommendations about the role of PRE-SRE are thus not known at this time.

---

29 Pre comments on NCEHR Accreditation options Paper. http://www.pre.ethics.gc.ca/activities-activites/projects-projets/docs/NCEHR%20Accreditation%20Letter%20May%202005%20REVISED%20Updated%20June.pdf (letter)

30 Process and Principles for Developing a Canadian Governance System for the Ethical Conduct of Research Involving Humans - April 2002; http://www.pre.ethics.gc.ca/english/policyinitiatives/governance01.cfm

31 http://ncehr-cnerh.org/english/Task%20Force%20Report_FINAL_18%20July%202006.pdf

32 http://www.hrppc-pphrc.ca/english/sponsors.html

33 Presentation to the Experts' Committee, January 2007: Governance for a Culture of Research Ethics - http://www.pre.ethics.gc.ca/english/pdf/Governance%20Experts%20Committee%2025Jan07%20Update.pdf; Process and Principles for Developing a Canadian Governance System for the Ethical Conduct of Research Involving Humans - April 2002 with a 2006 Preface; http://www.pre.ethics.gc.ca/english/policyinitiatives/governance01.cfm

34 The Experts Committee for Human Research Participant Protection in Canada (2008). *Moving Ahead: Final Report*, http://www.hrppc-pphrc.ca/english/movingaheadfinalreport2008.pdf. , p. 83

35 < http://www.pre.ethics.gc.ca/activities-activites/projects-projets/docs/Experts_Committee-Response(final)_E_21jan2008.pdf>

36 Sponsors' Table communiqué, July 18 2008, http://www.hrppc-pphrc.ca/english/sponsors.html.

Stakeholders' views of PRE-SRE contributions

In general, the views of those most closely associated with PRE-SRE's contribution to the dialogue were moderately positive. Twelve out of 23 respondents to the current evaluation survey of PRE and PRE Committee members agreed or strongly agreed that PRE-SRE had contributed effectively to the dialogue about governance of research involving human participants (but only six of 23 agreed that PRE-SRE had contributed effectively to dialogue about accreditation and monitoring of REBs). Some stakeholders commented that PRE-SRE had been engaged in all of the key discussions: *"They are a player, and they should be a player."* Its role in promoting the TCPS as a Canadian standard in the context of multiple national and international rules and guideline has been seen as a positive contribution. It was also noted that PRE-SRE has provided a consistent presence in the dialogue: "*It's the go-to organization for us. It gives us continuity, as opposed to Health Canada being involved intermittently, PRE-SRE provides us with some sense of consistency."*

PRE and PRE Committee members' views were somewhat mitigated by the rather peripheral role it had sometimes seen itself accorded. Several respondents emphasized that PRE-SRE's efforts, while consistent and constant, have not been heard by the actors in this area, and in particular the Sponsor's Table: "*At best it can be said that there are interests working in parallel. PRE has contributed to the best of its ability, but I am not sure they have been heard as much as I would like. However the dialogue is ongoing" ; "I think that the inputs from PRE-SRE have greatly improved. At the same time, I think that the committee involved in writing the document on oversight has viewed PRE-SRE as ineffective and unable to create change."; PRE-SRE has contributed to the dialogue, but it is not at all clear that the Sponsor's Table has listened".* PRE's leadership in the area was thus questioned by some PRE and PRE Committee members (e.g., *"they should lead by example and for the most part they haven't."; "The Panel has not been proactive enough on these issues*").

The Agencies' expectations for PRE-SRE's role in the governance dialogue and especially the Sponsor's Table reflect the official mandate of PRE, which is that of an advisory body to the Agencies. This would mean that in some situations including the Sponsor's Table, PRE's participation would have been redundant as the Agencies were already directly involved. Representatives of the three Agencies as well as SRE were of the general view that PRE-SRE is starting to play its own role in the governance dialogue, although this had in the past been limited. SRE staff pointed out that the Sponsor's Table's position had become more open to PRE-SRE having a role than previously.

Echoing previous findings about TCPS evolution, PRE-SRE is seen by some PRE and PRE Committee members as having championed a social sciences and humanities position (e.g., *"PRE-SRE's position has been consistent and does serve to protect the interests of the university sector, particularly the social science and humanities constituency. It is not as clear that this position considers the needs of participants is all kinds of research, including clinical trials*"). Some external stakeholders also held this view: "*In all the discussions I've had, PRE is seen as representing the social science community. It's a bit of a puzzle as why this should be the case. They don't seem to include needs of biomedical sciences. For example they just seem to be denying the clinical trials needs"; "My sense is that it appears to have taken more the perspective of the social sciences".* Representatives of the biomedical community expressed frustration with this perceived stance.

It was also pointed out that PRE's position in the debate can be seen as self-protective rather than disinterested: *"PRE-SRE is, in my opinion, too concerned about their own survival to be able to provide meaningful and convincing arguments in the debate."*

A few external key informants, in various positions, perceive that PRE's contribution to the governance dialogue had been inhibited by a style they characterized as uncollaborative or secretive, which has contributed to ineffectiveness: *"They have been secretive in the way they operate"* ; *"PRE is seen as a black box, we don't know what's going on."*

While REB chairs and university research officers were not questioned directly about the effectiveness of PRE-SRE's contributions to the governance dialogue, several made open-ended comments relevant to this issue. These echoed the range found among internal and external stakeholders, from:

- confusion: "*I've heard the term "Sponsor's Table" - but am not certain of its function. In general, there seem to be a lot of groups involved (and many acronyms) and as a result only the key players seem fully aware of the various functions.:",* to
- support for PRE-SRE's position: *"I much prefer the facilitative and supportive approach manifested through increased education to the more critical and, I believe, less effective approach of mandatory accreditation followed by remediation of fault.";* to
- support for the Experts' Committee: *"I support the position of the Experts Committee";* to
- comments on PRE's perceived lack of effectiveness: *"PRE has had over 10 years to demonstrate its leadership in the areas outlined above. For various reasons this leadership has not been obvious to the research or research ethics communities. Although PRE's response to the Expert Committee's report is logical, its lack of effectiveness over the last decade makes its proposal seem rather unlikely*."

Thirty-six percent of respondents to the survey of REBs and university research officers stated that they agreed with PRE's response to the Sponsors' Table's initial report – but 28% stated they did not know.

3.8.2 Resolution of the issue of perceived structural conflict of interest

The evaluation examined the issue of perceived structural conflict of interest, identified as a high-risk, moderate-impact area in the PRE-SRE RMAF. Overall, the evaluation results show that this risk has not been successfully managed: the issue persists in ongoing internal and external debates about PRE-SRE, and continues to be divisive along disciplinary lines.

Origins of and responses to the issue

The perceived institutional conflict of interest issue formally surfaced in 2002, when CIHR's Standing Committee on Ethics took position on the structural conflict of interest it believed existed in the governance structure for the TCPS:

> "*The CIHR Standing Committee on Ethics supports the concerns raised at both meetings of the Institute Advisory Board Ethics Designates with respect to the perceived systemic conflict of interest within the governance structure of the Tri-Council Policy Statement. The Standing Committee on Ethics is of the view that there is a*

systemic conflict of interest in the dual role of the federal funding councils - CIHR, SSHRC, and NSERC - to both promote research and regulate its ethical conduct. The Standing Committee on Ethics urges Governing Council to explore with the two others federal Agencies the problem of systemic conflict of interest with a view of making structural changes to avoid such conflict of interest.'

This position was tabled at and accepted by CIHR Governing Council, and it was moved that the President meet the Presidents of the other two Agencies "*to discuss the structural changes needed to address this issue."*[37] Differing views among the three Agencies' management about structural conflict of interest still existed by the time of the Special Study in 2005; that study recommended that the Agencies: 1) Open a discussion among the three Agencies about their definitions of, and respective perceptions of, the question of structural conflict of interest; 2) Enhance efforts to manage perceived structural conflict of interest; 3) Re-activate follow-up dialogue with Health Canada about their status of activities with regards to accreditation and monitoring of REBs, to help clarify responsibilities for the regulatory function; 4) Expedite PRE's internal work on Institutional Conflict of Interest. Although document review showed that in February 2006 IMC approved and agreed to post their revised response to the Special Study on the PRE website, this response was not located.

PRE struck a Conflict of Interest Working Committee in 2006. It dealt with three issues, of which the first was the perception described above that PRE as a structure was in institutional conflict of interest. PRE conducted a literature review and developed a draft framework for dealing with institutional conflicts of interest, which also appeared to address a second, broader issue about non-financial structural conflicts of interest in research ethics management. The Committee also concerned itself with defining the concept of institutional conflict of interest. It produced a draft document in October 2006 and a final document in April 2008[38]. It did not explicitly deal with the issue of PRE being in perceived institutional conflict of interest although it extensively discusses the American situation and the creation of the Office of Human Research Protection, "*whose genesis and current administrative locale of OHRP results partly from the identification and management of an institutional conflict*." (p.4) The American situation was used as a model for a framework and for a definition of institutional conflict of interest.

Respondents to the survey of PRE and PRE Committee members did not appear to be aware of the PRE's actions in this area, nor whether PRE had clarified its views about whether it is in a structural conflict of interest: *"This is an issue in which I have a great interest, and I know nothing of any clarification. "* No respondent mentioned the discussion paper produced by the Conflict of Interest Committee on this topic*:* Nine out of 23 respondents to this survey agreed or strongly agreed that PRE-SRE have clarified their views on whether PRE is in a position of institutional conflict of interest. – a number equal to those who responded 'don't know" However, 14 of 23 agreed or strongly agreed that PRE-SRE have made it clear to other organizations involved in research ethics that PRE is not involved in regulating institutional research ethics management (seven of 23 did not know).

The second issue tackled by the Conflict of Interest Working Committee was managing perceived conflict of interest in PRE grants process, and the third was developing a framework for recognition and action on

---

[37] http://www.cihr-irsc.gc.ca/e/13135.html; meetings of the 18th meeting of Governing Council, November 20-21 2002.

[38] "Institutional Conflict of Interest": Towards a Working Definition and Management. Interagency Advisory Panel & Secretariat on Research Ethics, Working Committee on Conflicts of Interest, April 2008.

perceived non-financial institutional conflicts of interest. The approved procedures for the former do not appear to be followed completely, as search of the PRE website did not reveal a list of grants awarded (for example, there is no list of the grants awarded to National Aboriginal Organizations, NCEHR, CAREB, SSHWC, among others).

CIHR's Standing Committee's position may continue to resonate in the ongoing governance discussions. In the report of the Experts' Committee released June 2008, referring to PRE-SRE as an arm of the Agencies, it is stated[39] : *"For example, federal research granting Agencies are statutorily mandated to promote research and at the same time they are stewards of one of the most significant research ethics instruments in Canada, the TCPS. While the Councils seek to manage these dual and sometimes competing responsibilities, a transfer of the oversight function to an external body could serve to eliminate the difficulty inherent in the present situation. It is worth noting that the Governing Council of CIHR has explicitly acknowledged this dual mandate is not tenable."* (p. 28), and *"CIHR has signalled that this arrangement is no longer tenable."* , (p. 72) No source is provided for these affirmations, so it is unclear whether this is referring to the 2002 position of CIHR's Standing Committee on Ethics, or some other unpublished source of information.

More data on the continued relevance of PRE-SRE's structure and mandates are provided in section 3.7.

Current points of view contrasted

Both internal and external stakeholders commented on the extent to which PRE-SRE had clarified and dealt with the perception among some stakeholders that it is in institutional conflict of interest. As would be expected from the above, views on this issue range widely. At its heart seems to be the question of whether or not PRE is independent of the Agencies: for those who maintain that PRE remains in institutional conflict of interest, the raw nerve is the relationship between the PRE-SRE and the Agencies, and within that relationship, the fact that all major PRE-related decisions must be approved by Agency Presidents, whose authority is delegated through the IMC. This applies to the nomination of PRE members and SRE staff, as well to approval of PRE documents. This, to these respondents, signifies that PRE is not structurally independent of the Agencies – that it is in fact an arm of the Agencies. As such, it is seen as conflicted: it is part of an organization whose primary aim is to see that excellent research gets done. In this view, situations could arise where protection of research participants might mean putting constraints on the research, i.e., acting against its own best interests. This is in contrast to other stakeholders, who maintain that while PRE-SRE receives overall direction from the Agencies, it is independent (a somewhat hybrid position). PRE has always understood itself as independent of the Agencies in substantive ethics matters40. Some stakeholders maintain a diametrically opposing view: that PRE needs to be (more) closely linked to the Agencies in order to ensure that there is ongoing dialogue and connection with the real world of research, because, in this view, the primary aim of the Agencies is to fund ethical excellent research.41 The table below uses verbatim quotes to illustrate these contrasting views among external stakeholders.

---

39 http://www.hrppc-pphrc.ca/english/movingaheadfinalreport2008.pdf

40 Panel meeting minutes, Nov. 1-2, 2001.

41 This issue becomes divisive along disciplinary lines because biomedical research is generally believed to be more likely to put human participants at risk than is social science research. Those who maintain that PRE-SRE is in institutional conflict of interest are concentrated in the biomedical community; these views have already been made public through CIHR's Standing Committee on Ethics' 2002 position on PRE-SRE – see footnote 28..

Although this survey was not a representative referendum of external stakeholders, the number of entries in the table likely reflect the relative prevalence of these points of view.

Table 39: Contrasting positions on institutional conflict of interest, external stakeholders

Respondent's position		
No institutional conflict of interest	Some influence, some independence	Panel is not independent
"Its not too close – its an appropriate relationship – there is no conflict of interest"	*"I have no problem with the structure. It's important that they not be in bed together, but they also need to be able to talk. The real question is where to make the separation"*	*"The role of Council in funding research and ethics governance – is a deeply conflicting agenda.* *"As long as PRE is beholden to Councils, you have to suspect politics – how can you divest them from politics or the bureaucrats? It's important to have independence. "* *"Because of answering to the Presidents, this produces a conflict of interest in a fundamental level."* *"There is a structural conflict of interest when the Tri-Agencies are responsible for both the development and the endorsement of the TCPS. The conflict rests on the potentially opposing interests of promoting research and protecting research participants. Promotion will almost always trump protection. The Tri-Agencies need to restructure this by separating development and endorsement so as to formally equalize the relationship between promotion and protection."*

3.9 Ongoing relevance of PRE-SRE

In all surveys conducted for this evaluation, respondents were asked for their views on the ongoing relevance of PRE-SRE, the appropriateness of its mandates, and potential alternatives.

3.9.1 Overall relevance

Perhaps not surprisingly given their investment in the existing structure, PRE and PRE Committee members surveyed support the ongoing existence of PRE-SRE (see Table 41) , stating for example: " *PRE-SRE could be improved but replacing it with a new agency would be a waste of time and money. To the extent that it is broken, fix it.* " There were few qualitative responses to these questions that did not echo previous ones about the PRE-SRE's overall effectiveness, e.g.: *"Overall I think it is a good idea to have a PRE, but I object strongly to the way it has been constituted.";"PRE-SRE has been extremely slow to produce anything. A much more effective organization is needed."*

Also shown in Table 40 are responses from REB chairs and university research officers about PRE-SRE relevance. Striking about these responses is the high proportion of "don't know" responses. About 40% of respondents agree or strongly agreed that PRE-SRE is the best means for the Agencies to steward the TCPS, but one-quarter do not know. Half this sample (51%) indicated that PRE-SRE's overall mandates are appropriate.

Table 40: REB chairs and university research officers, Panel and Committee members - Ongoing relevance of PRE-SRE

	REB chairs and research officers (n = 103)		Panel and Committee members (n = 23)	
	% Agree or strongly agree[1]	% Don't know	No (%) Agree or strongly agree[1]	No. Don't know
Overall, the Panel and Secretariat on Research Ethics is the best means for the Agencies to ensure stewardship of the TCPS.	41.8	25.2	17 (74%)	1
The Panel and Secretariat on Research Ethics' overall mandates are appropriate.	51.4	23.3	17 (74%)	2

[1] Out of all responses, including "don't know".

External stakeholders' views generally endorsed the ongoing relevance of PRE-SRE's role: *"I clearly see the need for an advisory group to the Tri-Councils. I see the need for an interpretation and education body on the TCPS. This is a lot of the PRE-SRE mandate."* However, consistent with the perspectives described above, some noted that its performance had not fulfilled expectations: "How effective this group is compared to what could be, I don't know". Some external stakeholders expressed optimism that recent changes in PRE-SRE will redress former performance problems.

3.9.2 Relevance of PRE-SRE's mandate elements

As Table 41 shows, among REB chairs and university research officers, support for PRE-SRE's mandates is highest for evolution (62%) and interpretation (57%). Just over half (52%) feel the education mandate is appropriate, and less than half support the implementation mandate. These results are echoed by those from PRE and PRE Committee members, who generally endorse all PRE-SRE's current mandates but most strongly for evolution and interpretation.

Table 41: REB chairs and university research officers, Panel and Committee members - relevance of PRE-SRE mandates

	REB chairs and research officers (n = 103)		Panel and Committee members (n = 23)	
	% Agree or strongly agree[1]	% Don't know	No. (%) Agree or strongly agree[1]	No. don't know
The Panel and Secretariat on Research Ethics' mandate for evolution of the TCPS is appropriate.	62.2	16.5	18 (78)	2
The Panel and Secretariat on Research Ethics' mandate for interpretation of the TCPS is appropriate.	57.3	20.4	18 (78)	2
The Panel and Secretariat on Research Ethics' mandate for education about the TCPS is appropriate.	51.5	23.3	17 (74)	2
The Panel and Secretariat on Research Ethics' mandate for supporting the Agencies in implementation of the TCPS is appropriate.	46.7	21.4	16 (70)	2
The Panel and Secretariat on Research Ethics' mandate for contributing to the governance dialogue is appropriate.	n/a	n/a	15 (65)	1
The Panel and Secretariat on Research Ethics' mandate duplicates that of other organizations.	11.7	35.9	3 (13)	4

[1] Out of all responses, including "don't know".

With respect to the specific issue of duplication of mandates with other organizations, it was noted that there is some overlap with NCEHR, universities and disciplinary-based associations and professional associations in the education mandate, and with Health Canada. Stakeholders did not necessarily see this as negative for PRE-SRE: *"There is some overlap in education and governance but PRE plays a unique role and has worked hard to distinguish its contribution" ; "There is definite overlap between PRE-SRE and other organizations, but this does not mean that PRE-SRE is unnecessary or has an inappropriate mandate. Personally, I feel that there are two problems with overlapping mandate that would best be solved by changing the other organization not by changing PRE-SRE".*

3.9.3 Alternatives to PRE-SRE

There is clearly not unanimity, even among PRE and PRE Committee members, about the relative merit of the alternative structures proposed by the Experts' Committee and by PRE itself. Only about half of PRE and PRE Committee members with an opinion (10 out of 19) agree with PRE's published response to the Experts' Committee (Table 42). However, few respondents to the survey of REB chairs and university research officers agreed that other structures would be more effective than the PRE-SRE for ethics policy development (11%) or TCPS education (10%).

Table 42: REB chairs and university research officers, Panel and Committee members - Alternatives to PRE-SRE

	REB chairs and research officers (n = 103)		Panel and Committee members (n = 23)	
	% Agree or strongly agree[1]	% Don't know	No. agree or strongly agree[1]	No. don't know
Other structures could be more effective than the Panel and Secretariat on Research Ethics to ensure development of ethics policy for the Agencies.	10.7	34.0	3 (13)	5
Other structures would be more effective than the Panel and Secretariat on Research Ethics to ensure development of ethics education for the Agencies.	10.7	33.0	5 (22)	3
The proposed Canadian Council for the Protection of Human Research Participants (proposed by the Experts' Committee) is an appropriate mechanism for governance of research ethics with human participants in Canada.	n/a	n/a	5 (22)	2
The Panel on Research Ethics has proposed a model of collaborative oversight based on an expanded Sponsor's Table that reflects the diversity of decision-makers. The model would focus on supporting education and policy development using existing mechanisms and resources. This would be an appropriate mechanism for governance of research ethics with human participants in Canada.	36.0	28.2	10 (43)	4

[1] Out of all responses, including "don't know".

In reaction to PRE's proposal for an expanded Sponsors' Table, some external informants were in favour of this because of the opportunity to expand dialogue with other stakeholders, including those at the institutional level: *"Expanding the Sponsor's Table would be very appropriate, because it would allow for a shared mandate with other stakeholders, including universities.'; "Certainly I would say that other interest groups may have an interest in participating in some capacity".* However, other external stakeholders argued that PRE-SRE's role should be conferred on an organization external to the Agencies: "*this function should be completely separate from the Council. It is necessary to have a different kind of independent body that would have all of the same mandates."* For some external stakeholders, an organization with regulatory role is essential, but it is not clear whether PRE-SRE can or should play that role: "*In my view, I see the Secretariat and Panel as a feedback mechanism rather than governing mechanism. The question is whether there is a need for a governing mechanism. The view at (XXX) to have more structure rather than less, and the desired model would include a regulatory role …At some point, you need someone to knock heads, to make sure that corporate money isn't skewing the whole ethical framework, and I'm not sure that anyone is stepping up to the plate."* ; *"Institutions have not been pushed to meet standards.".* Nonetheless, some expressed support for a PRE-SRE role in research ethics regulation: *"They are in need of a discussion about the governance and oversight of ethics on human research, and it seems appropriate that it comes from the PRE. Their experience indicates that there is a need for a serious look at research oversight, so this should continue to be a priority."*

One key external stakeholder organization suggested that PRE-SRE should concern itself only with policy development, as "*a policy powerhouse*" (i.e., not education, implementation, or governance) but that it should widen its policy umbrella to include other policy areas that also affect the lives of researchers, such as research integrity and conflict of interest. This was corroborated by a national organization who, based on experience, decried the fragmentation of these issues across multiple agencies, and the great difficulty

with which researchers can seek support to articulate and deal with highly complex questions, some of which may be tangled up in questions about treatment of human participants, about the conduct of research in a modern and evolving research environment.

Agencies' endorsement of PRE-SRE

Overall, the three Agencies continue to endorse PRE-SRE within their current mandates: seeing it as the "right organization at the right time, although perhaps in need of more visible championing, while maintaining a need for flexibility and openness to future changes. While acknowledging that PRE-SRE's performance had been disappointing in the past, in the views of the Agency respondents, effective corrective action has already been taken with the change in SRE Executive Director and the PRE Chair. These respondents uniformly maintain that PRE-SRE is now on the right track to achieving it and the Agencies' objectives. With respect to its mandate elements, internal stakeholders concur that PRE-SRE's evolution, interpretation and education mandates are core.

For its part, SRE continues to emphasize TCPS evolution as its priority. Although for some SRE staff, the idea of separating PRE-SRE from the Agencies would have the advantage of reaching a broader community, disadvantages of changing structures were noted. It was suggested that a body be created to deal with all aspects of the Memoranda of Agreement with institutions (finances, ethics and other aspects of institutional eligibility), freeing SRE for additional focus on the TCPS. SRE continues to emphasize education and training over an accreditation approach. With the imminent release of the second edition, SRE sees PRE-SRE as poised and ready to make a concrete and useful contribution.

In the future light, two of the Agencies stated that PRE-SRE should eventually be separated from the Agencies and its function vested in a national nongovernmental organization, similar to the model of the Canadian Council on Animal Care. This organization would, like other national standards organizations, receive federal funding. With an NGO status, it would not be affected by the jurisdictional issues that are now present for PRE-SRE. It would also allow broadening PRE-SRE's scope to include research not funded by the Agencies, which according to some internal respondents, is the direction the research milieu is moving, as evidenced by the position of the Sponsors' Table. The third Agency appears to be in disagreement with this position, maintaining that PRE-SRE should be attached to the Agencies and that the oversight role, through monitoring of compliance with the TCPS, be carried out by PRE-SRE.

4. CONCLUSIONS

4.1 Limitations on interpretation

We begin the conclusion to this evaluation report by reiterating the limitations of this evaluation. Being essentially descriptive, this evaluation does not benefit from comparisons to external objective benchmarks that could be used to assess performance. PRE-SRE performance was mainly judged by comparing results to stakeholder expectations. The research ethics community in Canada is small, and has been frequently solicited by PRE-SRE and other players in the last year; this may have exhausted the availability of some individuals consulted as part of this evaluation, resulting in the lower than expected response rates. .As well, it must be said that given the current uncertainty in the environment, some potential respondents may have considered that the PRE-SRE evaluation is moot – the organization's fate will rest on the results of the Sponsors' Table's activities. The low response rates should be kept in mind in the overall interpretation of the significance of the findings.

As well, we note that the timing of this evaluation was less than ideal. It preceded the release of the second edition of the TCPS, such that respondents were unable to assess a key PRE-SRE result. The conduct of the evaluation also coincides with important changes in the environment of the PRE-SRE through the work of the Expert Committee and Sponsors' Table. The evaluation's timing should also be considered in the interpretation of the results.

That being said, this evaluation benefits from the input of a substantial number of individuals belonging to a vast array of interest groups vis-à-vis the issues of ethics in research: PRE, Standing Committee and Working Committee members; institution research officers; chairs of REBs; tutorial users; interpretation requesters; researchers; CIHR, SSHRC and NSERC staff; former and current senior SRE staff; disciplinary and student associations; university representatives; REB administrators in the public and private sectors; representatives from federal and provincial government departments, and other organizations involved in research ethics. All in all, more than 1,100 individuals contributed to a better understanding of PRE-SRE performance. So, despite the lower than expected response rates, the broad variety of opinions expressed suggests that the evaluation results have captured the range of views in the community, although their exact distribution is less certain.

4.2 Ongoing relevance of PRE-SRE and alternatives

Although it is traditionally the last evaluation question to be addressed, we next turn to the findings about the ongoing relevance of PRE-SRE. Overall, above a generally low level of awareness, there is mitigated support for PRE-SRE as a structure, but strong support for the relevance of its mandates. It appears that the three Agencies remain committed to PRE-SRE as a stewardship structure for the TCPS, but there are also clear differences among and within the three Agencies and across their respective research communities in views about how TCPS stewardship should be positioned vis-à-vis the Agencies. In terms of alternatives, the evaluation found no consensus about the relative merit of the alternative structures proposed by the Experts' Committee and by the PRE. There are signs that the Agencies' position on PRE-SRE's as a structure could evolve in the medium term: two of the Agencies stated that PRE-SRE should eventually be separated from the Agencies and its function vested in a separate, national and nongovernmental organization. It now appears that in some ways the positions in some sectors of the biomedical and social sciences communities that were present in debates surrounding the relationship of

PRE-SRE to the Agencies have merely been transferred to the Sponsors' Table. The overall relevance of the existing PRE-SRE thus remains an open question in the ethics community, both in the short and longer term. The evaluation data give us little reason to be optimistic about an easy resolution.

4.3 Reach and support to the research community

The TCPS appears to be well-entrenched in Canadian research communities: almost all researchers whose work involves human participants have heard of it, and REB chairs and university research officers know their and the Agencies' roles and responsibilities with respect to it. This suggests that the Agencies' overarching aim of ensuring that its harmonized policy statement would become an integral part of the research landscape has been met.

The role of PRE-SRE within this landscape is not as easy for these stakeholders groups to discern, and their level of awareness is correspondingly lower. While it may not be a concern that one-third of researchers have heard of the TCPS stewardship structure, it is of interest that only two-thirds of REB chairs and research officers are aware of PRE-SRE's mandate, and only half are aware of its activities. This is somewhat surprising given the relatively large investment made by PRE-SRE in communications and partnering. This may point to the need for more effective, targeted communication efforts in these communities, for which the release of the second edition of the TCPS may afford excellent opportunity. There is support among the researchers surveyed for a more proactive role for PRE-SRE, in communicating about the TCPS and its activities. The recently-adopted communications strategy specifically targets these audiences, among others[42].

4.4 PRE-SRE mandate elements

This evaluation provides evidence about the relevance of PRE's mandate elements of evolution, interpretation, education and contribution to the governance dialogue. According to the evaluation findings, the need for the first three is certain, although how they should be organized is less clear. In the sections below, the findings for each mandate element are summarized.

Evolution of the TCPS

The mandate accorded to PRE-SRE to evolve the TCPS and more specifically, to correct what were perceived by many to be serious flaws in the first version, was its most central and generated highest expectations in the research ethics community. At time of writing, PRE-SRE is within months of launching a very extensive revision of the TCPS, with substantial changes in 20 topic areas based on extensive community consultation and debate, including two new chapters (on ethics of research with Aboriginal peoples and on qualitative research). This launch is, however, occurring years later than expected. The evaluation data suggest that a combination of overambitious planning, ineffective leadership and/or capacity to adjust leadership styles as the projects' needs and timelines changed, and inefficient volunteer work processes all conspired to check TCPS evolution. Alternative and more effective ways of working and of organizing the work could be, and may have since been, identified.

---

[42] PRE-SRE Creative Strategy, version 2 May 2008.

Slow progress in TCPS evolution has in some areas created a vacuum of ethics guidance. PRE-SRE's approach to the evolution work, while successful in increasing acceptance of the TCPS in the social sciences and humanities community, has also resulted in alienation of at least part of the biomedical community, and caused CIHR to question the return on investment. That a vacuum in the Aboriginal research area was partly filled by CIHR added to the perception of PRE ineffectiveness. However, possibilities for complementarity with CIHR's guidelines are now becoming apparent, as the new Aboriginal chapter of the revised TCPS builds extensively on the CIHR work, but with the advantage of having achieved national political buy-in.

These difficulties notwithstanding, the entire field is looking forward to the second edition of the TCPS. Future evolution work can profit from the lessons learned in this first decade, starting with realistic and achievable targets given the amount and type of resources available.

Interpretation of the TCPS

The various sources of data on the interpretation mandate provide an overall picture of a service that has struggled to become adequately organized, but is now showing signs of improvement. There has been dissatisfaction among interpretation requesters with the timeliness of the services; however, there has been a substantial reduction in response times to interpretation requests over 2008. There has also been a perceived lack of clarity and applicability of some responses which may point to a larger issue: while the aim of the interpretation function is to help orient TCPS evolution through interpretation of broadly applicable policy elements, the service provision is geared toward helping users with specific context- and time-bound decisions.

Overall, the level of utilization of the published interpretations is moderate, and about 40% of respondents in the key user group of REB chairs and research officers were not aware of the interpretation function. The download rate, at an overall average of about 39 downloads per month per published interpretations, seems low when the size of the overall population of REBs (let alone the population of researchers) is considered. At the same time, many users and observers of the interpretation function are satisfied and have found the interpretations useful. The mechanisms linking TCPS evolution and interpretation may require clarification.

Education of the research community

PRE-SRE's approach to its education mandate got off to a contentious start (particularly in relation to initial plans for site visits the handling of alleged breaches of ethical conduct), but developed more smoothly once the proposed plan to conduct educational visits was dropped. Although it was slower than expected in producing its main output, the TCPS on-line tutorial, despite some limitations in depth and coverage, is clearly successful in reaching the research community. Its national accessibility could, however, be examined more closely, in relation to institutional policies about mandatory completion. The prospective survey also provided some evidence that the tutorial is being applied in research decision-making in ways that improve ethics practices. This on-line tool thus appears to be meeting needs at several levels as well as producing positive impact. The role of PRE-SRE vis-à-vis other players in ethics education, most notably NCEHR but also universities and professional bodies, remains unclear.

Contribution to the governance dialogue

PRE-SRE has consistently and thoughtfully attempted to contribute to the governance dialogue, but has not always been afforded legitimacy within the conversations. Some of the reluctance to admit it to the debate arises from concerns about possible conflict of interest related to the nature of its relationship with the Agencies. CIHR appeared to hold this position, in contrast to the other two Agencies, in 2002 and may hold it still. Although this was identified as a risk to PRE-SRE in 2003, response to it has not so far enhanced its external credibility, and in any case is not widely known, even among people closely involved with PRE's work.

4.5 Support in the achievement of Agency objectives

Agencies' capacity to ensure that research is carried out with highest ethical standards

PRE-SRE's role enhancing the Agencies' capacity to ensure that the research they fund is carried out with the highest ethical standards has generally been positive, although more positive for NSERC and SSHRC and less so for CIHR. However, the recent changes within PRE-SRE have been associated with greater coordination with CIHR. Support provided by SRE to the Agencies in policy adherence review seems to be of greater salience and value to the Agencies than it is to the institutions. Tangible Agency support to PRE-SRE, in the form of financial and human resources, were likely adequate, but they were not used by PRE-SRE as effectively nor as completely as possible. Intangible support from the Agencies to PRE-SRE may not have been optimal.

Balancing risks and benefits

A strong majority of both researchers and those involved in applying the TCPS in institutions agree that the ethics review process is effective in protecting research participants. Researchers are less likely to maintain that ethics review processes using the TCPS are ensuring a balance of risks and benefits for research participants. PRE-SRE's role in balancing risks and benefits is, not surprisingly, less clear. There are equally prevalent views among researchers that the TCPS is an important tool for protecting participants but that the way it is applied constrains some types of research. PRE-SRE's role in contributing to increased assurance that research participants are adequately protected and risks are balanced against the benefits of research is indirect and supportive, as direct responsibility rests with institutions and researchers.

4.6 Overall conclusion

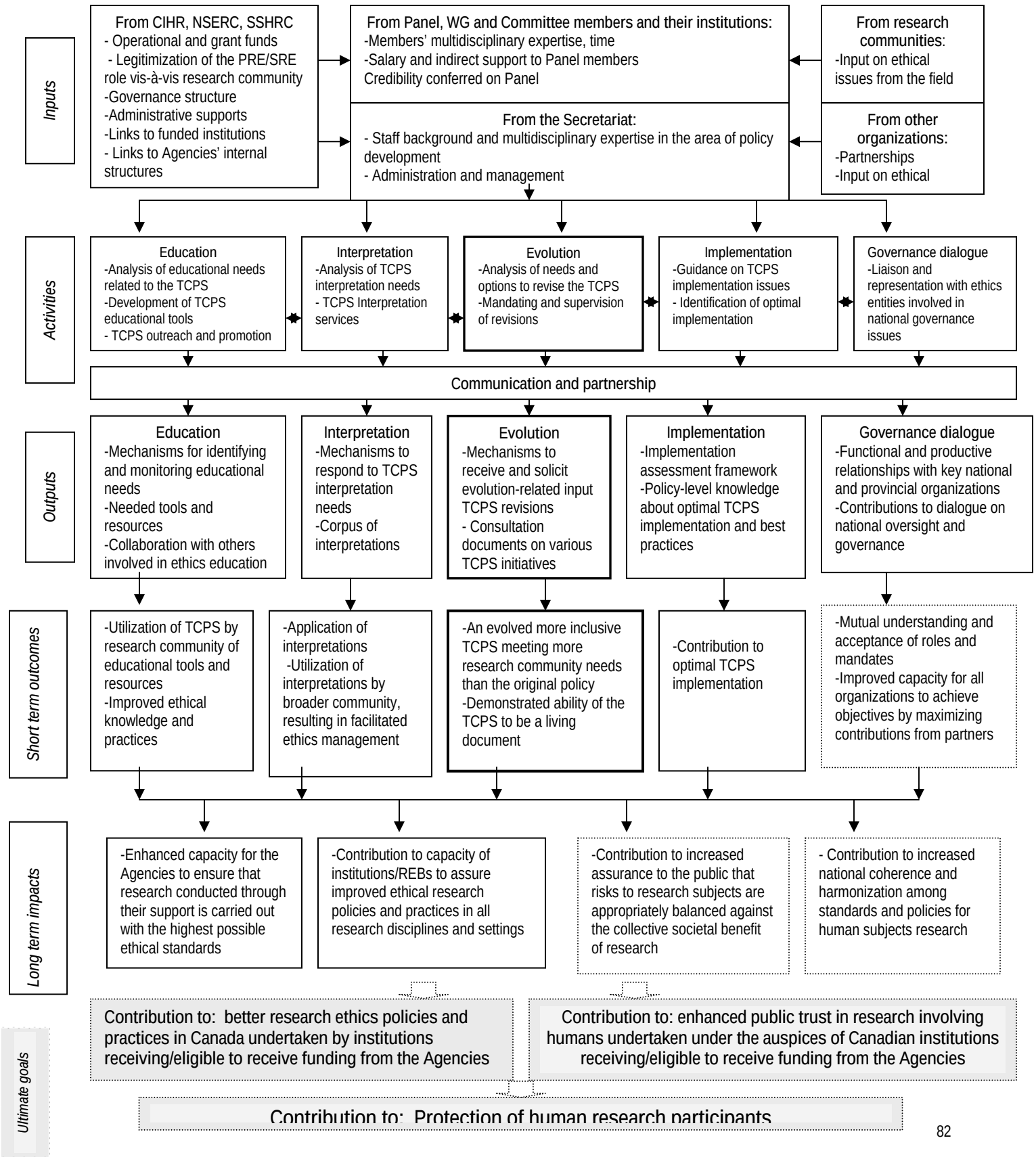
This evaluation concludes that despite the current commitment of the Agencies to the existing structure, it remains contested in some important quarters of the research ethics community.

Overall, the evaluation has shown that PRE-SRE has made much progress, but that its path and pace have not been straightforward nor rapid. Internally to the Agencies, there is optimism that current and future action will redress past difficulties; externally, there is also optimism but also some scepticism. A key lesson

to be learned from the period 2001-2009 would be about the need to strike a better balance between productivity and earnest, thorough and inclusive debate. Additional and more effective supports to this type of work could be explored. Another lesson would be about the need to maintain an open and collaborative approach in working with the many other organizations that have direct and indirect roles in research ethics policy, education and governance, working together to overcome fractiousness and competition. Finally, increased awareness about the mandate and activities of PRE-SRE as well as education of research community stakeholders about the controversial issues that remain regarding PRE-SRE, would help develop more informed opinion and clarify how PRE-SRE's contributions can be more clearly framed and delivered, and how stewardship of the TCPS should best be managed.

Appendix 1: PRE-SRE Logic Model

PRE-SRE Objective: promote high ethical standards of conduct in research involving humans through the development, evolution, interpretation, and implementation of the TCPS



Appendix 1: Logic Model for the support of SRE to the Agencies