Interagency Advisory Panel on Research Ethics (PRE)

Position Paper

Process and Principles for Developing a Canadian Governance System for the Ethical Conduct of Research Involving Humans

April 2002*

** Reprinted with a 2006 Preface*

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Canada

The Interagency Advisory Panel on Research Ethics (PRE) has been created by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada, to provide independent and interdisciplinary advice to these three agencies on the interpretation, evolution and use of the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* (TCPS).

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2006-2007 Preface

When PRE released this position paper in 2002, Canada was debating proposals for the governance of the ethical conduct of research involving humans – including national accreditation and certification, federal regulation and public assurance mechanisms. To contribute, PRE outlined some basic process principles for the national dialogue on governance:

> *PRE believes that a publicly accountable governance framework should be defined and developed prudently, considering and respecting the perspectives and needs of diverse stakeholders. There are many elements to an effective governance system. These include high ethical standards, effective process, and appropriate structures. Indeed, the strength of a research ethics governance structure is intimately tied to the integrity of the process that developed it. This paper expresses PRE's views about the principles for the process of governance development.*

In the last four years, Canada has mixed prudence with innovation in its public analyses, debate and implementation of several governance initiatives. Health Canada has created a departmental REB and has heightened its oversight of drug trials,[1] including ethical aspects. By 2003, some 100 Canadian universities and colleges had signed the Tri-Agency Memorandum of Understanding[2] that included agreement to adhere to the standards of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS). In a recent report that benefited from public input, the Task Force on Accreditation of the National Council on Ethics in Human Research proposed accreditation models and entities,[3] and a Parliament of Canada Committee has recommended the accreditation of research ethics boards that review clinical trials research.[4] PRE has proposed annual institutional reporting duties as part of a TCPS Implementation Feedback Framework[5] and has recently called for Canada to develop a pan-Canadian research ethics education strategy, as a component of good ethics governance. As 2006 drew to a close, Newfoundland had adopted legislation for a provincial health research ethics committee,[6] Quebec had released an evaluation report on governance mechanisms for health research ethics,[7] and a coalition of research sponsors, the Sponsors' Table for Human Research

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1. Health Canada. *Clinical Trials Regulatory Framework Review – Results of 2006 E-Consultation*. Dec. 2006. In winter 2007, HC will undertake a second consultation exercise to further explore options and solutions to address the requirements stemming from the clinical trials regulatory review.
2. CIHR, NSERC, SSHRC. Memorandum of Understanding on the Roles & Responsibilities in the Management of Federal Grants, Schedule 2: *Ethics Review of Research Involving Humans*. 2002.
3. National Council on Ethics in Human Research (NCEHR), Task Force for Development of an Accreditation System for Human Research Protection Programs. *Promoting Ethical Research with Humans*. July 2006.
4. Parliament of Canada, Report of the Standing Committee on Health, House of Commons. *Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs*. Ottawa, April 2004.
5. PRE. *TCPS Implementation Feedback Framework (TIFF) for the Ethical Conduct of Research Involving Humans in Agency-Funded Institutions and Partnering Organizations*. 2004.
6. Newfoundland. *Health Research Ethics Authority Act*. Statutes of Nfld. & Labrador, Chap. H-1.2, 2006.
7. Sonya Audy, Ministère de la Santé et des Services sociaux, l'Unité de l'éthique. *Le Plan d'action ministériel en éthique de la recherche et en intégrité scientifique: une entreprise insensée?* Québec, 2006. http://ethique.msss.gouv.qc.ca/site/122.0.0.1.0.0.phtml

Participant Protection in Canada, had formed an Experts Committee to advise on " the development of a system for human research participant protection in Canada, considering accreditation and alternative models."[8]

Such initiatives have international parallels. In 2002, the Organization for Economic Co - operation and Development (OECD) identified ethics frameworks as a means of preserving public trust in the governance of research.[9] South Africa has been accrediting health research ethics committees since 2003;[10] Britain since, 2005;[11] and New Zealand for over a decade.[12] European Union privacy law standards have spawned international and Canadian legislative reforms relevant to using identifiable personal information in human research. And over the last five years, the US has been experimenting with non - governmental accreditation of institutional "participant protection programs."[13]

These developments underscore important points.

- "Governance" in human research ethics captures an array of issues, depending on how narrowly, broadly or precisely it is defined.
- The Canadian initiatives indicate that governance activities have not been static; they continue, are evolving and remain dynamic.
- Some governance initiatives focus on process; some, on structures; and some, on standards. The most ambitious ones focus on all three, for all sectors and disciplines of research.
- Canada has not embraced a single, central, universal form for the governance of research involving humans.

As another phase of the governance dialogue advances, Canada faces some defining questions:

Problem: Is there agreement on specified ills or problems in human research ethics that

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8. Accessible via Health Canada: http://www.hrppc-pphrc.ca/english/experts.html
9. Organization for Economic Development and Cooperation (OECD). *Governance of Public Research: Towards Better Practices*. Paris, 2003, p. 21.
10. South Africa, Dept. of Health. *Ethics in Health Research: Principles, Structures and Processes*. 2004.
11. See National Health Service, National Patient Safety Review Agency, Central Office of Research Ethics Committees (COREC). *Building on Improvement*. London, 2006.
12. New Zealand, Health Research Council of New Zealand. *HRC Guidelines for Ethics Committee Accreditation*. October 1996; New Zealand, Health Research Council Ethics Committee. *Guidelines for an Accredited Institutional Ethics Committee to Refer Studies to an Accredited Health and Disability Ethics Committee* ('Referral' Guidelines). August 2003.
13. U.S., Department of Health and Human Service, Office for Human Research protections (OHRP). *Final Report of the Secretary's Advisory Committee on Human Research Protections' (SACHRP) Accreditation Subcommittee*. March 2004; U.S., National Research Council. *Responsible Research: A Systems Approach to Protecting Research Participants*. Washington: National Academy Press, 2003.

warrant governance reforms?

Scope: Is there evidence of universal, national, regional, sectoral or institutional problem(s) that require systemic or targeted solutions for particular standards, structures or procedures?

Goals: What are the goal(s) of the governance initiative (e.g., risk management, quality assurance, harmonization, protection, economics, precaution, enforcement, education)?

Means: Do we rely on consensus or voluntary adherence, or conditions on funded research, or mandatory legislation/regulation, as implementing means commensurate with key problems and high priorities?

Models: How do we best draw on international models and their presumptions (e.g., are Canadian and US governance needs, priorities and values so synonymous that Canada should adopt the US model of central federal regulatory oversight)?

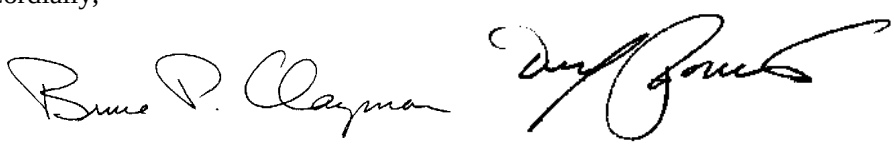
Pluralism: How to harness competing visions of governance ideas, problem(s), options and answers for our diverse research ethics community?

Time will tell how Canada answers the new and perennial governance questions.

Meanwhile, our paths of ethical reflection help define how we think about and respond to the questions and issues. The process principles and values that PRE proposed four years ago thus remain pertinent today for the study, debate and choices of deliberative democracy in national governance considerations. Canada still needs robust public participation, with inclusive and critical community dialogue, experience and expertise for rigorous analyses; transparency of process; and community engagement and models that respect diverse research disciplines, build on existing resources, and reasonably draw on international lessons – all, to advance public accountability and trust.

We thus recommend anew PRE's process principles. They offer fair, effective and prudent paths towards a new and sustainable culture of research ethics.

Cordially,



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Process and Principles for Developing a Canadian Governance System for the Ethical Conduct of Research Involving Humans

Executive Summary

This document presents the views of the Interagency Advisory Panel on Research Ethics (PRE)[1] on principles and process for the development of a Canadian governance system for the ethical conduct of research involving humans.

PRE recommends (a) a set of process principles to guide the development of a national governance system, and (b) the creation of a national task force (or its equivalent) with appropriate representation to assist in the development of a national governance system. Consistent with its terms of reference, PRE has further recommended to the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) that it participate, on behalf of these three granting Agencies, in the national task force and governance discussion and advise the Agencies on related developments. PRE's recommendations have been endorsed by the Presidents of CIHR, NSERC, and SSHRC.

Introduction

The protection of human participants in research is of paramount importance to all Canadians. The governance of the ethical conduct of research involving humans in Canada is of major concern to the Interagency Advisory Panel on Research Ethics (PRE) and the communities it serves. A governance system should implement the cardinal principle of modern research ethics: respect for the human dignity of research participants, as elaborated in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) of 1998[2]. This principle aspires to protect the multiple interests of the person— from bodily, to psychological, to cultural integrity.

PRE believes that a publicly accountable governance framework should be defined and developed prudently, considering and respecting the perspectives and needs of diverse stakeholders. There are many elements to an effective governance system. These include high ethical standards, effective processes and appropriate structures. Indeed, the strength of a research ethics governance structure is intimately tied to the integrity of the process that develops it. This paper expresses PRE's views about the principles for the process of governance development.

The Government of Canada, through the leadership of the Minister of Health, is evaluating how and whether to proceed with a national governance system for research ethics involving humans. To that end, Health Canada has undertaken a bi-lateral consultation process in recent months. It is now beginning a process of broader stakeholder consultation, to explore broader needs and perspectives. PRE believes that the work of Health Canada and others will be helpful for identifying various options for a governance framework. To further such initiatives, it is fitting and timely to chart leading elements of a robust consultation process. We outline the following process principles to do so.

Models & Processes for Developing a Governance System

At least three different, but not mutually exclusive, perspectives on research ethics governance have been proposed recently:

- The National Council on Ethics in Human Research (NCEHR) has proposed a system of accreditation as basis for governance;[3]
- The Social Sciences and Humanities Research Council has proposed a public assurance system for the academic community and affiliated institutions receiving Agencies' funding;[4]
- Health Canada, as noted, is coordinating an undertaking for initial consideration of approaches to accreditation and governance.

While each of these initiatives has merit, they have employed developmental processes characterized by varying degrees of consultation with those who will be affected. Each may contribute elements to the development of a governance system. Other models and options are likely to emerge. Still, PRE believes that a coherent and effective ethics governance system for research involving humans in Canada may best be developed through a defined public process to identify, evaluate and integrate different approaches. It

is impractical to have a patchwork system of governance that segments the research community into those in the academic, government and private sectors. The research community needs a shared vision – one that will help to define and build an overarching ethics governance system that protects human participants regardless of the provenance of the researcher, while facilitating research important to society. Given the national and even international implications and resources, it is time for all players to work together toward common solutions based on an agreed set of principles.

Accordingly, PRE recommends the following seven principles for the development of a pan-Canadian research ethics governance system:

- Transparent consultation. A governance system should be developed openly, collaboratively, and inclusively. **Consultations must:**

  - **be transparent** and provide for synergistic exchanges of perspective;
  - **be inclusive** with appropriate representatives from key stakeholder groups, including the academic, government, private and public sectors and potential human participants in research;
  - **foster critical dialogue** in an environment conducive to the free sharing of ideas.

  A transparent consultation process should help build consensus for the resulting governance system among its constituencies: Research Ethics Boards (REBs), researchers, institutions, the public, government, and industry.

- **Deliberative planning:** The importance of this initiative to all Canadians requires careful and deliberative planning. The development of a governance system should not be conducted in an atmosphere of "quick fix" and crisis.

- **Public participation and accountability**: The governance system should protect human participants and ensure public trust in the research enterprise. The development process must include and be accountable to the public.

- **The spectrum of research involving humans**: The governance system must protect human participants across the entire range of disciplines engaged in research. While doing so, it must recognize the diversity of research approaches and the degrees of risk to individuals, groups, communities and collectivities.

- **International perspectives**: Because Canadians conduct research in a global context, the development of an ethics governance system in Canada must be informed by international standards and approaches.

- **Feasibility**: The resulting governance system must acknowledge the fiscal realities of governments and institutions, and the capabilities of the research community and the public to participate in its administration. The crucial role of volunteers in the administration of ethics must be fully recognized, supported and integrated into the system of governance.

- **Build upon available resources & expertise**: The development process should take full advantage of existing resources and build on the current foundations for governing research ethics.

PRE's Mandate: Stewardship & Governance

The terms of reference of PRE outline its roles in stewardship of the TCPS and in contributing to the national governance dialogue.[5]

First, under its terms of reference, PRE has stewardship responsibilities for the TCPS. Stewardship of the TCPS includes responsibilities for its evolution and interpretation, educational implications, and its promotion and implementation. PRE considers all components of its TCPS stewardship mandate to be integrally connected.

Second, PRE is mandated by the three Agencies to participate in on-going discussions on the development of a national oversight system for the ethics of research involving humans. PRE's current mandate excludes it from becoming an accrediting body. Under a concerted and planned evolution of the research ethics community, the TCPS could eventually be integrated into a coherent national governance system. The work of PRE as presently constituted would then need to be reconsidered.

Evolving Roles: PRE, the Agencies & the Community

The roles of PRE derive from the work of the granting Agencies in responding to the evolving needs of the research community. Under their formal public mandates, the

Agencies began collaborating with research institutions, investigators and the ethics community on the development of national research ethics norms as early as the 1970s. In the decades since, they have dedicated significant and diverse resources to help build the national research ethics infrastructure. The commitment has gradually fostered interdisciplinary expertise and enhanced the capacity of Canada in research ethics. It has yielded national research ethics norms that have long been relied on by the public, universities, ethics committees, industry and the federal government.

In the 1990s, the granting Agencies integrated and harmonized their research ethics initiatives into the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* of 1998. The Agencies' creation of PRE to steward the TCPS continues a long-standing commitment to modern research ethics. PRE's stewardship responsibilities for the TCPS engage it in a diverse community. It implicates one of the largest communities of researchers, institutions, and Research Ethics Boards across Canada, covering virtually every discipline.

A more recent Tri-Council initiative underlines the breadth of the TCPS's impact on the research community and the continuing national search to enhance adherence to research ethics norms. The three granting Agencies (CIHR, NSERC, and SSHRC) have been developing a Memorandum of Understanding (MOU) on roles and responsibilities of the Agencies and Institutions. The MOU includes a schedule on ethics.* The MOU is to be signed by the Agencies and the institutions that receive funds from them. Under the terms of the MOU, the TCPS must be implemented by institutions for *all* of the research involving human participants that the institutions administer, not just for those projects that the Agencies fund. The requirement extends the community of those working with the TCPS beyond those researchers funded by the Agencies. Thus, the TCPS and MOU form a potent force for promoting a culture of ethics and responsible research. PRE is committed to identifying and advancing effective mechanisms that integrate adherence to modern research ethics norms with education initiatives and evolution of the TCPS.

* CIHR, NSERC, SSHRC. Memorandum of Understanding on the Roles & Responsibilities in the Management of Federal Grants, Schedule 2: *Ethics Review of Research Involving Humans*, (2002): *www.nserc.ca/institution/mou_e.htm*.

PRE's Roles

Against the background of the historic and evolving roles that the Agencies have played in national research ethics matters, PRE may contribute in important ways to the development of a national governance system:

- As PRE begins to identify, evaluate and otherwise address key areas of the TCPS that require amendment or modernization, its deliberations should define new national needs and norms for the research ethics community . PRE will collaborate with other Agencies involved in administering and regulating research and ethical conduct, to harmonize research ethics norms. PRE's stewardship function thus contributes to a more coherent national system of policy development.

- PRE will support and catalyze TCPS research ethics educational programs for REBs, researchers, and institutions. Effective education programs advance public assurance that research ethics functions are appropriately managed and implemented. This enhances public trust in research. PRE will advance TCPS educational initiatives by engaging existing resources, expertise and organizations in fruitful collaboration and partnerships.

- PRE is contributing resources that assist in the development of a governance system. PRE:

  - is committed to participating collaboratively in the consultation process with all stakeholders;
  - has access to the community of academic researchers, REBS, universities and their partners in Canada, and serves as a conduit for communication an d dialogue;
  - is establishing a website that will serve as a portal for the diverse communities working with the TCPS and related dimensions of human research ethics;
  - may help to coordinate regional or national fora on governance issues.

A Way Forward

PRE believes that steps toward the creation of a national governance system should be based on the principles outlined above. Indeed, it is incumbent on all parties to establish a national consultative structure and inclusive process. PRE appreciates the work that has been done to date on research ethics governance by Health Canada and others. [6] To advance it, PRE again recommends coordinating efforts and creating opportunities for a broader, inclusive dialogue.

On the basis of the principles outlined above, PRE believes that it is time to enact a transparent and inclusive process for the development of a national ethics governance system in Canada. A national task group should coordinate the process with appropriate representation from key stakeholders. PRE would support federal government leadership for this development process.

PRE, though recently established, is built upon decades of involvement with Canada's major research communities. As PRE begins to discharge its stewardship and governance duties, PRE looks forward to working with others in the coming years to establish a stronger research ethics culture across the country. Canada takes an important step towards doing so by defining and then developing a coherent national governance system for the ethical conduct of research involving humans.

Recommendations

PRE recommends

- That the three granting Agencies recommend to the Government of Canada, through the appropriate Minister(s), the establishment of a national task force (or its equivalent), to examine the development of a national governance system for the ethical conduct of research involving humans;
- That the national task force adopt the principles outlined in this document to guide its work;
- That PRE participate in the national task force on behalf of the three granting Agencies and advise on the development of a national governance system.

On 5 April 2002, the Presidents of the three granting Agencies (a) reiterated their support for improving the protection of human participants in research through the development of a Canadian governance system; and (b) endorsed the above recommendations of PRE.

Contact

For further information on PRE, its terms of reference, and the TCPS, contact the Secretariat on Research Ethics at secretariat@pre.ethics.gc.ca, or visit us at our website at *www.pre.ethics.gc.ca*.

References

1. Created in November 2001 by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, PRE membership draws on diverse professions, disciplines, and perspectives in modern research ethics, such as research, administration, ethics, law, health consumers, nursing, sociology, medicine, etc. 2002-03 PRE members are:
   Dr. Howard Brunt, Chair – University of Victoria, BC
   Dr. Bruce Clayman – Simon Fraser University, BC
   Mr. Pierre Deschamps – McGill University, QC
   Dr. Hubert Doucet – Université de Montréal, QC
   Dr. Norman Frohlich – University of Manitoba, MB
   Mr. Paul Johnston – Precarn Incorporated, ON
   Dr. Carol Sawka – Toronto-Sunnybrook Regional Cancer Centre, ON
   Ms. Maureen Smith – Ottawa, ON
   Dr. Susan Sykes – University of Waterloo, ON
   Dr. Will van den Hoonaard – University of New Brunswick, NB
   Dr. Peter Venner – Cross Cancer Institute & University of Alberta, AB

   PRE's mandate is summarized in note 5, below. PRE is complemented and supported by the mandate and functions of the Secretariat on Research Ethics (SRE). Current SRE members are:
   Derek J. Jones, Executive Director
   Hanan Abdel-Akher, Policy Analyst
   Natalia Bendin, Policy Analyst
   Thérèse De Groote, Policy Analyst
   Jacqueline Jorge, Administrative Officer

2. *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* . Ottawa, 1998 (with 2000, 2002 and 2005 amendments). Online: *www.pre.ethics.gc.ca*.

3. NCEHR. *The Final Report of the Task Force on Accreditation.* Ottawa, 2002.

4. SSHRC, Standing Committee on Ethics and Integrity. *Public Assurance System for Research Involving Humans in Council-Funded Institutions*. Ottawa, 2001.

5. PRE's mandate includes the following duties, to:
   Advise on the evolution of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)
   Learn from and respond to issues, practices and the context of research ethics
   Consult experts and the public
   Advance implementation of the TCPS
   Undertake TCPS interpretation and education initiatives
   Contribute to the National Dialogue on Oversight and Governa nce Systems
   Promote high ethical standards for research involving humans

6. See, e.g., Parliament of Canada, Standing Senate Committee on Social Affairs, Science and Technology. *The Health of Canadians -- The Federal Role: Interim Report*. April 2002, Vol. Five, (Principles and Recommendations for Reform), ch.5.7.1 - 5.7.2 (Applying the Highest Standards of Ethics to Health Research): *http://www.parl.gc.ca/37/1/parlbus/commbus/senate/com-e/SOCI-E/rep-e/repapr02vol5-e.htm*.