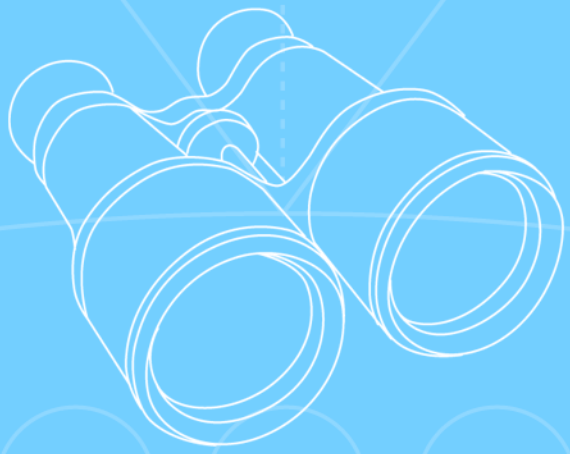
August 2001

Public Assurance System for Research Involving Humans in Council-Funded Institutions



SSHRC Standing Committee on Ethics and Integrity

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Social Sciences and Humanities Research Council of Canada
Conseil de recherches en sciences humaines du Canada
Canada

Public Assurance System for
Research Involving Humans in Council-Funded Institutions
August 2001

Introduction and Background

The SSHRC Standing Committee on Ethics and Integrity (CEI) submits for comment and feedback its proposal of a Public Assurance System as a procedure for national oversight of the ethics review of research involving humans. The context and rationale for the Standing Committee's development of this proposal is explained in this introductory section. The observations and process that guided the committee's thinking and the Public Assurance System proposal itself follow in the remainder of the document.

At the October 2000, meeting of Council, the Standing Committee on Ethics and Integrity (CEI) recommended that Council should advocate an asymmetric approach to national oversight of the research ethics review process. It was effectively argued that the oversight process for research in the social sciences and humanities should be different from that applied to biomedical research. There are clearly different needs for ethics oversight within the two communities, the biomedical community needing a strict adherence to standards for informing participants in clinical trials with precise consent procedures requiring the patients' signatures, whereas the social sciences and humanities community need broader ethical issues to be weighted and quite different options explored before ethical decisions are made. Council agreed with the Standing Committee recommendation.

However, subsequent developments have shown the context for the development of a national oversight mechanism to be changing rapidly. Concerns about the oversight of research ethics involving humans for government funded research and for research in the private sector in Canada have been building over the past several years. These concerns have arisen most dramatically within biomedical research, but they exist as well for the oversight of research ethics in the social sciences and humanities. Recent research ethics developments in the U.S.,

such as the news in June, 2001, about the death of a healthy volunteer in an asthma-related clinical trial, news about researchers pursuing the cloning of human life, and the Presidential review and decision regarding stem cell research have all heightened concerns about the oversight of research ethics decisions. The internationalization of biomedical research, expansion of clinical trials within the private sector, and the revision of regulations for clinical trials within Canada, have combined to produce increased pressure for development of a national accreditation process for research institutions and Research Ethics Boards as regulatory procedures to provide the Canadian public with needed protections.

In addition, the SSHRC Standing Committee has come to recognize that the public, researchers in other disciplines, and the government agencies responsible for developing a national system for oversight of research ethics do not appreciate the desire of the Social Science and Humanities community for asymmetrical national oversight policies. Rather, calls for separate policies are seen, albeit inappropriately, as desires for different, i.e., lesser standards, for our research. These attitudes and concerns have been evident within the U.S. where it has not been possible under their regulatory system to have a duo-policy or separate policies governing national oversight of the ethics review process. Given these conditions, the SSHRC Standing Committee felt it to be prudent not to continue to fight for asymmetry, but rather to develop and promote a single approach to oversight that could be regarded as workable for both biomedical and social sciences and humanities research undertaken under the auspices of institutions receiving Council funding. The Standing Committee did not abandon its view that research ethics takes different forms and has different needs for research in the social sciences and humanities than in biomedical research, but rather gave serious consideration to the ways in which these differences could be accommodated under a single national oversight mechanism.

The Committee spent the next several months looking at two oversight approaches: the precise rule-defined accreditation system and a public assurance system based on annual reporting and educational and formative procedures allowing for the evolution of an ethics culture within research communities. The Standing Committee concluded in favour of the latter approach and recommended this mechanism and the attached Public Assurance System to the SSHRC Council

meeting in June, 2001. The Committee's recommendations including the following Public Assurance System was unanimously approved by the SSHRC Council as an oversight model that would provide appropriate public assurance for research undertaken in institutions receiving Council funding.

SSHRC Council has recommended the PAS proposal to the new Panel on Research Ethics and Secretariat on Research Ethics, to the Boards of the Canadian Institutes of Health Research (CIHR) and the Natural Sciences and Engineering Council of Canada (NSERC), and to the Policy Branch and Ethics Division of Health Canada with an invitation to discuss this proposal in the context of their deliberations on oversight for research ethics governance and functions. The SSHRC will further consult with appropriate groups of social sciences and humanities researchers with a request to provide their feedback on this proposal.

The Public Assurance Proposal

Need for a national ethics oversight process

Canadian society and the Canadian government look to research to advance knowledge as a means to promote economic development, to advance the health of Canadians, to solve the country's social problems, and to improve the quality of our lives. Accordingly, the research enterprise in Canada is supported strongly by the government and its support is growing. The public must be confident that these expenditures are justified and effective, and that the research is of the highest standard while protecting the human participants. Councils require peer review of all proposals as a means of assuring the public that they fund research of the highest merit. As a companion step, the Councils issued a *Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans* (TCPS). Its adoption by Canadian universities for all research undertaken under their auspices was made a condition for the institutions to continue to receive funding from the federal granting agencies. The policy was designed to ensure that human participants in research are well protected through prior ethical review and approval of the proposed research.

Councils invested the research ethics review process in the institutions they fund who in turn are expected to have set in place an appropriate system of research ethics review based on the principles and guidelines outlined in the TCPS. To date there has been only a paper review of these institutional policies by the Tri-Council Advisory Group. There is need for a transparent and open accounting on a regular basis of the functioning of these institutional policies, procedures and interpretations to assure the Canadian public that the policy is being implemented and that the institutional review system is being followed.

To address these needs, attention has turned toward some form of accreditation, or monitoring of the performance of the ethics review process within institutions. The need for an accreditation system has been strongly expressed by the former Ethics Committee of MRC, within the Tri-Council Advisory group, and most recently within CIHR. The internationalization of health

research and accompanying international codes and guidelines for clinical research as well as international recognition of the adequacy and equivalence of Canadian ethics review standards are driving forces behind a move toward accreditation. Moreover, the TCPS likely will become the standard for all human research in Canada with its application to government labs, hospitals, and research in the private sector. Agreement was reached within the Coordinating Committee of NCEHR that Health Canada should take the lead in developing the consultation on a model for accreditation.

Context: Implementation of the TCPS within Universities

On September 9, 1998, after four difficult years of policy negotiation and drafting, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) was announced by the three Council Presidents. Universities were required to adopt policies implementing the first two sections of the TCPS in order to remain eligible for Councils' funding. Most universities had complied by an extended deadline of December 1, 1999, and their policies were reviewed and letters indicating approval or requesting modification were sent to each University by the Tri-Council Ethics Secretariat (NSERC) by the Summer of 2000.

However, this task proved to be a much greater undertaking than had been anticipated. In a number of universities the realities of dealing with objections raised by various university committees, including Faculty Associations or unions, and obtaining approval of a final policy by University Senates proved difficult. As of this writing several universities still do not have an approved policy in place. In consultations with institutions on the Memorandum of Understanding on Roles and Responsibilities, it was suggested that September 1, 2001 might be the deadline for compliance before Council action may be required.

Nonetheless, the policy has been reasonably well accepted by universities. Aside from complaints of the costs of its implementation, most universities are dedicated to the task and are conscientiously pursuing ethics reviews of research. Indeed, several universities have dedicated new organizational positions to persons whose sole or primary function is to administer the

ethics review process. Most universities have applied the TCPS to all research under their jurisdictions. However, during this three-year period, there has been no formal monitoring of REBs nor of universities. Some assurance of compliance with the policy would seem to be in order and even expected, especially following the suggested September 1, 2001 deadline.

But this oversight mechanism should take into account the fact that universities will continue to need help and feedback. Some REBs have yet to experience the range of difficult decisions they will have to face. Some policies and procedures may have to be modified based on experience. In addition, all institutions face a new task: they have been asked and required through the TCPS and Memorandum of Understanding to develop educational programs to enhance their review process and promote a climate of ethics. This context implies the need for an oversight mechanism that is based on an educational, formative approach with room for flexible and consensual improvement of the system rather than on strict evaluations of how well they have met some procedural standard.

Context: Different Discipline and Research Ethics Issues

All fields of research have to address a common core of ethics practices and concerns. Yet each discipline has specific issues to deal with in the nature of their topics, subjects, methodologies and data. A more sophisticated ethical approach would allow and be enriched by discipline-specific reflections on ethics issues. For some disciplines that have previously not required ethics review, institutions will need to encompass them within the ethics review process and work with researchers to promote sensitivity to ethics issues and practices. At the same time, research crossing discipline boundaries intersects varied paths of ethical thinking, and the review process and oversight mechanism must allow for this discipline cross-fertilization and enrichment to take place.

The TCPS and ethics review process are built around the concept of minimal risk. Risk is an evolving concept, with higher-risk research needing a more control-based approach and lesser risk research requiring a more formative approach. The protection of the human subject participating in research is complex and multidimensional and should be weighted appropriately

to the level of risk. In addition, the population that is the focus of the research varies widely from very large clinical trials, to small cohorts of interviewees. As a rule, the larger sized cohort magnifies the scope of risk and hence necessitates a different level and approach to oversight. This may lead to the need for a more control-based oversight of the REB ethics review for some and a more flexible approach for others.

Context: The Canadian vs. the American Ethics Review System

In the United States, research involving human participants, sponsored or carried out by federal departments and agencies is subject to the Code of Federal Regulation (1991), "the Common Rule" that requires research ethics review for biomedical and behavioural sciences. Since its introduction in 1991, only 18 federal departments have adopted the Common Rule.

The history of ethical regulation applying to biomedical, health and behavioural sciences in the U.S. is marked by cycles of increasing regulation and oversight following non-compliance with previous regulations. For example, the death of a research participant in a gene-therapy study and the temporary suspension of all federally sponsored research activities in some institutions and federal departments in the US has resulted in renewed efforts to enhance the protection of human participants in clinical trials with legislation proposing fines for institutions and investigators involved in research not in compliance with the research ethics review requirements.

In addition, the Department of Health and Human Services has commissioned a two-phased study by the Institute of Medicine (IOM) on how to improve the structure and function of human research review programs, including standards for accreditation. In a separate initiative, Veteran Affairs (VA) commissioned the National Committee on Quality Assurance (NCQA) to develop accreditation standards for research sponsored and undertaken in VA Medical Centres; this accreditation process will begin July 2001. In a third initiative, Public Responsibility in Medicine and Research (PRIM&R), a non-profit organisation for IRBs, has also developed draft accreditation standards. Looking at all of these, the IOM recommends (in a very recent advanced report) the adoption of the NCQA standards, primarily because they seem to emphasize

flexibility in achieving human protection. It should be observed that the IOM recommendation is only for a pilot testing of an accreditation system revealing the acknowledgement that further changes and evaluation of pilot testing programs may be required. The IOM report also recommends a non-governmental voluntary accreditation process.

Following a history of breakdowns in compliance with regulations, the next cycle of re-engineering the U.S. federal oversight process shows recognition at last of the need for an emphasis on education, and greater flexibility in the evaluations of informed consent. Indeed, the Office of Human Research Protection (OHRP) is setting up an enhanced educational program (workshops, conferences, presentations, educational site visits, town meetings, public education, and online library of educational resources) for research investigators and IRB members as well as providing guidelines on IRB resources and workload. These shifts in the focus of oversight approaches in the US seem to indicate recognition of the importance of promoting a culture of ethics as advocated in the present proposal.

In contrast, Canada has had a national policy statement that, unlike the U.S. regulations, covers all research fields and disciplines. Similarly, their lengthy experience with ethics regulations differs substantially from our own where a policy has been in place for less than three years and full implementation is still in the process of being finalized in some institutions. Discussion on accreditation has taken place in several fora, such as the former MRC Standing Committee on Ethics, the present CIHR Working Group on Ethics, the Coordinating Committee for NCEHR, the Policy Branch and Therapeutic Products Programs Division of Health Canada, the Tri-Council Advisory Group and the SSHRC Standing Committee on Ethics and Integrity. The spectrum of views extends from those advocating a rapid move to a legislated system of accreditation to the introduction of a more flexible, formative approach to oversight and control.

In Canada, the Councils are in the process of establishing the Panel on Research Ethics and the Secretariat on Research Ethics with the objective to ensure a coherent response to the needs and expectations of Canadian researchers, research institutions, research ethics boards and the public. To achieve a governance structure that involves all groups involved or affected by the research ethics within academic settings, will require the construction of learning loops through which

concerns, issues, questions as well as solutions, recommendations and best practices can be addressed and shared in a collaborative way. As a point of convergence for these debates and discussions, the Panel and Secretariat will support the nation-wide development of a culture of ethics. The participation of the various groups, institutions, organizations and individuals will help to bring the research ethics governance and discussion to a higher level.

Definitions of Accreditation and Assurance

Accreditation is defined in many ways, but basically involves the introduction of a set of rules or standards to which all must comply. Accreditation has been defined in the U.S. as "a conformity assessment process in which an organisation or agency uses experts in a particular field of interest or discipline to define standards of acceptable operation/performance for organisations and measure compliance with them" (PRIM&R), and the accreditation process as “a routine, independent evaluation of compliance with federal policies and regulations (NCQA). The Canadian Council on Health Services Accreditation similarly defines accreditation as “a detailed comparison of an organisation's services and method of operation against a set of national standards. The process includes a self-assessment by the organisation to measure its own compliance against national standards and independent surveyors undertake the accreditation survey using the same national standards to independently measure the organisation.” All of these organisations have focused their approach for developing standards primarily on facilities undertaking health-related research. Accreditation standards are typically articulated by a national body which authority and then must be met by all.

By contrast, assurance is defined as "as an agreement or contract between the institution and the oversight body .... stipulating the method(s) by which the organisation will protect the welfare of research subjects in accordance with the regulations. Assurance, approval of which is a condition of receipt of support for research involving humans subjects, spells out the organisation's responsibilities for meeting the requirements of the federal regulations”(NCQA). Similar to SSHRC/NSERC financial management agreements with institutions, site visits under an assurance model can be undertaken to check and to provide support and advice on the institution's procedures and practices.

The Challenge of Defining an Appropriate Public Assurance Mechanism

The various options for an oversight mechanism extend from a model that seeks the voluntary cooperation of universities to an across-the-board imposed, formal accreditation system. The introduction of a national oversight mechanism for the TCPS is an important step for which the readiness of the agencies, university administrations, the research community, and newly established REBs is crucial. It is an understatement to say that the task of defining a national oversight mechanism is challenging. Given the newness of the policy and REB review process in Canada, the diversity of research approaches and ethics issues across disciplines, the range of levels and scope of risk encountered in such research, the varying levels of experience with the ethics review process, we view the introduction of an accreditation model to be premature. Rather an assurance system with broad flexibility and scope for all disciplines should provide subjects with better protection, the public with immediate assurance, be applicable to all disciplines and yet allow for more stringent oversight where necessary, and promote remedial or formative development of the review process in early stages of its implementation, and growth and refinement of the TCPS. Such as system should be universal, i.e., required of all REBs in all institutions within Canada. Regular accounting would demonstrate the seriousness with which institutions, REBs and researchers are following the TCPS, and of the willingness to engage only in research that has been evaluated against strong ethical standards and principles. Good governance implies accountability, effectiveness and transparency.

Any national assurance mechanism should also be accompanied by a promotion of best practices and educational materials and activities that would consolidate and enhance the consistency of application of the TCPS across the country while at the same time respecting the varied research disciplines and their methodologies. These educational activities should assist in furthering and enhancing a culture of ethical research in every research institution. To achieve this goal, an oversight mechanism should not only evaluate the procedures of the research ethics review system, but also contribute to debate and discussion around major ethics issues of concern to particular research disciplines and to the public. These debates among researchers and the public

will in the end nourish the reflections of REB members, the research community and the public at large. The Standing Committee concludes that all of this can be best achieved only under an assurance model.

The Proposed Public Assurance System (PAS)

To meet these challenges and all of the foregoing complex issues and diverse disciplines governed by the TCPS, the SSHRC Standing Committee on Ethics and Integrity proposes the Public Assurance System as the model for oversight of the ethics review process. This system will provide the public with assurance that the institutions are appropriately providing protection for human participants in the research that Council funds. The elements of the proposed Public Assurance System (PAS) are outlined below and described in a chronological and functional manner in the Appendix.

The Public Assurance System (PAS) is based upon:

1. **Three policy documents:** (i) The *Tri-Council Policy Statement: Ethical Conduct for research Involving Humans* (TCPS), (ii) the institutional policies and procedures implementing the TCPS, and (iii) the Memorandum of Understanding on Roles and Responsibilities between the Agencies and Institutions. This MOU has relevant schedules on (a) Research Ethics, specifying that the TCPS will apply to all research (not just Council-funded research) and that institutions will develop ethics education programs, (b) the Tri-Council Policy Statement on Integrity in Research and Scholarship for addressing individual infractions of the ethics policy, and (c) the manner for investigating and resolving institutional breaches of agency policies.

2. **Governance of the policy and PAS** through the Panel & Secretariat on Research Ethics or contracted agents of the Secretariat as required.

3. **Two Oversight Mechanisms:** Procedures and practices will be monitored through two oversight mechanisms**:**

   (i) ANNUAL REPORTS requiring institutions to specify annually (a) the number of REBs (their areas of responsibility & composition), (b) the number of protocols

reviewed through full REB- & expedited-review, (c) the number approved, rejected, and pending protocols, (d) the nature and extent of educational programs for REB members and researchers, and (e) a description of major ethics issues & problems encountered during the year.

(ii) SITE VISITS: contracted out by the Secretariat on Research Ethics. Site visits will be conducted at all institutions on a rotating basis (once every five years). The site visits will be conducted following a pre-visit report. The purposes of these site visits will be (a) formative & corrective for the Institution (helping to develop appropriate procedures and correct problems), rather than evaluative and punitive (assessing compliance against fixed procedures and rules and issuing ultimatums) and (b) diagnostic: identifying ethics issues & problems for the Secretariat & Panel to address.

4. **Policy Refinement & Development:** The PAS is designed to treat the TCPS as a living document by various mechanisms leading to policy refinement and development. This will be achieved through new issues & policy problems identified by users, submitted in Annual Reports and in Site Visit Reports. These issues and problems will be reviewed & changes recommended by the Panel on Research Ethics. In addition, the Panel and Secretariat will pursue policy gaps such as addressing the ethics of research with aboriginal communities, participatory-action research, qualitative research, naturalistic observation and other policy matters. In addition, the Panel and Secretariat would also address implementation issues, such as resources for REB functioning, and on-going monitoring of research.

5. **Education:** The goal of developing a culture of ethics will be addressed through the development of workshops, materials for the education of REB members and chairs, principal investigators, and students (both graduate and undergraduate), focused discussion sessions on significant issues identified locally, and through the organization of national workshops and conferences. These will have to be undertaken by the various players such as the Panel and Secretariat as well as institutions and REBs.

6. **Sanctions for infractions** (1) by researchers will be dealt with under the Tri-Council Integrity

Policy Statement in which the university reviews the evidence, imposes sanctions if necessary, and reports the review process & decision to the relevant agency; and (2) by universities under the Memorandum of Understanding conflict resolution mechanism in which persistent compliance failure will be dealt with by withholding funding

7. **Evaluation, Continuation or Modification of PAS**. PAS is a fundamental assurance system applicable to all disciplines; easily adapted to add-ons for biomedical research or other changes should they be required. The proposal is for PAS to be independently evaluated after five years, and to be continued if found satisfactory or to be modified or discontinued if independent assessment indicates changes are warranted.

Special Features of the Proposed Public Assurance System (PAS)

The proposed Public Assurance System is appropriate for the conditions within Canada at this time. It is formative in approach to ensure that the standards of ethics review are meaningful for the broad spectrum of research governed by the TCPS, and it promotes and encourages the growth of a more sophisticated ethics perspective. Some of the distinctive features of the proposed system include:

1. **Universality:** There should be one Public Assurance System that applies at a fundamental level to all research ethics review in Canada. The PAS should apply to all institutions and all REBs in their review of all research. A subsequent accreditation system, should it be necessary, would be based on a solid implementation of the research ethics review process for all fields of research in all institutions

2. **Educational and Formative:** The objective of PAS is to strengthen and develop the review process for better protection of human subjects and to provide greater public assurance that a valid system of ethics review is in place. Effective public assurance is not achieved by a system that merely audits and punitively corrects flaws or omissions, but one that provides for growth of ethical thinking and promotes a culture of ethics among all researchers. This Public Assurance System would be much more radical and demanding than a restricted, rule-

bound application of the policy.

3. **Evidence-Based**: The Public Assurance System of institutional REB functioning through annual reporting will provide evidence-based information on how ethics review is being implemented, and whether there are ethical questions and issues that have to be addressed to ensure that human participants are being well protected through REB review. This evidence-based approach will also provide baseline information and insights for reviewing and modifying the governance structure and even within the review process if necessary. Rather than imposing rules for application of the policy, guidance will be best worked out through consensus and experience.

4. **Best fit to a Broad Range of Disciplines:** The Public Assurance System provides oversight that is fair and equivalent for all disciplines. Rather than dictated by one set of disciplines or methodologies, the PAS ensures that discipline-specific research ethics issues and considerations are reviewed, evaluated and resolved within the framework provided by the TCPS and REB review process.

5. **Allow for Growth of the Policy and of the System:** The proposed Public Assurance System through annual reporting of ethics issues allows for the growth and evolution of the system. The proposed Public Assurance System would encourage learning loops between REBs and researchers, and between researchers, REBs and institution on the one hand and the human participants and the public at large on the other hand. The TCPS and its application in the institution would be the basis for stimulating discussion and debate at several levels within the institution and in society. This, in turn, would encourage the growth of the system in the Canadian context.

6. **Possible to Implement Immediately:** A distinct advantage of the proposed system is its readiness for immediate implementation. In this context, an educationally-oriented public assurance system (PAS) would be seen as simply the logical, immediate next step in the implementation of the TCPS. Moreover, a gradual evolution of the policy into the next phase

promotes national oversight within a positive and constructive climate.

7. **PAS is Fundamental Oversight; Allows for Add-ons as needed**: The PAS is proposed as a fundamental oversight system. The proposed PAS would likely be sufficient for most REBs in the majority of universities, but could be supplemented by additional oversight as required for biomedical research, and still other special attention to more radical research with special ethics issues. Biomedical clinical trials may require closer scrutiny and demonstrate a need for stricter rules and regulations than the proposed PAS provides. Still higher levels of scrutiny are required for stem cell research and other forms of biomedical advances that are at the edge of societal ethical concerns.

APPENDIX

PUBLIC ASSURANCE SYSTEM FOR RESEACH INVOLVING HUMANS IN COUNCIL-FUNDED INSTITUTIONS

Proposal of SSHRC Standing Committee on Ethics and Integrity

June 8, 2001

Stage	Assurance Mechanism	Institutional Activity	Time Frame
1	**Tri-Council Policy Statement (TCPS)**	Institutions to draft policies implementing the TCPS	September, 1998
2	**Tri-Council Ethics Policy Monitoring -** Tri-Council Secretariat reviews policies and gives feedback requiring revisions	University submitted policies to Tri-Council Ethics Secretariat (Policies revised according to feedback received)	1999-2001
3	**Panel & Secretariat on Research Ethics: Implementation Monitoring** (REB composition reviewed; feedback provided; National implementation status report compiled as baseline for the country)	Universities to report on implementation status on September 1, 2001, the proposed final deadline given by Councils for development and initial implementation of the policy (Report to include number of REBs and the composition of each)	September, 2001
4	**Tri-Agency Memorandum of Understanding (MOU)** as basic agreement on roles and responsibilities of agencies and of Universities re: ethics and integrity in human research	University agreement to role in human research ethics: Agree to apply TCPS to **all** human research; to develop program of education; and to report annually on these activities	2001-2002
5	**Annual Monitoring Reports received by Panel & Secretariat** who will review, evaluate, and provide feedback; and compile an annual national report	Universities report annually on number of REBs and composition; protocols reviewed (full & expedited), approved and rejected, educational activities & significant ethics issues & problems.	Annually: 2002-2007
6	**Further development of the TCPS** Panel to review reports of significant ethics issues and to recommend policy modifications and additions to the TCPS.	Universities to consider and respond to significant ethics issues arising within its REBs and to report problems/and or suggestions to the Panel & Secretariat	Annually

	Secretariat to contract working groups to examine and develop policy on areas not addressed within the TCPS.		
7	**Site visits of human subject ethics review process at each Institution** (Contracted agents of Secretariat to conduct annually site visits of institutions on a rotating basis) Review to be formative and educational for the institution, but to provide informative feedback and areas needing policy development to Panel & Secretariat	Institutions to facilitate site visit by providing access to all persons and records related to ethics review process for formative advice in shaping the structure and process.	2002-2007
8	**Research ethics infractions or misconduct by investigators** Reviewed and dealt within a timely manner by the university in accordance with the MOU and the Tri-Council Policy Statement on Integrity in Research and Scholarship	According to MOU, Universities to investigate and to apply sanctions in accord with the Tri-Council Policy Statement on Integrity in Research and Scholarship. Under this policy universities are to report on its review, conclusions and any sanctions applied.	At any time
9	**Research Ethics System Failure** Failure of the REB or University to report or to function in accord with the policies or the MOU will be addressed by the actions specified in the MOU for conflict resolution.	Memorandum of Understanding between institutions and agencies provides a process of conflict resolution for addressing any problem.	At any point
10	**Evaluation of Public Assurance System (PAS)** Independent review of structure, functioning and effectiveness of Public Assurance System overall and for different fields of research.	Institutions to provide input into evaluation process.	2007-2008

SOCIAL SCIENCES AND HUMANITIES RESEARCH COUNCIL OF CANADA

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