

**Governance of the Ethical Process
for Research Involving Human Subjects**

Final Report

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**Centre on Governance, University of Ottawa
Ottawa, Canada**

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Executive Summary

On the release of the Tri-Council Policy Statement on September 17, 1998, Dr. Henry Friesen, President of the Medical Research Council, stated that: "Canada is the first country to produce a comprehensive ethical policy statement for research involving humans in all academic disciplines."¹

This courageous experiment is fraught with difficulties, both in regards to substance and process issues. Not surprisingly, a number of hiccups have emerged; accordingly, the Medical Research Council, the Natural Sciences and Engineering Research Council, the Social Sciences and Humanities Research Council, the Royal College of Physicians and Surgeons of Canada, Health Canada and the National Council on Ethics in Human Research contracted the Centre on Governance of the University of Ottawa to conduct a study of the current governance process in promoting ethical conduct in research involving humans.

Starting in January 2000, the Centre interviewed about 60 individuals, some in person and some on the telephone, went through many forests of documents, and issued an Interim Report on February 22nd. On the basis of the responses to the Interim Report and further reflection on these difficult questions, the Centre has prepared this Final Report.

We recognize that not everyone will be entirely happy with the recommendations that we are making; however, our view is that the proposals will advance the cause of the protection of human subjects in a real and substantive way. Many will come forward with the argument that only the "ideal" or "best" solutions are acceptable, but as Gilles Paquet has written, "the best is often the enemy of the good".²

We are putting forward a workable solution to create a learning process among the various stakeholders for a five-year period. The "double diamond" set of relationships will simplify the current structure, clarify the roles and functions of the various organizations and generate a learning system among researchers, review boards and funding councils.

We are recommending that the Tri-Council Policy Statement (TCPS) and its implementation within the areas of jurisdiction of the three Councils be the initial focus of the governance process. When the TCPS was released, the three Presidents made clear that it was an evolving document and indeed there is much still to be done. Once that content and process have been solidified and working well, then consideration should be given to broadening aggressively the application of the policy. We envisage the TCPS becoming the "gold standard" for research not only within universities, but also within government, non-profit groups and the private sector. But this objective will not be achieved unless we get the initial implementation right.

¹ Press Release, "Joint Policy Statement on Ethics--A First for Canadian Research Councils". Ottawa, September 17, 1998.

² G. Paquet, "The best is enemy of the good", *Optimum*, Vol. 22, No. 1, 1991, pp. 7-15.

In this Report, we present a sketch of the historical background that led to the present arrangements (Chapter 1), a sketch of the arrangements presently in place (Chapter 2), a review of the problems mentioned to us by our respondents about the present structure (Chapter 3), a list of the priority issues to be resolved (Chapter 4) and a brief examination of alternative ways to resolve these difficulties together with a proposal of what we feel would be the sort of governance structure required to do the job (Chapter 5). In conclusion, we reiterate key messages of this Report – the very recent and experimental nature of the arrangement in place, the critical difficulty of arriving at a totally satisfactory solution in the very short run, the need to allow some time for social learning, and the necessity to revisit the problem after five years to see if additional modifications are then seen as necessary.

Introduction

Research involving human subjects is an important component of the research enterprise in the private, public and university worlds. It has been defended as a leading source of new knowledge that has led to the development of effective responses or cures to many human and social ailments.

The ethical problems raised by such research have to do with the potential harm that can be inflicted on humans and communities wittingly or unwittingly. Within the logic of research to proceed unimpeded by extraneous considerations, the researcher may be led to impose experimental conditions that may prove destructive or likely to have deleterious effects on human subjects.

The tradeoffs between the *benefits* to researchers (and their sponsors and employers) and the *malefits* to human subjects is a difficult balancing act. As long as the *malefits* are minor and the *benefits* significant, such research projects may be affirmed, but the problems of defining what are minor or major risks to human subjects and the question of who should be authorized to make such a determination are of great concern to researchers, academics and governments.

The guiding principle that would appear reasonable in this context is a sort of Hippocratic Oath that researchers would not impose on human subjects experiments that might harm them. Such a proscription is not as helpful as a guide in the research process as it might first appear. In most instances, the researcher and the human subject are not facing an either-or choice, but a more-or-less choice. Obviously, one may ponder whether a small inconvenience to human subjects is not a reasonable price to pay to gain significant new knowledge likely to be of benefit to humanity. But what is an acceptable trade-off and who should decide?

The question of the limits (dictated by *prudencia*) beyond which researchers should not proceed, or should proceed only with very elaborate auxiliary precautions, is therefore quickly becoming of central importance. In the process of defining these limits, the interests of the researchers and of the research enterprise have to be balanced with the safety of the human subjects.

Two types of errors

Two types of errors can be made in the process of determining what is permissible: one may restrict unduly the research process or prohibit its pursuit by imposing excessive constraints when in fact human subjects are not in any real danger (Type I), or one may legitimize and accept unquestioningly or constrain insufficiently the research process when in fact human subjects are at risk (Type II).

At the core of the ethical concern about research involving human subjects is the central interest in preventing errors of Type II, i.e., accepting as legitimate protocols, procedures and intrusions of all sorts that might be detrimental to human subjects. Such a concern is not groundless since a number of scandals have revealed that some research projects undertaken by scientists have had

such impacts on human subjects. On the other hand, it should not be presumed that all research involving human subjects has of necessity deleterious effects. Ethical concern has focused on preventing errors of Type II because of the fact that human subjects are in most cases the most vulnerable participants in the research venture, and that as such they may require a modicum of protection against other participants.

Research involving human subjects ranges over a wide array of fields and may be more or less intrusive. This has led many observers to suggest that such variety calls for very diverse auxiliary institutions to protect the human subjects. On the other hand, it has also been noted that there has been such a convergence of research ventures from the physical, medical and behavioral and human sciences over the last few years that the boundaries between fields has often become quite porous. Consequently, while there are various protocols in place in the different research fields, there is a case for a general statement of principles applying to all areas, when concerns about human subjects are examined. This was the rationale for the Tri-Council Policy Statement (TCPS).

Long-term objective

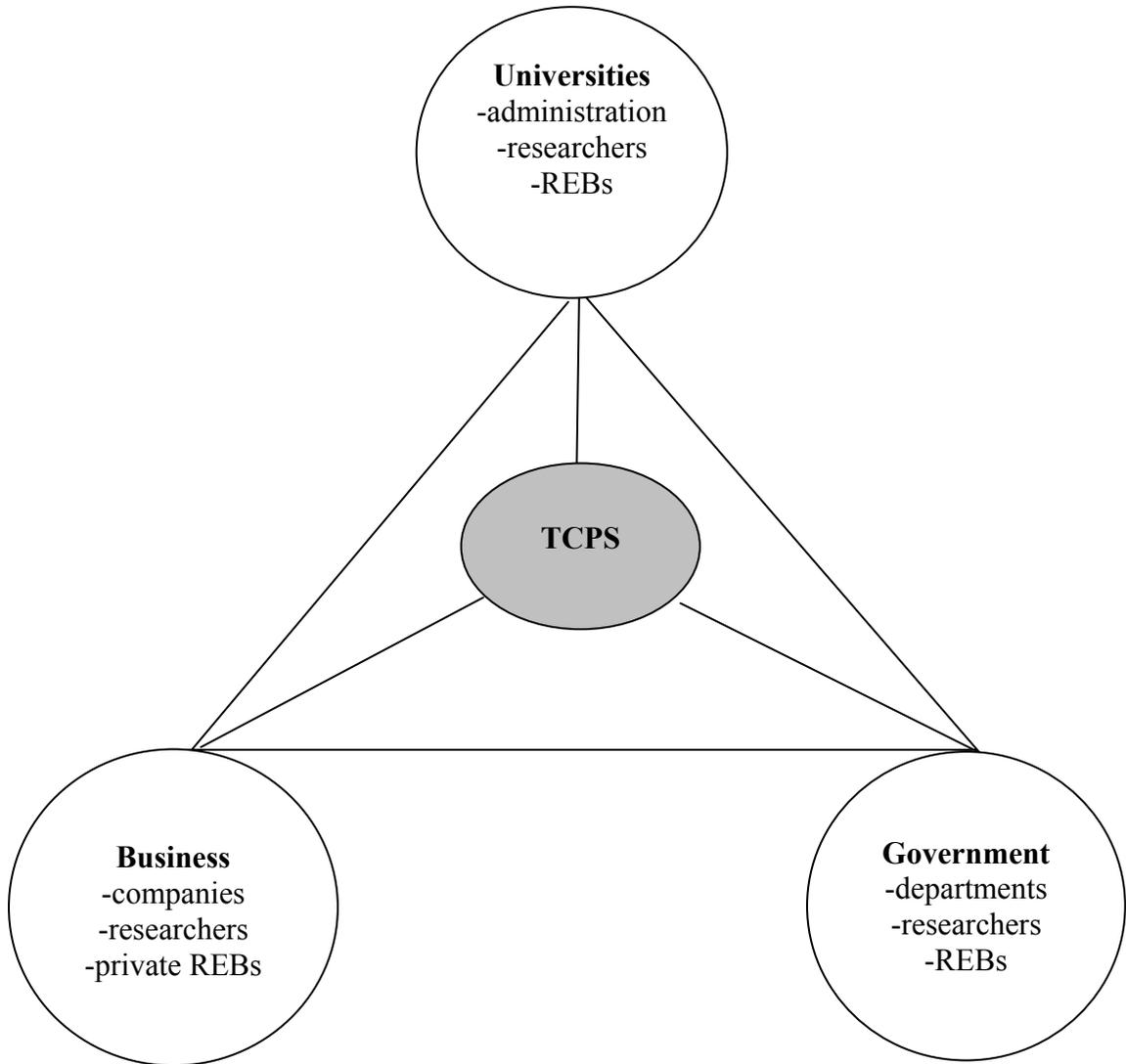
In this Report, we see the long-term objective of the TCPS as that of becoming the *minimum standard* for research involving human subjects in the university sector, within the federal and provincial governments, and within the private sector. However, in order to achieve this long-term objective, it is necessary first to get the policy and process right in the university community—initially for research funded by the three Councils, and then for all university research.

While this first phase is being worked out, some incursions into the world of research conducted by government and business can be made. But it must also be recognized that what is currently going on in the university world of research is itself exploratory in nature. For instance, we see the current initiatives by Health Canada and the Department of National Defence to apply the TCPS, and the possible involvement of Indian Affairs and Northern Development or the National Research Council as leading the way as well.

Finally, the private sector will hopefully be encouraged by those initiatives in the university and government sectors to adopt the TCPS as the minimum standard to guide their research process when human subjects are involved. Broader recognition of the TCPS as a minimum standard only increases its value, in much the same way as the increasing adoption of a piece of software builds its own momentum in the information economy.

Figure 1 expresses our longer-term vision of the centrality of the TCPS among universities, government and business.

Fig 1 Long-term Objective



The production of a general policy statement may be regarded as a necessary first step in the protection of human subjects against abuse, but such a statement must be of necessity rather broad in its scope and general in its language. This is strategically important in order to ensure that the statement applies as much as possible to a wide range of circumstances. Indeed, since circumstances are also changing quite rapidly in the research world, the policy statement has to remain somewhat general while allowing precisions to be added if and when it might prove useful. This is the reason why the TCPS has been presented explicitly as an evolving document, i.e., a document that would have the capacity to be of use over time by being transformed according to circumstances and learning.

This approach, while quite defensible, poses clearly the problem of what sort of governance process of the TCPS is likely to serve best the intent of the three Councils.

Required characteristics of the process

On the basis of our interviews, it appears that the general process of governance of the TCPS could be characterized by six attributes, reflecting process and focus characteristics:

(a) process characteristics

-transparency

as the main way to ensure that ethical issues will be dealt with appropriately, since if all parties and stakeholders are fully informed they will be able to take action to demand redress when necessary

-room for learning and evolution

for it should be understood that the process will of necessity be the basis of much learning on the part of all the stakeholders and therefore that the statement should evolve through time

-fairness and inclusiveness

so as to ensure that the process ensures that all stakeholders have a voice in it, and that they feel that their voice is heard

-clear accountability relations

so as to ensure that the process of governance minimizes zones of tension and the possibility of counterproductive turf wars

(b) focus characteristics

-it must engage REBs and researchers

for it is essential to realize that unless ownership of the TCPS shifts over time from the three Councils to the research institutions and researchers, the practice of research will not be transformed in any meaningful way and the objectives of the policy statement will not be accomplished.

-it need not be a unique process

because the differences between the medical and non-medical research approaches may require different processes.

Our consultations have revealed that the current governance process that is charged with the administration of the TCPS does not meet these standards. It is not transparent; it does not provide an effective mechanism for learning; it is not inclusive and indeed is perceived by some as being unfair; it lacks clear accountability relations; it does not engage REBs and researchers as much as it should; and it is probably too wedded to single-wicket approaches.

This has led us to propose a different governance process.

Conclusion

In closing, we would like to draw attention to a particularly important problem that we have discovered in the course of our interviews since it has had a determining effect on the structure of our report and has influenced the design of our proposed strategy.

The TCPS and the governance process in place is very new. There is still very much to be done, both in substance and process, to regularize its application. Consequently, it has not permeated the consciousness of the researchers, of the REBs and of the university community to such a degree that the observers we interviewed were always able to express their concerns in terms of the governance process *per se*. Often, the concerns about the process were expressed obliquely through a critical assessment of certain participants in the process (researchers, REBs, universities, NCEHR, etc.). In arriving at a diagnosis about the priority issues that had to be addressed, we have had often to translate concerns about participants into concerns about process.

This has persuaded us that one of the most important characteristics of the process of governance that should be put in place is *simplicity*. In order for the learning process to be effective, the governance of the TCPS should be such as to be easily understood by all at a glance with the responsibility of each participant clear and well defined. Only if this is the case can one expect effective social learning. This also explains some of the diffidence that we felt in dealing with the various expectations of the roles and responsibilities of the key players as per the Terms of Reference, preferring to group these issues within a larger framework.

Another point that was derived from our interviews is the need to proceed gradually, with due diligence and extreme care, in the efforts to put in place an ethical framework for research dealing with human subjects. While many might be tempted to try to effect a new regime with one stroke, applying it to all sectors and all fields of study, this has appeared to us to be unduly ambitious and likely to fail. It is more useful to proceed in steps, and to refurbish the new process of governance accordingly if and when it appears to have outlived its usefulness.

For instance, the process of certification that we wish to see implemented over the next five years will undoubtedly reveal problems we have not uncovered. It would be equally as unwise to launch a futile attempt to anticipate all of these problems and to deal with them with a 'one-size-fits-all' solution as it would be to ignore these possibilities.

We have therefore suggested a governance structure that we feel provides ample room for learning and evolution. This sort of approach avoids the dead-end of “definitive solutions” but requires a good dose of *compromise and patience* – two of the most politically incorrect virtues, as Michel Rocard has reminded us.³

³ M. Rocard, *Ethique et démocratie*. Geneva: Labor et Fides, 1996.

Chapter 1-- Historical Background

Introduction

The post-War concern with the protection of human subjects in research began with the promulgation of the Nuremberg Code following the Nuremberg War Crimes trials. The Nuremberg Code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners, and was intended to assure the public that research involving human subjects would in the future be carried out in an ethical manner.

The development of what came to be known as “bioethics” is generally thought to have begun in the mid-1960s. Its original aim was to find a better balance to the growing trend toward the ‘Flexnerian’ specialization then dominant in the education of physicians.⁴ The ideal was a scientifically competent, but humanistically sensitive, physician.

Perhaps the first major statement on this topic was the adoption of the Helsinki Declaration by the 18th World Medical Assembly in June 1964.⁵ The term “bioethics” was introduced virtually simultaneously at Georgetown University and the University of Wisconsin in 1971. The Georgetown perspective saw bioethics as a branch of philosophy, while the Wisconsin view was broader, embracing biology, ecology and environment along with ethics.⁶

The Situation in the U.S.

A key moment came with the inauguration on October 1, 1971 of the Joseph and Rose Kennedy Institute for the Study of Human Reproduction and Bioethics, later called the Kennedy Institute of Ethics.⁷ Housed at Georgetown University in Washington, D.C. through a grant of US\$1.35 million by the Kennedy Foundation, the Institute was the first institute principally devoted to ethics research to be established at a university. It soon became famous for the development of the first systematic secular, principle-based approach to bioethics.

Senator Edward Kennedy’s comments at the inauguration press conference perhaps best reflect the intent of the Institute and the prevailing attitude of the time: “Human life is too precious and the decisions regarding it too important to leave to any one group of specialists—doctors, lawyers, scientists, political leaders, or theologians.” The Institute was expected to follow a collaborative decision-making process.

⁴ See Abraham Flexner, *Medical Education: A Comparative Study*. New York: Macmillan, 1925.

⁵ As amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, the 41st World Medical Assembly, Hong Kong, September 1989, and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

⁶ Warren Reich, “The Word ‘Bioethics’: The Struggle Over Its Earliest Meanings”, *Kennedy Institute of Ethics Journal*, 5: 19-34.

⁷ See for example *The Washington Post*, October 2, 1971, p. A1.

Soon after that, Senator Kennedy led the effort to bring into existence the National Research Act, which was signed into law on July 12, 1974.⁸ This Act established the first-ever national ethics commission, known as the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and was in response to the public outrage against the disclosure of the abuses in the Tuskegee Syphilis Study.⁹ One of the objectives of the Commission was to identify the basic ethical principles that should support the conduct of research involving human subjects, and to develop guidelines that should be followed to ensure that such research was conducted in accordance with those principles.

After an intensive four-day period of discussions held in February 1976 at the Smithsonian Institution's Belmont Conference Centre, the Commission issued the justly famous Belmont Report on April 18, 1979. Known formally as *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, the Belmont Report attempted to summarize the basic ethical principles identified by the Commission during its deliberations.

They identified three principles or general prescriptive judgments: respect for persons; beneficence; and justice.

At about the same time, the influential book, *Principles of Biomedical Ethics*, was published in 1979, with an emphasis on the concept of "principlism".¹⁰

The National Commission was succeeded by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. The President's Commission recommended the adoption of a common, core set of regulatory requirements for human research conducted or sponsored by the more than 20 federal departments and agencies. It would take nearly a decade to reach an agreement on the content of the regulations, known as the Common Rule. The ensuing saga of the Biomedical Ethics Advisory Committee (BEAC) and the National Bioethics Advisory Commission (NBAC) is too complex to summarize here.

The Situation in Canada

At about the same time, significant developments were going on in Canada. Of particular interest was the creation by the Canada Council of the Consultative Group on Ethics with Respect to Research Involving the Use of Human Subjects, chaired by J.A. Corry of Queen's University. Its Terms of Reference were to advise on:

- a common ethical code which institutions would be asked to apply before forwarding applications involving the interests and legitimate concerns of human subjects to the Canada Council;
- the composition of the institutional committees reviewing such applications; and
- the procedures to be used by the institutional review committees.

⁸ Pub. L. 93-348.

⁹ See David J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making*. New York: Basic Books, 1991, p. 3.

¹⁰ Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*. New York: Oxford University Press, 1979.

In his foreword to the Final Report in February 1977, Charles Lussier, Director of the Canada Council noted that the Council had become “increasingly anxious to ensure that the research it supports is conducted according to ethical principles”. He described these principles as “universally accepted”, but indicated that “problems seem to arise out of the considerations brought to bear in their application”.¹¹

They identified clearly the dilemma faced in dealing with ethics issues as “how to strike a proper balance between respect for the rights and sensibilities of the individual or collectivity, on the one side, and society’s need for advancement of knowledge on the other”. Research contributed to societal progress in substantive ways and was therefore important and necessary. As such, society “recognizes certain rights” as the researcher’s prerogative; but they also noted that over history, these rights had been sometimes abused, often inadvertently. Therefore, “whenever human beings or their intellectual or cultural properties are used in research, and whenever the legitimate interests and concerns of individuals or collectivities are affected in the cause of scientific advance”, then ethical issues must be considered.

This led to the creation and application of the *Ethics Guidelines: Research with Human Subjects* in 1979.

Not surprisingly, the Medical Research Council of Canada was in the forefront of these issues, and in 1978 brought out its *Ethics in Human Experimentation*. A decade later, in 1987, in response to the recognition of new ethical problems arising in medical research, the MRC produced the *Guidelines on Research Involving Human Subjects*.

In order to promote those guidelines and respond to the ethical concerns confronting medical researchers, the MRC promoted the creation of the National Council on Bioethics in Human Research (NCBHR). They wanted NCBHR to be an independent body and approached the Royal College of Physicians and Surgeons of Canada (RCPSC) to participate since the majority of medical researchers subject to the MRC guidelines were members of the RCPSC. The RCPSC agreed, and NCBHR was established as a semi-autonomous organization, reporting administratively to the RCPSC, with funding provided by the MRC and Health and Welfare Canada.

The Terms of Reference for NCBHR were to:

1. Interpret and promote the implementation of existing guidelines for the ethics of biomedical and health-related research involving human subjects.
2. Advise and consult with university, hospital and other research ethics boards (REBs) to establish guidelines and procedures for the evaluation of such REBs and of the institutional process of ethics review of research with human subjects, including site visits by invitation or at request.
3. Advise and consult with bodies funding research with human subjects on relevant ethical matters.
4. Assist institutional REBs with unresolved issues involving biomedical and health-related research with human subjects, particularly those concerned with the process of ethics review.

¹¹ *Ethics: Report of the Consultative Group on Ethics*. Ottawa: Minister of Supply and Services Canada, 1977.

5. Foster the education and dialogue with health professional and the public on the ethical aspects of biomedical and health-related research involving human subjects.

Unlike the situation in the US or in countries such as France, NCBHR had no legal status in the legislated mandate of the MRC. That position continues today.

A five-person Committee, chaired by Dr. John Dirks, Professor of Medicine and Health Administration at the University of Toronto, was created in July 1993 by Dr. Henry Friesen, President of the MRC, and Dr. Gilles Hurteau, Executive Director of the RCPSC, to review NCBHR's mandate and structure in the light of operating problems experienced by NCBHR. The Review Committee reported in January 1994 and endorsed NCBHR's role in support of the medical research community.¹² It proposed a revised management structure "to tighten up lines of reporting" and recommended a broader mandate "in keeping with the expanding interests of medical science and research investigators".

At around this time, in 1993, the MRC, SSHRC and NSERC, had begun a collaboration on the joint development of guidelines dealing with integrity in research.¹³ Recognizing the increasingly blurred disciplinary lines in research, they also undertook a process to develop new guidelines for the three Councils covering all research involving human subjects under one document. In 1994, they appointed a Working Group.

One rationale for developing an integrated set of guidelines was the rising expectation in terms of accountability, both from the government and the public at large.¹⁴ There was some concern that legislation could be introduced and that by acting together the Councils could demonstrate that they had their ethical house in order. It was also felt that a unified policy could better deal with new approaches in research, including interdisciplinary research and public/private partnerships, as well as emerging issues.

Much of the first two years were used to develop a mutual understanding of the cultures, vocabularies and concepts of the many research areas. There were significant differences in the outlooks and approaches of the members resulting in very slow progress.

In the spring of 1996, the Working Group completed a draft Code of Conduct for Research Involving Humans, which the three Councils disseminated as a consultation document. The three Councils asked for responses especially to the following three questions:

- Will the Code enhance the protection of participants in research?
- Will the Code allow research to be carried out without unreasonable constraints?
- Will the Code provide effective mechanisms to review ethical requirements and enhance the accountability of universities, research councils and researchers?

¹² *Review of the National Council on Bioethics in Human Research* (the Dirks Review). [no publisher, no date].

¹³ *Integrity in Research and Scholarship: A Tri-Council Policy Statement*, 1994.

¹⁴ The following section is based on a presentation to the International Humanities Forum, Ottawa 1998 [available from the SSHRC].

While the response from the biomedical research community was generally positive, if somewhat muted, the reaction from the social sciences and humanities (SSH) and natural sciences and engineering (NSE), was highly, perhaps even violently negative.

Generally they criticized the document for being biased to a biomedical perspective. They objected to the use of the term “Code” because of its legalistic connotations, and argued that the 130 articles were too prescriptive, appropriate perhaps for biomedical research but not for SSH and NSE research.

The proposal that REBs assess scholarly merit was seen by many researchers as an intrusion on academic freedom since peer review was already part of the funding evaluation process. Further, the REBs were seen by SSH and NSE researchers as lacking the scholarly credentials to undertake such an assessment.

It was argued that there were fundamental differences between ethical issues in the SSH and NSE disciplines and the biomedical sciences, especially in terms of the element of risk. These were reflected in specific recommendations, for example, that historians had to obtain approval from research subjects before they could publish their results and to the extension of the scope of review to include dead humans.

One section proposed that researchers obtain informed consent from both individuals and the “collectivities” that they represent in the design of their research as well as in the publication of results. Collectivities included governments, business, native groups and other cultural, religious, ethnic and social groups.

In general, SSH and NSE researchers argued that adopting the Code would stop most, if not all, critical research.

The proposed REB structure was designed to standardize the membership and operation of the estimated 350 REBs across the country. The Working Group proposed that REBs be constructed along U.S. lines, under which REBs must include at least two scientific experts, one ethics expert, one lawyer, and one public member. University administrators criticized the proposal as an enormous financial and human resources cost, especially in the smaller universities.

A final consultation process was launched in July 1997 to assess the support in the research community for a new policy.

As a result of the consultations and after significant revisions by lawyers from the Department of Justice the final document, *Ethical Conduct for Research Involving Humans*, was released in September 1998.¹⁵ The name of the document was changed from “Code” to “Policy Statement” to convey continuity with the guidelines approach favoured by the SSH and NSE community. The prescriptive language was toned down, retaining about 50 of the 130 articles. Safeguards

¹⁵ Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. Ottawa: Public Works and Government Services Canada, 1998. The document is also available at the websites of the three Councils.

were incorporated. The Policy Statement was identified as a “living document” with a major review by September 2001.

Funding from the three Councils was dependent on compliance with the Policy by researchers and institutions.

The three Councils recognized that their mission was to promote “ethical research”. The appropriate ethical norms transcended disciplinary boundaries and the fundamental ethical issues and principles in research involving human subjects were common across the jurisdictions of the three Councils, reflecting the shared fundamental values expressed in the “duties, rights, and norms of those involved in research”.

As the Tri-Council Policy Statement (TCPS) notes: “Research subjects reasonably expect that their rights shall be equally recognized and respected, regardless of the researcher’s discipline. Similarly, Canadian society legitimately expects that the benefits and harms of research shall be fairly distributed.”

The guiding ethical principles adopted were: respect for human dignity; respect for free and informed consent; respect for vulnerable persons; respect for privacy and confidentiality; respect for justice and inclusiveness; balancing harms and benefits; minimizing harm; and maximizing benefit.

It was noted that along with the right of academic freedom came the responsibility of conducting research that conforms to the guiding ethical principles.

Along with the publication of the TCPS came the requirement to assist the REBs in implementing the policy. Although the organization was not mentioned in the Policy Statement, and although its background and experience was exclusively in biomedical research, the three Councils had agreed that NCBHR should play an important role in the implementation process. As a result in 1997 NCBHR changed its name to the National Council on Ethics in Human Research (NCEHR) to better reflect its new mandate.

Their inclusion was viewed by many individuals as an accident of history and was not enthusiastically endorsed.¹⁶ NCBHR’s lack of expertise and familiarity with the SSH and NSE disciplines, and the lack of familiarity of SSH and NSE researchers with NCBHR, was a concern. Subsequent problems between the three Councils and NCEHR reflect that starting point.

¹⁶ It was often described as a case of “we needed a group to do that role; NCBHR was already there; so we went with them”.

Chapter 2 -- Current Governance Structure

Introduction

The current governance structure of the ethics process is complex. To provide an adequate representation of its nature and functions, it is crucial to present it as both a set of actors or players AND a process. This is the way in which we are presenting it here.

A. The various players

The attached organization chart (Figure 2) indicates the original and current governance structure. This structure has been described by observers as “a mess”, a reflection of overlaps and confusions that indicate a lack of trust in the partnership. The chart indicates less a coalition of partners as a forced merger of wary allies, a reflection of the historical background outlined in the previous chapter. The byword is “checks and balances”, not “joint learning”.

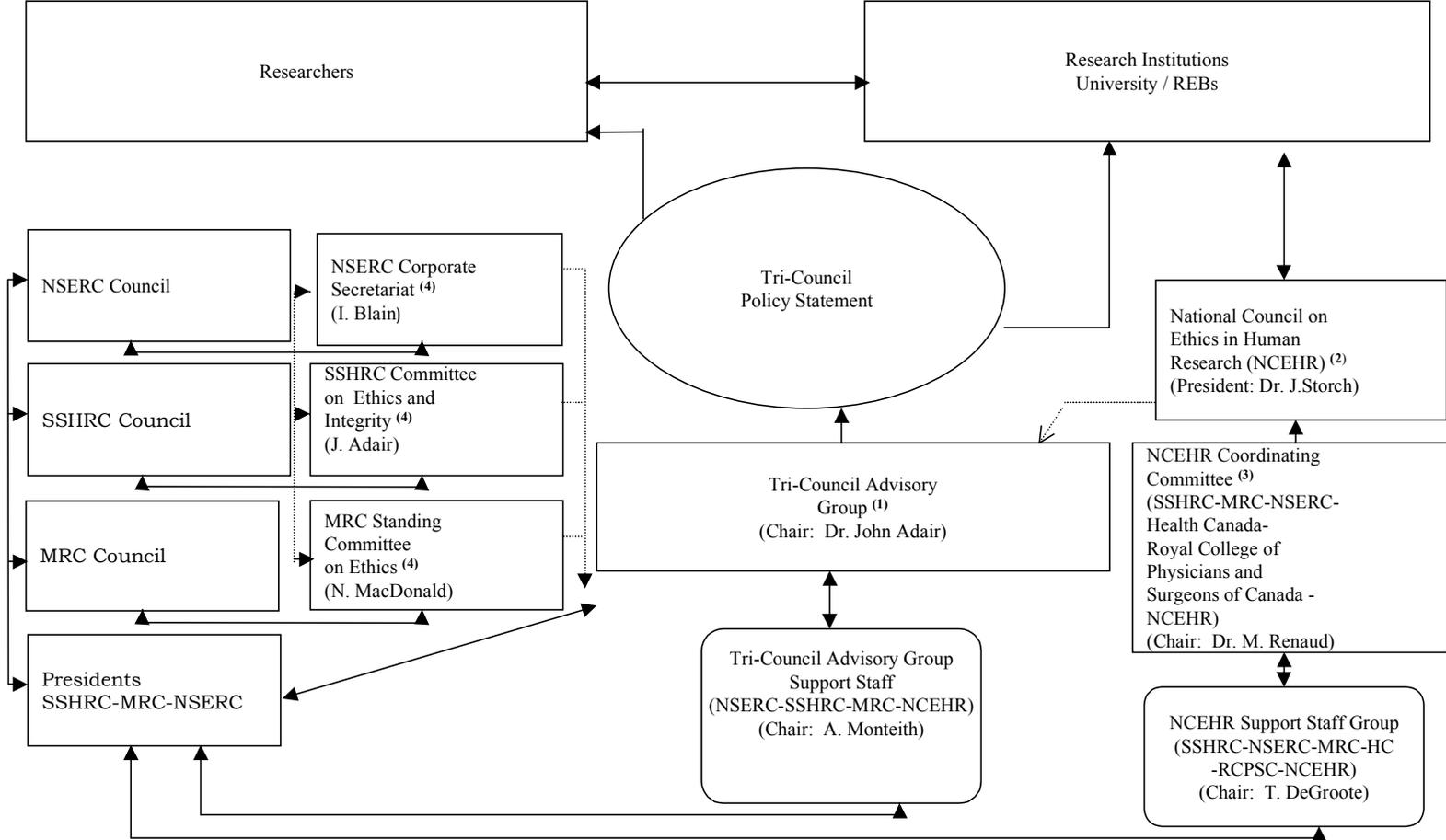
To begin, there is no simple name to the organization. The awkwardness of naming itself confirms an uncomfortableness with the enterprise. This is not one simple group working out the kinks of a new system but rather a hodgepodge of individual groups constantly eyeing each other. Therefore, there should be a name provided to give a continuing identity and image to the entire activity. We suggest the Tri-Council Group on Ethical Research (TGER).

In this way there is an immediate recognition that there is one organization that is identified with the issue, as well as indicating clearly that the objective of the group is the funding of ethical research, not unqualified support for any research, whether ethical or not.

There have been charges that since the objective of funding university research falls on the three Councils, that they are in a conflict of interest position regarding the protection of human subjects in that research. We reject that argument. The previous chapter outlined 25 years of efforts to ensure ethical research. There is no indication that suggests that the three Councils have no regard for the protection of human subjects in research. The development of a common policy and structure indeed suggests otherwise.

Some have suggested that there is an inherent adversarial relationship where one group of stakeholders promotes research of whatever ethical stripe while another group exists to protect human subjects from their efforts. We reject that dichotomy. Our view is that all the primary groups involved in this process, the three Councils, the universities, and the researchers desire to promote ethical research and to see a system put into place that is both effective and fair.

Figure 2: Current Governance Structure



- 1. Recommends to Presidents modifications to the Tri-Council Policy Statement and interprets the Policy
- 2. Advises on interpretation and implementation, education and awareness of Tri-Council Policy Statement
- 3. Approves funding level and workplan of NCEHR
- 4. Makes recommendations to Council on policy matters related to research ethics

Indeed, if the ethical considerations were simple, then we would not need much of a structure. However, all those we spoke to recognized the complexity of the issues and therefore a more interwoven and interdependent process seems necessary. This should be a learning structure that simultaneously promotes the education of researchers to avoid inadvertent unethical research, while “catching” dubious research before human subjects are affected. This requires an alliance between the Councils, the universities and the research community, preferably structured in a learning feedback loop that reinforces the education of all the groups.

That will be our orientation. But before developing such a proposal, it will be useful to describe the various players in greater detail.

Medical Research Council (MRC)

The mission of the MRC is to “promote, assist and undertake basic, applied and clinical research in Canada, in the health sciences, and advise the Minister [of Health] in respect of such matters relating to such research as the Minister may refer to Council for its consideration”. It has its own Standing Committee on Ethics, with 15 full members and five observers. As of April 1, 2000 the MRC will be replaced by the Canadian Institutes of Health Research (CIHR), whose perspective on health research will be broader than that of the MRC, further blurring the edges between biomedical and SSH/NSE research.

The MRC deals in a global environment with international standards on ethics for research involving human subjects, including the Helsinki Declaration and the guidelines of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH), especially its Good Clinical Practice (GCP) document. The GCP is designed to permit mutual acceptance of regulatory approvals for health care interventions. The MRC currently devotes three staff to the ethics process: the Director, a senior policy analyst and a special project assistant.

The MRC has the longest and deepest experience of the Councils in this area. They made the recommendation to create NCBHR and have been a strong supporter since. The MRC’s Standing Committee on Ethics has endorsed the NCEHR Vision Statement, supporting the position that “an independent arm’s length body be entrusted with the mandate of protecting and promoting the well-being of participants in research”.¹⁷ The overriding issue for the MRC is the need for an accountable, transparent, effective system for research ethics that supports excellence in research with excellence in ethics. Their view is that while this need may have started historically with the three Councils, it now goes well beyond academia.

They also co-fund the Canadian Council on Animal Care (\$530,000 per year) and have close links to the U.S. National Institutes of Health.

¹⁷ Minutes of the MRC Standing Committee on Ethics, October 31-November 1, 1999, Item 5.

The Interim Governing Council Sub-Committee on Ethics, chaired by Bartha-Maria Knoppers, identified four central functions of the ethics process within the CIHR:

- ensuring that CIHR-funded health research meets the highest standards of ethics;
- funding and stimulating ethics scholarship, research and training for health research;
- offering interdisciplinary advice on broad questions and policies in health research and exercising ethical leadership; and
- ensuring that public accountability and transparency concerns are met, and quality assurance reviews of research ethics operations are carried out.

An ethics office within the new CIHR Secretariat was recommended to have responsibility for serving as a general ethics resource and clearing house for the Institutes and assisting with the harmonization, integration and implementation of ethics processes and procedures across the CIHR.

Natural Sciences and Engineering Research Council (NSERC)

NSERC's mission is to invest "in people, discovery and innovation to build a strong Canadian economy and to improve the quality of life for all Canadians". It supports research in universities and colleges, research training of scientists and engineers, and research-based innovation. The Council promotes excellence in the creation and productive use of new knowledge, and seeks out new ways to increase Canada's capability to do that, both in terms of the skills and knowledge of individual Canadians and the number of Canadians with the necessary competencies.

NSERC fulfills this mission "by awarding scholarships and research grants through peer-reviewed competition, and by building partnerships among universities, colleges, governments and the private sector".

The proportion of NSE researchers who do research that involves human subjects is relatively small, estimated at about 5% of the total. The Council did not have a formal ethics document, but indicated that NSE researchers adhere to the terms of the policy of the more appropriate of the other two Councils. There is no ethics committee, but the Corporate Secretariat reports to NSERC Council on ethics issues. NSERC currently chairs the Tri-Council Advisory Group (TCAG) and the secretariat for TCAG. It acts as the contact Council for universities with respect to the overall issues raised by the TCPS and its implementation. NSERC devotes three staff positions to ethics issues: the Corporate Secretary, an ethics officer and one secretary. There are no national NSE researcher associations that currently play a role in the ethics process. They also co-fund the Canadian Council on Animal Care (\$530,000 per year).

Social Sciences and Humanities Research Council (SSHRC)

The functions of SSHRC are to "promote and assist research and scholarship in the social sciences and humanities" and "to advise the Minister in respect of such matters relating to such research as the Minister may refer to the Council for its consideration".

SSHRC has had an ethics policy in place since 1979. It has a Committee on Ethics and Integrity with three members. SSHRC currently chairs the Coordinating Committee on NCEHR and the support staff group. They devote 1 policy analyst, one director and one secretary to ethics issues. Additionally, the Humanities and Social Sciences Federation of Canada (HSSFC) plays an important role in the ethics process.

Health Canada (HC)

HC's mandate is to provide "national leadership to develop health policy, enforce health regulations, promote disease prevention and enhance healthy living for all Canadians". It works closely with other federal departments, agencies and "health stakeholders" to reduce health and safety risks to Canadians.

It funds much of the health research in Canada, especially clinical trials. HC also has a significant international link, especially through the ICH/GCP. They are undergoing a major shift in their processes. For example, recent proposed changes within the Therapeutic Products Protection Branch makes guarantees of a response within 48 hours as opposed to the previous 60 days from time of submission. A separate ethics unit of the Ministry has been established within Policy and Coordination under an Assistant Deputy Minister. HC has been from the beginning a financial supporter of NCBHR and NCEHR. Its role on the Coordinating Committee comes as a funder of NCEHR rather than as a developer of the TCPS.

Royal College of Physicians and Surgeons of Canada (RCPSC)

RCPSC's mission is to be "an organization of medical specialists dedicated to ensuring the highest standards and quality of health care". They established NCBHR in 1989 and continue to provide in-kind contributions. Until 1995 they selected the members of NCBHR's Council. The RCPSC participates in the Coordinating Committee through its Executive Director. Its role also comes as a funder of NCEHR rather than as a developer of the TCPS. It does not directly fund research.

Tri-Council Advisory Group (TCAG)

The TCAG was established in 1999 and provides advice to the Presidents of the three Councils on the TCPS and its implementation "as a living and evolving document". The TCAG has the authority to make minor changes to the Policy which do not affect its "goals, rationale and/or guiding principles". Among other things, they are expected to recommend priority areas for policy development and/or change, to recommend specific, major changes to the TCPS and the Councils' implementation of it, and "to take into account the concerns of the broader research community and the public at large, concerning the ethics of research involving human subjects". The TCAG was originally established to aid in the implementation of the TCPS.

The TCAG is comprised of volunteer academics and stakeholders, and operates at arm's length from the Councils. There are six voting members (two appointed by each Council), one non-voting member (from NCEHR) and one observer (representing the Canadian Association of University Research Administrators). It meets once or twice a year. Support staff come from the three Councils and NCEHR.

The TCAG has identified a list of priority issues, including:

- university compliance to TCPS;
- review procedures for on-going research;
- research with Aboriginal Peoples;
- clinical trials and Good Clinical Practices;
- women;
- minimal risk;
- naturalistic observation;
- included/excluded research;
- participatory research;
- legal implications of Good Clinical Practices on liability and indemnification; and
- an impact evaluation of the TCPS.

National Council on Ethics in Human Research (NCEHR)

NCEHR was originally formed by the RCPSC on the recommendation of the MRC and in collaboration with HC in 1989 as the National Council on Bioethics in Human Research (NCBHR). The impetus came largely as a result of MRC's 1987 *Guidelines on Research Involving Human Subjects* to assist medical Research Ethics Boards (REBs). From the beginning they have been housed as an in-kind contribution by the RCPSC. NSERC and SSHRC became sponsors in 1995 at the start of the development process for the Tri-Council Policy Statement. In 1997 NCBHR changed its name to NCEHR to recognize its expanded focus.

As noted in their financial statements, the nature of their organization is to “encourage high ethical standards in research involving human subjects in Canada”, to work “towards these standards by consulting with and advising institutional research ethics boards (REBs), investigators, and research granting agencies”, and to foster the “education of professionals and the public in research ethics and assists in the national implementation of guidelines and pronouncements on research ethics”.

At their retreat in September 1999, the NCEHR Council adopted the following vision statement for NCEHR:

Accountable to the Government of Canada, the National Council on Ethics in Human Research is an independent national body, at ‘arms-length’ from sponsoring organizations, advising Canadians on ethical issues in human research, both in terms of its impact on human participants directly involved in research and its impact on humans as a result of the research findings.

Governance of the Ethical Process for Research Involving Human Subjects

The Council provides advice and services to all Canadians involved in research, whether they are participants, Research Ethics Boards (public and private), academic partners and researchers, funders, or regulators. We monitor trends, identify issues, take leadership in the development of normative statements, disseminate information, educate researchers and assess research ethics boards functions. We exist to raise the consciousness among the Canadian public about ethics in human research.

We are a Council of committed Canadian volunteers and professional staff made up of researchers knowledgeable about research ethics and public members who enlist the help of other individuals and groups as needed to reflect on the impact of research on humans.

The Council is composed of 20 volunteer members, plus the Executive Director of the organization. They have seven Committees: Executive; Communications; Evaluation; Consent; Ethics of Research Design; Nominating; and Finance.

Funding is provided by the five sponsoring organizations (MRC, HC, RCPSC, NSERC and SSHRC). Over the past three years funding levels have been as follows:

Sponsor	1997-98	1998-99	1999-2000	Total
MRC	\$200,000	\$200,000	\$240,000	\$ 640,000
SSHRC	50,000	75,000	90,000	215,000
NSERC	50,000	75,000	90,000	215,000
HC	40,000	75,000	95,000	210,000
Total	\$340,000	\$425,000	\$515,000	\$1,280,000

As noted, the RCPSC provides significant in-kind contributions in terms of accommodation and administration.

The five Sponsors plus NCEHR form the **Coordinating Committee for NCEHR (CC)**. Established in October 1995, the mandate of the CC is to review the activities of NCEHR and provide an annual funding level for its activities. Its original Terms of Reference note that it was established “as a demonstration of the prime importance that all its constituent organizations place on the ethics of research involving human beings.” It serves “as a forum for discussion and collaboration of institutional research ethics initiatives among its membership, particularly as regards (NCEHR)”.

The Coordinating Committee is assisted by a support group, made up of a staff member from each of the six groups.

The intention and expectation of NCEHR is to have complete arm’s-length responsibility for the TCPS, similar to the role played by the Canadian Council on Animal Care. This

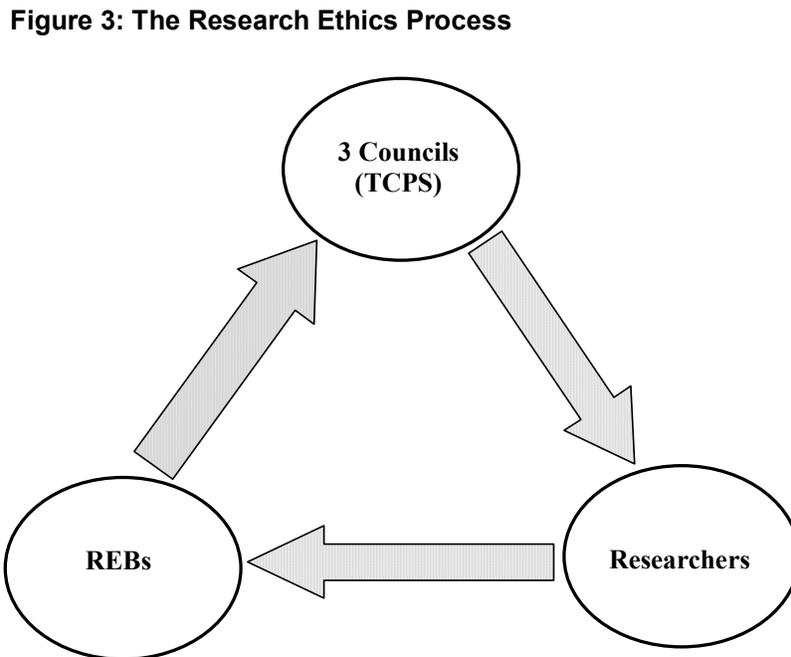
has become problematic since the NSE and SSH research communities generally do not at this time have much knowledge of or faith in NCEHR, especially in its ability to be sufficiently sensitive to their needs and concerns. It appears that the level of knowledge and approval from the biomedical community is different (and generally more supportive).

B. The ethics process

There seems to be general agreement that a key objective of the ethics process should result in a shift from the view of research ethics as a hurdle for researchers to one in which it is seen as contributing to research excellence. In an era of more collaborative interdisciplinary research and a unified tri-council policy on ethics, cultivating a spirit of cooperation and trust is paramount. The study has concluded however that such a spirit is more of an aspiration than a reality.

In many ways, the theoretical, rather than actual, ethics process for university research is fairly simple. A researcher prepares a proposal for funding by one of the Councils. The plan is reviewed by an REB at his/her university. The REB recommends the research based on its confirmation that by compliance with the TCPS human subjects will be protected. Revisions to the policy are then based on the experience of the researchers and the REBs, which then becomes the basis for subsequent REB reviews.

Figure 3 describes this basic research ethics process.



So what's gone wrong? If we compare Figure 3 with Figure 2--the current governance organization chart--we note that a relatively simple research process has been overlaid with a complex administration process. The problem lies with too many players

intervening in an evolving system, resulting in a confusion of roles and an overlap of responsibilities. Any governance system that has a chance of working effectively will need to sort out clear lines of responsibility, making the governance process as simple as the research ethics process. It is also our view that before aggressively expanding the reach of the TCPS into other sectors, such as government departments or the private sector, the ethics and the governance processes should first be solidified and better integrated.

Despite the considerable goodwill that is evident toward a unified ethics process, the current system has been described as “confusing”, “complex”, “unfair”, “going too far”, and “not going far enough”.

The current structure has been estimated to cost more than \$1 million, not counting the considerable time spent by volunteers, but its administration lacks coordination and an integrated approach. No one (and no group) is responsible for the integrated management of the system. This leads to too many Council staff spending too much time sorting out inter-group issues, a lack of priority setting and a lack of control over financial resources and budget.

Hence, no one is happy with the status quo—and with good reason.

Chapter 3 -- Issues Raised During the Interviews

Introduction

The current governance structure/process has created problems for the research community. It has appeared mainly as opaque and difficult to understand. As a result, our interviewees tended to focus mainly on certain players within that process to underline the ways in which it was felt that their role was unclear, unhelpful, undesirable, etc.

We have recorded these observations while fully realizing that they were addressing only in an oblique way the process we were interested in. However, we were forced to realize as our interviews proceeded that these expressions of malaise could be understood only in the context of a process that was itself not very well understood.

Consequently, we have recorded the issues raised in the interviews and reported them here. In the next chapter, we attempt to translate these recorded concerns into process terms.

Interview summary

Over the first six weeks of the project, the Centre on Governance interviewed a total of about 60 individuals with an active involvement in this field. Their comments cover a wide range of issues and concerns. In this Chapter, we present a summary of their process-related concerns that help us to address the governance issues that are the focus of this report. See Appendix 2 for a list of the persons interviewed.

We group these concerns into three broad categories – issues dealing with researchers, issues dealing with the REBs and universities, and issues relating to the nexus of activities around the TCPS and the attempt to make it a living document.

A. Researchers

The main concerns for practising researchers is that the process be fair, clear and “not take too much time”. Researchers do not want to be penalized by a lack of uniformity in the application of ethical rules or be over-burdened by bureaucracy. Researchers also wanted to be assured that those evaluating their research protocols have some background knowledge of their area of research. This concern often led to a discussion of the different biomedical vs. social science and humanities approaches to ethical issues. Recognizing these differences, it was emphasized that the objective of this study should be to optimize the governance structure as an “on-going dialogue among various disciplines of research”. We were told that the process is not solely about protecting the public because that could be achieved by having no research at all. The need was better

framed for us as, “what is reasonable to ask researchers to do to ensure that the public interest is not neglected?”

B. REBs and the universities

It was clearly evident from everyone that the REBs are the cornerstones of the entire process. The REBs balance the needs of researchers and the concerns of the public. The participation by researchers in REBs helps them to be mindful of researchers needs while REB approval is essentially societal approval of a research protocol. The REBs therefore should not be constituted to stop research but “to assist researchers within the constraints of the TCPS”.

It was not surprising, then, that much of our discussions with interviewees centred on how to improve the effectiveness of REBs. There were concerns about the competence of REBs, who they reported to, how well they were resourced and supported, whether there was sufficient ethical and community input, and whether they needed to be certified. A major weakness identified was the monitoring of previously approved research, or more specifically the lack of monitoring. There was a widely held view that the REBs varied in quality from institution to institution and from region to region. The multiple sources of authority in terms of interpretation of the TCPS were found to be confusing for REBs and greater clarity was requested. It was suggested that in an environment where research was not only multi-disciplinary but also multi-institutional, that there was a need for more communication between REBs and for “cross recognition of approval among REBs”. It was also suggested that institutions should have two types of REBs, where appropriate, one for the biomedical fields and other for the social sciences and humanities and natural sciences and engineering.

It was suggested that universities be held accountable for all research being conducted by affiliated researchers and that each university sign an agreement to that effect, as already happens in the case of animal care. According to interviewees, more effort could be spent by universities in getting together to share their knowledge and experiences in local, regional and national conferences. It was also suggested that “there should be more direct exchanges between the universities and the three Councils” on the issues of TCPS-related content and processes.

Beyond the issue of the resourcing of REBs in general, it was felt by some that the members of REBs needed some incentive mechanism or professional recognition to encourage quality participation and commitment. This could also lead to local REBs becoming “local think tanks” on ethical issues in research.

There was some significant concern raised about private sector REBs. There were questions whether they adhered to the TCPS, whether they should be covered under the umbrella of the academic community, and whether they would fall prey to conflicts of interest that would inevitably tarnish the entire REB system.

C. The TCPS nexus

There was overwhelming support for the concept of the TCPS. The TCPS is “an excellent idea that has the academic community take front rank responsibility for ethical research”. Although some interviewees felt three policies didn’t make sense and only one policy was needed, others felt it was important to have a common set of principles and procedures but have flexibility in their application in different disciplines.

Interviewees identified the goal of the TCPS as the creation of a standard of practice such that institutions would feel it unwise not to follow this *de facto* standard of care. Since the Councils have no formal authority over non-Council funded research, this minimum standard was viewed as important, especially in areas of private research. The potential impact can be seen in DND’s adoption of the TCPS standard, despite DND’s not being part of the sponsor group and not having participated in the development of the TCPS.

Ownership of the TCPS was another hot topic. Some felt ownership of the TCPS should remain with the three Councils, while others felt it should be with the sponsors and any agency dealing with or funding research on humans. A key element was that it should remain with those who could administer sanction. Still others felt this function should go to an updated form of NCEHR or Tri-Council Advisory Group (TCAG). The document should also carry the names of its owners. Part of this debate centred on whether one perceived that the three Councils had a conflict of interest due to a funder/researcher bias. It was suggested that even the perception of conflict of interest might prove equally as bad in the long-run. The responsibility allotted to TCAG on this issue and TCAG’s infrequent meetings also suggest that this issue needs rethinking.

We were encouraged to emphasize the need for academic collegiality rather than having administrators managing ethics policy. On several occasions we were reminded that we should not forget the concerns and exhaustive experience of the individual disciplines nor the professional codes that exist outside of the biomedical professions. The TCPS document and its associated processes should reflect the diversity of conditions that exist in research: an approach of “one size fits all” doesn’t work. The organization responsible for the interpretation and change function needs an effective mechanism for consulting with the social sciences, the humanities, researchers in general, and with the public.

Whoever owns the policy must take information from the REBs, researchers and the universities in order to update it. This is a bottom-up approach rather than top-down. Thus the TCPS requires updating on a case by case basis, a sort of ongoing “connoisseurship”. It was suggested that to learn effectively a “learning loop”, a complex adaptive system”, or “research ethics clearinghouse” be put in place for all the players, from researchers to the three Councils. It was also suggested that a politicized process for changing the TCPS document was to be avoided. We should create a learning system of ongoing feedback for all of the participants through a “broad circulation of ideas”. A working group to bring emerging issues forward openly and transparently was suggested. Finally, it was felt that a focus on negotiation, as opposed to a focus on rigid rules or watered-down consensus, was required to support of this learning system.

Chapter 4—Priority Issues

Introduction

The consultation suggested that the following list of seven issues would need to be addressed in the governance of the research ethics process:

- Who “owns” the policy, i.e. who is ultimately responsible for the policy?
- Who will be responsible for revising the policy?
- Who will administer the policy?
- Is there an appeal process, and if so, who should be the final adjudicator?
- Who monitors compliance?
- Is ongoing research to be monitored, and if so, by whom?
- Who provides information/advice on the policy and its interpretation?

The answers to these questions will ultimately shape the governance structure to be recommended.

A. Who “owns” the policy?

The key issue is whether the policy belongs exclusively to the three Councils or has a broader ownership. For example, some individuals suggested that the TCPS become an element of general government policy, to be applicable to all departments of the federal government as well as the academic community. Some suggested that to cover the private sector as well the policy should be enshrined in legislation, and responsibility handed over to an independent third-party organization, perhaps a newly constituted body. This option was not just to adopt the U.S. approach that we will deal with later in the Report, but to provide some enabling legislation on principles and priorities with administrative funding to conduct oversight, possibly like the Office of the Privacy Commissioner.

After due consideration, our view is that the TCPS should remain the “property” of the three Councils, at least for the foreseeable future. This organic, evolving document still needs clarification as it applies to the academic community before broadening its application to other government departments or private organizations.

It is our view that the TCPS should be the minimum desirable standard for any organization that does research involving human subjects. Consequently, that perception needs to be reinforced. In the short-term, this would mean that the three Councils should concentrate their attention on developing a “gold standard” that would have credibility among a broad range of public and private organizations. These groups could be encouraged to voluntarily “sign on” to the policy, or adapt it to their particular circumstances with those standards as the baseline as DND has already done. Some, such as Health Canada, are in the process of doing so, while others, such as the National

Research Council, are looking into the possibility. Other departments, such as Indian Affairs and Northern Development, could be encouraged to explore this option.

However, in the end the Policy should remain strictly the Tri-Council Policy.

B. Who will be responsible for revising the policy?

If the policy remains in the hands of the three Councils, then responsibility for its revision must also remain there. Only the Councils have the capacity to take fully into account changes in the circumstances of researchers and human subjects across the full spectrum of disciplines. The Tri-Council Advisory Group would likely remain the main vehicle from which recommendations to the three Council Presidents for revisions come forward. There is also a need for a better and more transparent and inclusive process to connect the TCAG with research practitioners and stakeholders. This will call for a new structure to serve the TCAG in its learning function.

C. Who will administer the policy?

There seems to be broad general agreement that the proper location for the administration of the policy is with the universities through their Research Ethics Boards. We agree. There are, however, a number of issues that will need resolution, such as resourcing the REBs and university policies on teaching release time for faculty membership.

D. Is there an appeal process, and if so, by whom?

There was also broad general agreement that there should be an appeal mechanism in place for both researchers and human subjects, especially on process complaints. As a general principle, our view is that the administration of the policy should remain as local as possible but that in extraordinary circumstances some credible group should be identified to close the loop on fundamental disagreements, especially in protecting human subjects.

E. Who monitors compliance of REBs?

This issue is one of the most contentious, according to the consultation. Ranging from no monitoring and self-regulation to legislated compliance, there was a wide divergence on the topic. We believe that there must be some monitoring of compliance to maintain the credibility of the process with the public. As many universities already understand, monitoring compliance should be viewed as being in the interest of the universities themselves to assure the three Councils and the public generally that they are serious about the protection of human subjects. The most obvious concern here is the need to adequately resource this function.

A number of individuals suggested that the universities hire a certified Research Ethics Officer to provide expert support for the REBs and their administration, and that the three Councils authorize a certification process for such individuals. We agree that most large

universities would do well to have such expertise on hand, but do not recommend that this be made mandatory, nor that a certification process of this type be developed at this time.

F. Is ongoing research to be monitored, and if so, by whom?

This is a tricky, touchy subject that is being investigated by the three Councils, and we will leave that recommendation to them. Our own view, however, is that there should be no generalized monitoring unless authorized specifically by the local REB because of the nature of a specific research project. It is not possible to monitor all research, but it is reasonable to focus on research that by its very nature poses ongoing risk. However, by itself this continuous monitoring is not sufficient to assure the public that abuse is not taking place. The creation of an ombudsperson capacity would allow complaints about ongoing research to be assessed by an independent group. This function must be both at arm's-length from the three Councils and conducted by individuals credible to both the research community and the general public.

G. Who provides information/advice on the policy and its interpretation?

This issue was the most contentious one that we encountered. More disagreement and hard feelings were expressed than on any other issue, and despite the fact that there was general consensus on importance of and the need and information and advice, mainly for the REBs, on the interpretation and administration of the policy.

There is at the moment considerable overlap and duplication on this area, leading to confusion among researchers and REBs as to who is the most reliable and authoritative source of interpretation. More specifically, there is confusion as to whether NCEHR or the staff of the three Councils is that source. Some documentation suggests that NCEHR has that role and responsibility, and others suggest not. This issue needs to be cleared up.

A significant point of conflict between NCEHR and the three Councils is the issue of confidentiality. It has been the contention of NCEHR that advice given to researchers is confidential and therefore cannot be communicated to the three Councils. NCEHR's adherence to this view of confidentiality has its strengths and weaknesses; however, we are concerned about the learning implications of such a perspective. It will not be possible for the TCPS to evolve appropriately without direct access to such practical information. Therefore, we recommend that all interpretation be handled by the three Councils for the time being. As owners of the policy, the three Councils should be the only authorized interpreter.

There is, though, a significant need to raise the knowledge base of the research community about the policy, and we feel that the three Councils should contract an organization such as NCEHR to do this. They could create content for distribution, conduct education workshops and convene conferences around the country on specific ethics topics to raise the consciousness of the researchers and to support the REBs. Potentially, groups such as the RCPSC and the Humanities and Social Sciences

Federation of Canada (HSSFC) could also be playing a role here, although NCEHR is currently best positioned for this. This openness to alternative delivery systems could also be used for national consultations that will need to be conducted by the three Councils.

The Listserv was seen as a valuable resource to the research community, and should not only be continued but enriched. It has been an excellent learning forum, especially in comparing various perspectives on important issues. However, NCEHR has not become directly involved in the process. In our view the Listserv needs greater interpretative input from an authoritative source to increase the learning in the research community. Therefore, the three Councils need to be involved in this process in a more direct way so that both the three Councils and the research community will benefit. This does not mean that the logistics of hosting need be changed--the ownership of the Listserv (and interpretation role) should clearly be that of the three Councils, while technical and basic information activities can be contracted out.

Chapter 5--The Governance Structure of the Ethics Learning Organization

Introduction

The process concerns that were raised call for a refurbishment of the governance of the TCPS process. The major concerns consisted of:

- the need for transparency
- the need for an ongoing system of learning
- the need for fairness (real and perceived)
- the need for inclusivity
- the need for clear accountability

To deal with these concerns, a number of possible of alternative routes were discussed.

A. Models

Interviewees pointed out a number of models that they felt had aspects that we might want to consider, including:

- France – centralist view
- United Kingdom – decentralized, not-for-profit view
- Australia – draft code on collectivities
- Alberta – coverage of non-affiliated biotech researchers under the Alberta College of Physicians and Surgeons
- Canadian Biotechnology Advisory Committee – independence, broad representation and shared funding commitments
- Canadian professional associations – potential source of history and experience

We looked seriously at two models—the Canadian Council on Animal Care and the U.S. system.

Canadian Council on Animal Care (CCAC)

First, the example of the CCAC was presented as a working alternative to the present system. It was a model especially preferred by the biomedical research community.

The CCAC program has been in place for over 30 years and is based on Guidelines that give clear direction to institutional animal care and use programs.¹⁸ Co-funded by MRC and NSERC, the CCAC comprises 22 member organizations, whose representatives

¹⁸ The TCPS is the equivalent of the CCAC Guidelines.

include scientists, educators, and representatives of industry and the animal welfare movement.

Local institutional Animal Care Committees (ACCs) or Animal Research Ethics Boards (AREBs) were introduced by CCAC in 1968. These committees serve as the "conscience" of the institution in order to ensure ethical concerns are addressed in the protocols for and conduct of the research being undertaken. As with its documentation, CCAC's assessment program and suggested terms of reference for ACCs continue to be subject to considerable change as experience is gained and new technology becomes available.

Most of these changes have come in response to concerns expressed by the scientific community, although some have been influenced by concerns expressed by animal protection organizations. CCAC's mandate is to develop programs to enhance animal care and to make changes as required, based on sound expertise and input. Its mandate covers assessment, guidelines and education as well as operating at arm's-length from the funders.

The CCAC carries out its national responsibility for animal care through education in the form of workshops, publications, presentations, etc., and its assessment program, which focuses on animal care and use, and the evaluation of the effectiveness of the local ACCs. These institutional committees are responsible for assuring ethical animal use and compliance with CCAC Guidelines at the local level, and must evaluate the ethical aspects of proposed research before the study may commence. Assessments are based on the Guidelines and CCAC position papers. In-depth assessments are normally scheduled approximately every three years. In addition, a number of special or unannounced visits are conducted if a panel and/or the Council feels that the conditions at an institution so warrant, or upon request by the institution.

The CCAC has full responsibility for the Guidelines. CCAC Guideline development is the responsibility of the Guidelines Committee. Guidelines are developed in response to current and emerging needs of the research community, advances in laboratory animal care and in conjunction with the needs of the CCAC Assessment Program.

The CCAC assessments, for instance, of 190 institutions cover a three-year period -- examining their facilities, their care, and their AREBs. In doing so, the CCAC becomes informed of the needs of research institutions, of researchers and of the public and is able to incorporate these needs into modifications of existing Guidelines or through the addition of new Guidelines.

The CCAC feels that if it did not have the capacity to quickly update policies by those who are using them, it could encumber research. Interpretation of the Guidelines is not achieved for them by national consensus, it is acquired on-site. The members of the Council who are funders of research, such as MRC, have feedback from this process but only as one of the players not as a dominant player. The funding agencies are no longer directly involved with the operation of CCAC at this time.

While the CCAC has annual budgets, the organization is funded through three-year grants. On this basis the CCAC develops long-term policy. The performance of CCAC is reviewed every three years with the grant application and importantly the review is not conducted only by MRC and NSERC. This helps to resolve any perceived conflict of interest between sponsors, founders and decision-makers.

Basically, the CCAC is set up to:

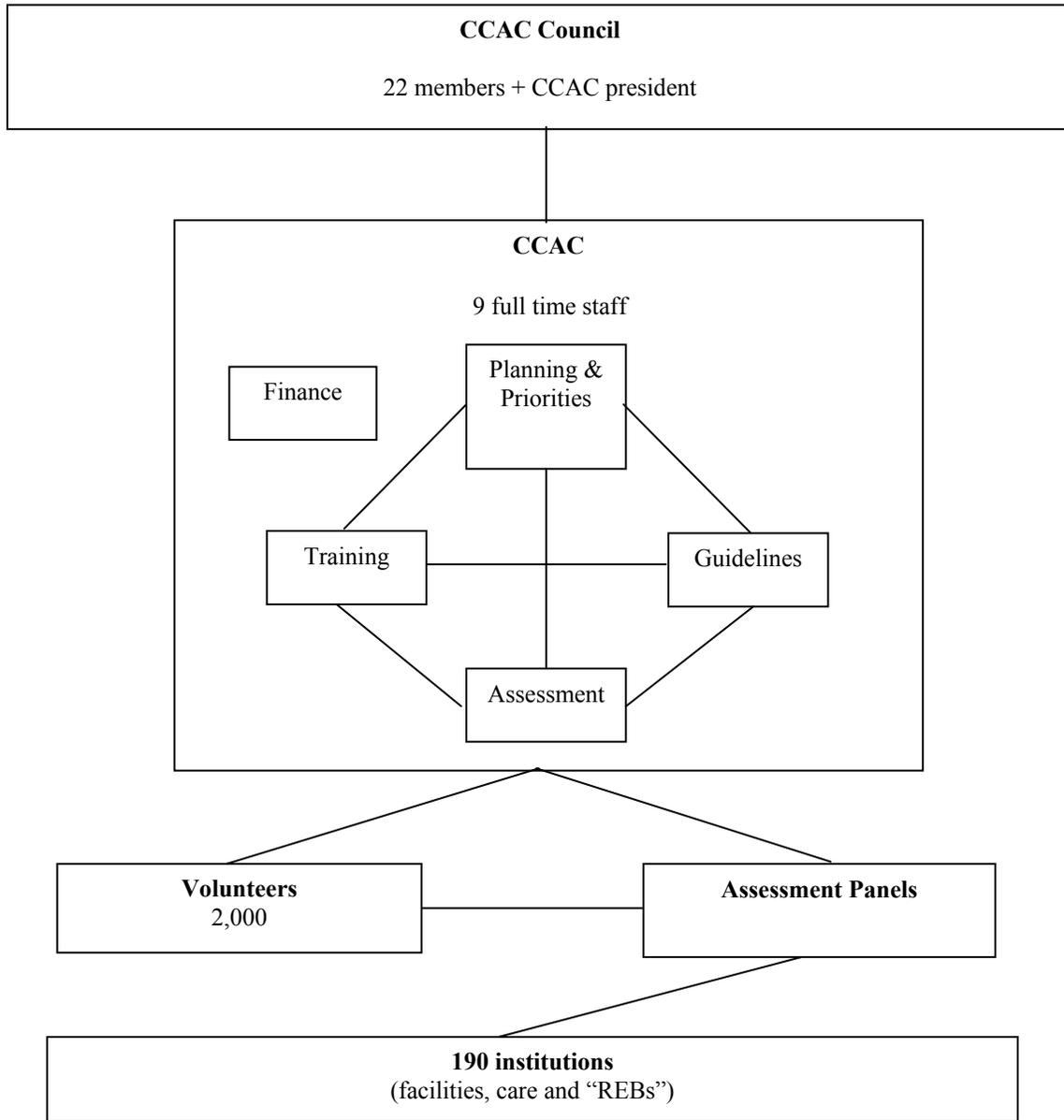
- enforce the established standards;
- develop a program to update the Guidelines; and
- educate

The CCAC has five Standing Committees. They are Assessment, Guidelines, Training, Planning and Priorities, and Finance. The CCAC has one staff member for each standing committee. The CCAC has a Board of Directors on which the President sits. He also sits on each committee *ex officio*. The CCAC has 9 full-time staff and about 2000 volunteers. It has a distributed management structure. Its corporate memory is distributed among its staff and many volunteers. New staff comes in on a part-time basis so that experience can be passed on to them before they become full-time. See Figure 3 for an outline of the CCAC structure.

At CCAC, 53% of its resources go to assessment. CCAC relies heavily on peer review. It seeks out experts who are external to the universities being reviewed. They have a large pool of assessment panel experts who have worked with them for many years. This is done to achieve credibility and objectivity. To achieve familiarity and fairness, one of the CCAC's evaluation criteria is that the institution knows the researchers, the research and the REB.

The Assessment Committee reviews assessment reports. The committee reviews the institutional response and recommends one of "compliance, conditional compliance, problematic, or non-compliance". The institution receives public certification as to their adherence to the Guidelines. For legal reasons the CCAC does not use accreditation. The main driver for enforcement is the Assessment Report that comes from the site visit. The report of the external panel goes to the assessment co-ordinator and then to the standing committee. If in the process a problem with the Guidelines is identified that may require revision, the Assessment Director advises the Director of Guidelines who advises the Chair of the Guidelines Committee.

Fig. 3: CCAC



The CCAC feels that it is credible because researchers are part of it and they have significant buy-in to the organization. For AREB volunteers or members of their evaluation committees, there is an incentive to be objective because of the expectation that in the future they want their own research to be judged fairly. The CCAC is not a policing institution, it is a facilitator. CCAC gives advice up front and then tries to give enough time for researchers to improve their protocols.

The stick for non-compliance is that the name of the institution is given to the granting council. In this the whole institution is at risk. Responsibility lies with the institution, not the researcher. Consequently, assessment reports are usually sent to the university

Vice President of Research. In the CCAC's experience, universities do respond to the threat of money being pulled. In only a few cases have universities come close to this point and when they did, it was used to obtain money to allow the university to comply. The CCAC standards apply for private sector research as well. All research protocols are reviewed. The funding source doesn't matter. The university signs an agreement to adhere to the Guidelines and universities are liable to meet those ethical protocols.

The Guidelines Committee is responsible for establishing a subcommittee composed of experts on the topic to be covered by the guideline. The experts are then responsible for providing a draft guideline including a background reading list. CCAC Guidelines are prescriptive, rather than descriptive and are justified through reference to the published literature.

Once the draft guideline is acceptable to the Guidelines Committee it is circulated widely to experts in the area, CCAC constituents likely to be affected by the Guidelines, and CCAC Council members. When revisions have been completed to the satisfaction of the Guidelines Committee, the final draft is placed before Council for approval. The guideline is then delivered to the CCAC Secretariat for final editing, formatting, publication and distribution.

One thing that CCAC cannot have is federal regulatory authority--because the jurisdiction for the regulation of animals lies with the provinces.

Assessment of the CCAC as a model

There is much to commend the CCAC as a model for the TCPS system. In particular, it has over thirty years of successful operation to its credit. The practical application of this model in the TCPS structure would be to empower NCEHR, a reconstituted NCEHR, or an NCEHR-like organization to act as the CCAC, with full responsibility for the TCPS. As noted, many members of the biomedical research community suggested such an approach.

Nevertheless, we are not able to recommend this approach at this time. While there are a number of substantive differences between the CCAC and the TCPS situation, one element that exists between the CCAC, its funders, and the research community is credibility and trust. That relationship does not yet exist between NCEHR and the broad university research community. And while the CCAC did not have that confidence at its outset either, it did have a longer prior history of its stakeholders working together.

As a result, since the basic criterion for moving in this direction is not in place, then moving to a CCAC-like system is likely to be counter-productive. Until NCEHR has developed much greater stakeholder consciousness and credibility, especially within the SSH and NSE research communities, then delegation of the development of the new TCPS system is not warranted.

We considered the possibility of “force-feeding” the system and accelerating the interaction between NCEHR and the SSH and NSE research communities, but the results of our interviews strongly suggested that such an action would not be wise.

The U.S. Model

The second model presented was the U.S. regulatory one. The practical application of this approach to the TCPS system would be for the three Councils to take over all responsibility for policy development and implementation, including education and evaluation of compliance. This system has the merit of ensuring tight control of the learning process at this early stage of development.

However, almost unanimously, interviewees felt we should take great pains to avoid following the path of the U.S.--too much bureaucracy, too expensive, too limited scope, and “too many big teeth wielded unknowledgeably”. This was the case even among those who felt there might be a need at some time to introduce legislative authority in Canada. Therefore, we have severe reservations about creating a new bureaucracy in Ottawa that would control the system.

B. Recommendations

The continuing evolution of the TCPS

From our broad consultation with the stakeholders, it has become clear that first and foremost it is essential to determine who has responsibility for development of the policy statement and whose responsibility it is to interpret and modify the statement as circumstances change. The answer to this question seems clear: this is a policy statement of the three Councils and therefore it is responsibility of the three Councils to interpret and modify it. Second, it has also become clear from our interviews that circumstances vary so considerably across fields of study that a single median process to govern the ethics process might run the risk of being too loose for some areas and too stringent for others. Consequently, while the process of implementation should have some basic common characteristics, it must also allow for different streams of implementation--for the medical and the non-medical research programs for instance.

In the first instance, therefore, the prime responsibility for the TCPS lies with the three Councils, through their Presidents. To assist the three Presidents we also recommend formalizing the current staff Working Group as a Tri-Council Secretariat (TCS). There need not be any increase in the number of personnel—indeed through streamlining, there may be an opportunity for less total staff time being spent on the process.

As well, we recommend the retention of the TCAG. To better reflect the orientation of the TCAG we suggest re-naming it to the “Tri-Council Ethics Panel” (Ethics Panel). The role of the Ethics Panel would be to recommend revisions to the ethics policy and process to the three Councils, and to suggest activities to better raise the awareness of the

university research community about research ethics. We suggest that the TCS also act as secretariat for the Ethics Panel.

Because of its link to the university community we suggest that the universities participate in the cost of the Ethics Panel, at least nominally. Therefore, we recommend that large universities contribute \$2000 each and small universities \$500 each for the maintenance of the group. This helps to encourage the attention of the universities in the deliberations. Further, this would better reflect the partnership basis of the entire process. While there is a justifiable concern about the cost to the universities of administration of the REBs, that is a separate issue from the small amount being suggested for this specific activity.

The current mandate and composition of the Ethics Panel could remain largely as it is, although the three Councils may wish to give consideration to its composition, and especially consider the role of AUCC. We recommend that the Ethics Panel consist of two representatives from each Council, a representative from CAURA and one from AUCC. Other groups could be invited as observers.

The current governance structure has engendered confusion about the authoritative source for the interpretation of the TCPS. Our view is that this activity should be located close to the source of the policy development, i.e. close to the three Councils. This should be the role of the new Tri-Council Secretariat. One expected by-product of this role should be a faster learning curve for the researchers.

Some have suggested that the education and interpretation functions are inseparable and should be brought together under one group. Our view is that while the functions are interdependent, they can be effectively handled through collaboration and reinforce each other in that way. A structural merging is, in our perspective, not essential nor, in this case, beneficial.

Implementing the TCPS

Everyone agrees that the REBs will continue to be the primary vehicle for implementing the TCPS. There are many concerns about the need for support to be provided to them, both resources and content. It is outside the scope of this study to consider issues such as teaching release time for membership on an REB, but it will be critical to the success of the policy for such a study and adoption of appropriate support systems for the REBs. The new Ethics Panel, with its closer cooperation with the universities, should take on this task.

The TCPS says the following about appeals: “In cases when researchers and REBs can not reach agreement through discussion and reconsideration, an institution should permit review of an REB decision by an appeal board, provided that the board is within the same institution and its membership and procedures meet the requirements of this Policy. No *ad hoc* appeal boards are permitted” and “The Councils will not entertain any appeals of REB decisions”. (TCPS, Article 1.11)

We are sympathetic to the Councils' reluctance to permit appeals to the Councils and the bureaucratic nightmare it might create. Nevertheless, in order to ensure that questionable approvals can be reviewed some appeals process is necessary to achieve fairness in the system, especially to the subjects. As noted in Article 1.11 a formal intra-university solution is expected in the decision-making process of each university. Many interviewees raised positively the possibility of inter-university agreements whereby universities agreed to act as each other's appeal board. This approach seems reasonable, especially if it is not *ad hoc*. However, we also feel that an outside group needs to be available in extraordinary circumstances, whenever there is a very strong feeling of unfairness to the human subject.

The public might be concerned that decisions might be taken for the wrong reasons and then "swept under the rug" by those within the system. A "closed loop learning system" as proposed here, while important for learning, could potentially reinforce that impression. It would therefore make sense to add a process "outside the loop" to which individuals can bring cases they feel are inimicable to the spirit of the TCPS. Therefore, we suggest the creation of an "Appeals Panel", a group of about 5 eminent persons from medical, social science, humanities, science, engineering and ethics backgrounds.

Any individual could raise a specific case to the Appeals Panel for their consideration. The Appeals Panel would decide whether or not to hear the Appeal. Since the main purpose of the TCPS is to protect human subjects, we envisage that only approved research protocols could be appealed. This would provide an important level of protection to human subjects. Researchers would not be able to appeal a negative decision on their proposals outside the intra- or inter-university process. This would add greatly to the public perception of fairness and provide an excellent learning opportunity on complex ethical issues.

We also see the Appeals Panel as fulfilling the role of Ombudsperson, an arm's-length group that anyone could petition for redress. For example, researchers who feel that an unfair process has rejected their proposal could present their case to the Panel. The Panel could decide to study the process and make recommendations to the three Councils. Individual decisions themselves would not in this circumstance be overturned, but changes to the REB or appeal process might be recommended.

The TCS should also act as the secretariat for the Appeals Panel.

Education and certification

One of the other major requirements is the need for continuing education for REB members and for the research community generally. On the recommendation of the Ethics Panel, the three Councils should instruct the TCS to contract an organization to conduct workshops and consultations on topics as proposed. Organizations that should be considered for this contract work would be NCEHR, the HSSFC and the RCPSC. In this way decentralization of the process and collaboration with experts is encouraged.

Our recommendation suggests limiting the process to a small number of groups in the first five-year period to ensure continuity and to develop ongoing contact and familiarity, and therefore we hope increasing credibility for the organizations.

A much-discussed issue was certification of REBs. Opinion among the interviewees was split, and there are clear positives and negatives about it. In the end, our view is that all universities should undertake such a process, to be defined by the three Councils. Over the next five years, each university should contract with an authorized certifier to complete the certification process. After completion the President of the university should indicate in writing to the three Councils that the institution has been certified as TCPS-compliant. A standard letter of agreement should be jointly developed for this purpose between the three Councils and the AUCC. Thereafter, each institution should renew its certification every five years.

The Ethics Panel should develop the criteria to be used for certification in this calendar year.

In the first instance, we recommend that the same groups as above (NCEHR, HSSFC, and the RCPSC) be invited to become certifiers by the three Councils. This limitation could be re-considered in five years time. Universities might contract with one or more organizations, e.g. contracting NCEHR or RCPSC for medical REBs, and HSSFC for the non-medical ones, or contracting a single group such as NCEHR to do all REBs in the institution.

The qualification of certifiers should be approved by the Ethics Panel, and should be completed within one year. This should give the three groups time to decide if they wish to become certifiers and to harness the necessary expertise.

With the TCPS as the “gold standard” for research ethics, we expect from DND’s experience that government departments will decide that they wish to “sign on” to the policy on a voluntary basis. Eventually, we foresee the need for departments to hire authorized certifiers to assist them in this process. In the same way, private REBs should be encouraged to submit to this process as well. We also foresee the time when private REBs will proudly display the sign “TCPS-certified” on their wall to confirm their credibility to their clients, and conversely that their clients will expect them to be certified before giving them their business. Certifiers qualified by the Ethics Panel would be in a position to contract with the government departments and private REBs to provide this designation, much as NCEHR is currently doing with DND.

Other support systems

An important support system for the REBs and researchers is the Listserve that is currently hosted by NCEHR. This activity is a significant learning device that needs to be continued. While the TCS could fulfill this function, our view is that decentralization should be encouraged wherever feasible, and we believe that it would be reasonable in this case. Our recommendation therefore is that the three Councils should contract out

the hosting of the Listserve to NCEHR on a continuing basis. We further recommend that the TCS should participate actively in the online discussions.

NCEHR should also be contracted to consolidate and analyze issues that have been already raised on the Listserve, and present them in an easily searchable format. As well, an important element in the learning system is the creation of an easily searchable repository of REB cases, available to researchers, REB members and the general public.

Proposed governance structure

Fig. 4: The Tri-Council Group on Ethical Research (TGER)—Proposed Structure

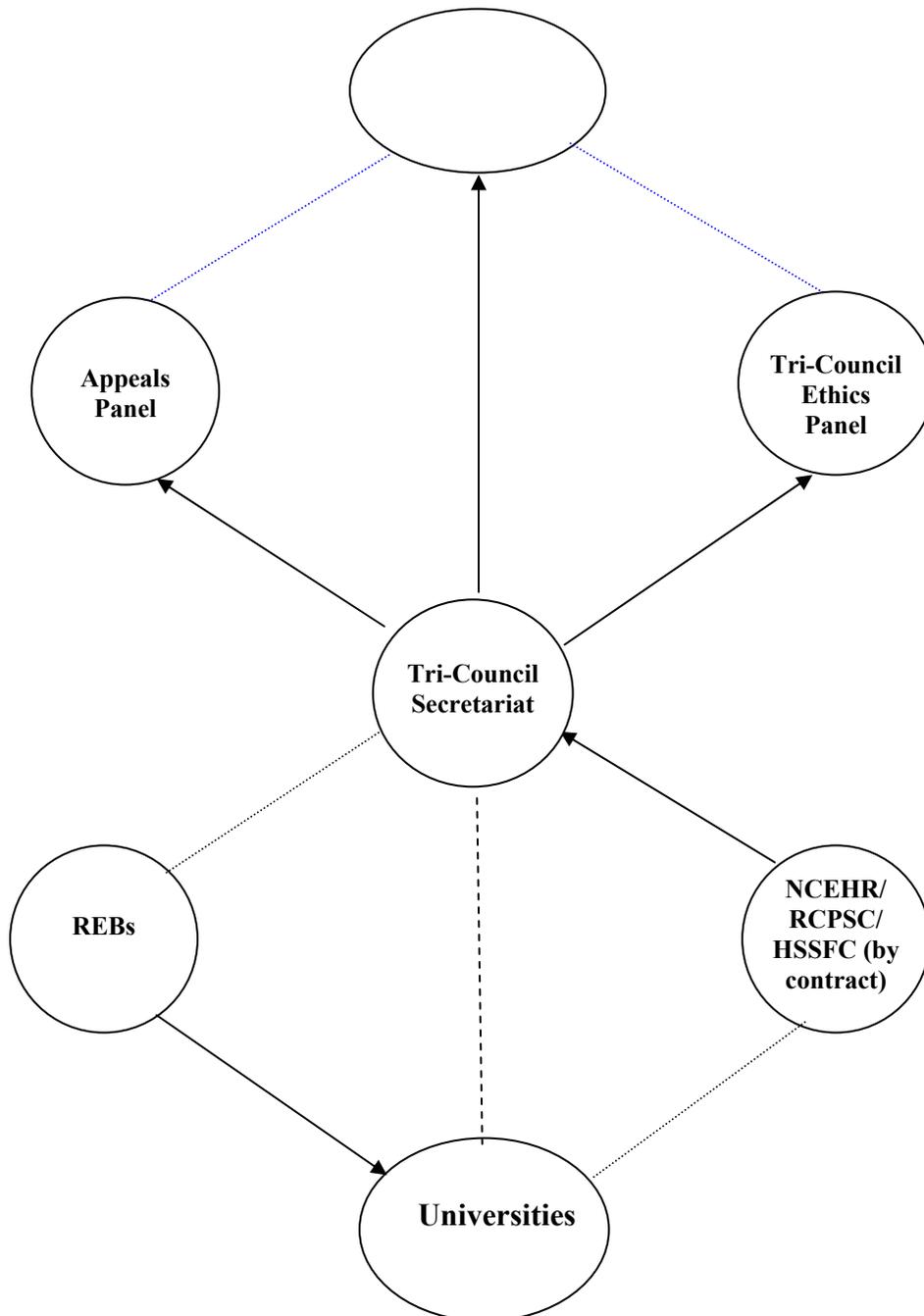


Figure 4 puts together all the elements of the proposed structure. As a feedback loop, the recommendation emphasizes the importance of learning over the next several years while the policy evolves. The simplified “double diamond” structure minimizes overlap and confusion while maximizing interaction and learning. We believe that this proposal will encourage and promote research while protecting human subjects from potential abuse.

Why is this model better...

We are not looking necessarily for the ideal system, but rather a simple system that can work well for the next five years to do two main things: protect human subjects; and solidify the Tri-Council ethics policy system through broad stakeholder buy-in so that it works extremely well within the Councils’ own spheres of influence.

The CCAC model has many advantages, and as a result there are a number of people who support this approach. However, the study has concluded that the basic ingredient of trust that fuels the system is missing here. The issues between stakeholders on human ethics are more complex than with animal care and there is simply not the history of working together that has existed with the CCAC. We do not argue that this situation cannot improve over time, and in fact would not be astonished if the system evolved eventually along CCAC lines. However, at present we would suggest a system that promotes the continuing interaction and collaboration that will help generate this trust rather than an independent arm’s-length body. The continuing hostility threatens to tear the system apart and an independent body is likely to exacerbate the situation further. A subsequent review after five years of experience and comfort may suggest new opportunities.

At the same time, a centralization of the process entirely within the three Councils is a retrenchment that will simplify the administration of the TCPS, but will not generate the broader learning throughout the system. This would threaten a return to a level of bureaucratization similar to that of the U.S., a circumstance feared by all, including those at the three Councils. The system relies on many dedicated and capable volunteers whose contribution needs to be valued and promoted. They need an environment that supports their efforts, not one that puts up roadblocks.

We have proposed a compromise model that encourages compromise and patience. We believe that the system is trying to do too much, too quickly, and therefore is falling over itself. The major fear of interviewees was that we would leave the system as it is, and that is telling.

In looking toward a long-term solution, it is sometimes better to move in smaller steps, ensuring that we “get it right” the first time. We also feel that moving in small steps does not mean moving slowly, only coherently. At the point where participants feel they are getting it right, an aggressive effort to expand the coverage of the TCPS will likely be welcomed.

C. Further issues

The three Councils will need to examine their own internal committee structures in the light of these proposals. But beyond this, there are three further issues that we wanted to highlight in conclusion. They were fundamental considerations and implications central to the formulation of our recommendations for a new governance structure. These issues were: conflict of interest; the role of HC and the RCPSC; and the future role and relationship of the new CIHR.

Conflict of interest

It has been argued that the three Councils as the promoter of research are in a fundamental conflict of interest in regards to ethics. We have noted that we begin from a different perspective, that the three Councils are in the business of promoting “ethical research”, not just research. Analogously, the peer-review system is intended to ensure that the research is “good research”, not just research. Thus we believe it is simplistic to make this charge. Nevertheless, the issue is of concern.

We believe that the proposed governance structure provides an additional comfort level on this issue. One reason for not adopting the U.S. model is the question of conflict, where countervailing views are limited. However, in this learning system, there are many organizations directly linked to the implementation of the policy. For example, while they do not here have direct authority, we see groups such as NCEHR, HSSFC and the RCPSC as providing a layer of “moral conscience”--a sense of moral authority if you will. As a continuous feedback loop rather than a hierarchical structure there are any number of nodes where caution can be introduced.

In addition, the creation of the Appeals Panel, both in its appeal and ombudsperson roles, provides additional support.

In these ways, we feel that we have provided a satisfactory resolution to the issue of conflict of interest.

The role of HC

Health Canada plays an important role in health research, but it is not clear what their relationship is and should be in regards to the TCPS. It has been described to us as an “accident of history” that they are on the Coordinating Committee. Currently, they have a privileged position as compared, for example, to DND, which has formally adopted the TCPS.

There is no specific role in our structure for HC, but we acknowledge both their past contributions and future importance. They play a significant role in demonstrating how a government department can benefit from their involvement in the TCPS process. As well, HC will be a key player if federal legislation is contemplated and enacted.

Therefore, we are making an additional recommendation that, once they officially sign on to the policy, HC be invited to sit on the Ethics Panel as an observer. In this way, they can participate directly in the consideration of the policy to which they are binding their research program.

As we previously indicated, we see the scope of the TCPS being extended over time to non-Council funded university research to all publicly-funded research and ultimately to all research in Canada, whether affiliated or not. HC is in a key and credible position to begin that process.

We also envisage that HC might wish to contribute financially to specific projects that come out of the Ethics Panel. For example, they might wish to fund TCPS research projects, workshops or consultations that benefit their stakeholders. They may also wish to provide direct financial assistance to groups such as NCEHR or the RCPSC, either for block funding or for specific activities. Thus, they can participate effectively in the learning system as a collaborator. We have no intention of cutting them out of the process.

In the same way, we recommend that any government department, such as DND, that signs on to the TCPS be invited to sit on the Ethics Panel as an observer.

The CIHR

Another key issue will be the impact of the creation of the CIHR, especially its new ethics unit. One of the cleavages within the system has been the perceived gap between the biomedical and SSH/NSE research communities. The expanded focus of the CIHR should help bridge that gap.

What is unclear is how their new mandate will affect the Tri-Council Secretariat and how it will affect NCEHR. Their staff complement may well be greater than that of the TCS and NCEHR combined, and their broad scope will certainly intersect with those two groups. The relationships and understandings between these groups will need to be carefully worked out in order that this dynamic not create a new set of overlaps and conflicts, generating confusion within the research community.

Conclusion

The basic message we heard during the consultation was the desire to make the TCPS work. There was a consensus that the experiment in designing and implementing one policy for all three Councils was worthy of considerable effort. At the same time, everyone agreed that the policy and process was organic and evolving. There were many issues that people felt needed to be worked out and understood. This means that an appropriate governance structure must be adapted in such an environment so that the Councils, researchers and organizations have an opportunity to learn together and revise the policy and process on an ongoing basis.

Because we see as the objective of the three Councils the encouragement of ethical research throughout the university community, we assume that a learning governance system should be a service in support of that purpose, rather than being a system of checks and balances or of jurisprudence. Such a governance system would not create the stereotypical confrontation we often heard described between a hypothetical group of individuals who wish to do unethical research versus the ethical “police” out to stop them.

Rather, this governance system would encourage the broad research community to work with ethicists and key stakeholders to balance the requirements of research with those of the human subjects involved. Everyone involved participates in a learning experience. The key would be to prevent possible abuse, inadvertent or deliberate, by inadequate access to knowledge, miscommunication or by unclear lines of accountability. For researchers, ethical reflection must become an integral part of the research agenda. This obligation is especially acute given our enhanced capacity to transform the lives of human beings.

Therefore we focus on learning and negotiation.

Appendix 1

Governance Study: Roles of the Sponsors and NCEHR in Promoting Ethical Conduct in Research Involving Humans

Objective

The purpose of the review is to clarify and improve the long-term organisational basis between the Sponsors, namely the Social Sciences and Humanities Research Council of Canada, the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada, Health Canada and the Royal College of Physicians and Surgeons of Canada, and the National Council on Ethics in Human Research (NCEHR) in order to manage effectively and efficiently activities related to ethics in research involving humans.

Background

In the mid-1980s the Medical Research Council of Canada (MRC) reviewed its guidelines on research involving human subjects and recognized that an ethics review system relying on autonomous review by local Research Ethics Board (REBs) required ongoing support and information exchange. In 1989, at the request of the MRC and with funding from MRC and Health Canada (HC), the Royal College of Physicians and Surgeons of Canada (RCPSC) established the National Council on Bioethics in Human Research (NCBHR) as an arm's length body to assist Research Ethics Boards (REBs).

In 1994, the three granting Councils, namely the Social Sciences and Humanities Research Council (SSHRC), the Medical Research Council (MRC) and the Natural Sciences and Engineering Research Council (NSERC), started to draft a joint policy statement on ethics in research involving humans to replace existing policies. In 1995, NSERC and SSHRC joined MRC, HC and RCPSC as NCEHR's sponsors. In 1997, the NCBHR changed its name to the National Council on Ethics in Human Research (NCEHR) to better reflect its mandate, which now extends to all areas of research involving human subjects.

In September 1998, the three granting Councils released the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), which replaces previous ethical guidelines developed by the three granting Councils. The TCPS is a living and evolving policy statement.

The Sponsors and NCEHR form the Coordinating Committee for NCEHR. The Coordinating Committee and its staff level support group provide fora for discussion and collaboration on university-based research ethics initiatives amongst its membership and review NCEHR's programs and budget. The Sponsors meet without NCEHR to reach final decisions on funding levels.

Mandate

SSHRC, MRC, NSERC, HC and RCPSC are undertaking in collaboration with NCEHR a review to improve the long-term organisational basis between the Sponsors and NCEHR in order to manage effectively and within limited resources activities related to ethics in research involving humans, in particular the Tri-Council Policy Statement.

Terms of Reference of the Governance Study

The Governance Study will assess:

- The organisational structure of the Coordinating Committee, its effectiveness, efficiency and appropriateness;
- The expectations of the Sponsors of NCEHR's role as it relates to activities related to ethics in research involving humans, in particular the TCPS;
- Conversely, NCEHR's expectations of its role;
- NCEHR's program delivery capacity as it relates to activities related to ethics in research involving humans, in particular the TCPS;
- The optimal means or alternative approaches to manage effectively and within limited financial resources the ethics of research involving humans.

Factors to take into consideration in this study include, among others:

- The Tri-Council Policy Statement has been established by the three granting Councils;
- NCEHR's roles as set out in its mission and mandate;
- The creation of the Canadian Institutes for Health Research and the disappearance of the MRC on April 1, 2000;
- Common macro goals but differing expectations from the Sponsors. The three granting Councils (SSHRC, MRC and NSERC) and Health Canada have different interpretations of their respective role and mandate beyond the university community.
- The Sponsors have different financial and human resources available.

The Governance Study will mainly, but not exclusively, be based on the following research methods:

- interviews and surveys including telephone interviews (50 to 100) with the members of the NCEHR Coordinating Committee and their respective staff support, with people responsible for the TCPS within the sponsoring organizations, and with NCEHR council members as well as the research community;

- analysis of relevant documentation such as terms of reference of the Coordinating Committee and NCEHR, NCEHR's strategic planning exercise of September 1999, NCEHR's annual workplans, budgets, annual reports, other documents prepared to support activities, and minutes of meetings, etc.;
- assessment of the organisational mechanisms and functioning, target public, key partners and network structure, of the member organisations of the Coordinating Committee.

The report will consist of an executive summary, a global argumentation of the Terms of Reference based on data gathered by the consultant and a series of explicit recommendations.

Six bound copies and one unbound copy as well as an electronic version of the report (Microsoft Word) will be provided.

Timelines

The report on Governance Study is to be delivered no later than February 15 [amended to March 15]. An interim report will be provided by January 14, 2000 [amended to February 24].

The consultant(s) is to develop a schedule for the Governance Study upon award of the contract. SSHRC as Chair of the Coordinating Committee, and co-ordinator of the organisational review, will receive the report on behalf of the Coordinating Committee. The report will be submitted to the members of the Coordinating Committee for discussion, approval, and further action.

October 20, 1999

Appendix 2

List of Persons Interviewed

1. John Adair Psychology, U of Manitoba (Chair, TCAG and Chair, SSHRC Standing Ctte on Ethics and Integrity)
2. Caroline Andrew Dean of Social Sciences, U of Ottawa
3. Isabelle Blain Corporate Secretary, NSERC
4. Michel Brazeau Executive Director, RCPSC
5. Tom Brzustowski President, NSERC
6. Johanne Burgess histoire, UQAM
7. Richard Carpentier Executive Director, NCEHR
8. Bruce Clayman VP, Research, Simon Fraser (CAURA rep on TCAG)
9. Doris Cook Policy Analyst, Health Policy Division, HC
10. Ellen Corin recherche psycho-sociale, Centre de recherche de l'Hôpital Douglas, Verdun (SSHRC Standing Ctte on Ethics and Integrity)
11. Martha Crago Associate VP, Graduate Studies, McGill
12. Lynn Curry Consultant, Ottawa
13. Frank Davey English, U of Western Ontario (ACCUTE member)
14. Kenneth Davey Distinguished Research Professor, Biology, York (NCEHR Council)
15. Thérèse De Groot Policy Analyst, SSHRC
16. Howard Dickson VP Research, Dalhousie (MRC Standing Ctte on Ethics)
17. Henry Dinsdale Kingston General Hospital (Past President, NCEHR; MRC Standing Ctte on Ethics)
18. Ken Dion Psychology, U of Toronto
19. John Dossetor Policy Advisor to the Minister of Health, HC
20. Michael Enzle Psychology, U of Alberta
21. Tim Flaherty A/Chief, Regulatory and Compliance Policy, HC
22. John Foerster Director of Research, St. Boniface Hospital Research Centre (Vice-President, NCEHR)
23. Henry Friesen President, MRC
24. Chad Gaffield Director, Institute of Canadian Studies, U of Ottawa
25. John Galaty Anthropology, McGill
26. Clément Gauthier Executive Director, Canadian Council on Animal Care
27. Glenn Griener Bioethics, U of Alberta (NCEHR Council)
28. Ira Jacobs Chief Scientist, Defence and Civil Institute of Environmental Medicine, DND, Toronto
29. James Jans Associate Dean, Student Affairs and Curriculum, Concordia
30. Joe Kaufert Community Health Sciences, U of Manitoba (NCEHR Council)
31. Bartha Knoppers droit, U de Montréal (MRC Standing Ctte on Ethics; Chair, IGC Subcommittee on Ethics, CIHR)
32. Kristine Koski School of Dietetics/Human Nutrition, McGill (TCAG)

Governance of the Ethical Process for Research Involving Human Subjects

33. Marcel Lauzière Executive Director, Canadian Council on Social Development
34. Chris Levy Law, U of Calgary (REB Chair; MRC Standing Ctte on Ethics)
35. Melody Lin Deputy Director, Office for Protection from Health Risks (OPRR), National Institutes of Health (NIH), Maryland, (Observer, MRC Standing Ctte on Ethics)
36. Barney Masuzumi Dene Cultural Institute, Yellowknife (NCEHR Council)
37. Daphne Maurer Psychology, McMaster (NCEHR Council)
38. Michael McDonald Director, Centre for Applied Ethics, UBC
39. Neil McDonald Centre for Bioethics, Institut de recherches cliniques de Montréal (Chair, MRC Standing Ctte on Ethics)
40. Barbara McGillivray Medical Genetics, UBC (NCEHR Council; TCAG)
41. Marcel Mélançon sciences religieuses et d'éthique, U du Québec à Chicoutimi (NCEHR Council)
42. Jim Miller History, U of Saskatchewan (SSHRC Standing Ctte on Ethics and Integrity)
43. Anne-Marie Monteith Research Ethics Officer, NSERC
44. Karen Mosher Executive Director, MRC
45. Robert Peterson Associate DG, Therapeutic Products Program, HC
46. Marc Renaud President, SSHRC and Chair of the Coordinating Committee for NCEHR
47. Louise Robert Executive Director, HSSFC
48. Francis Rolleston Director, Ethics and International Relations, MRC
49. David Roy Centre for Bioethics, IRCM, Montreal
50. Don Savage Consultant, Ottawa
51. Katherine Schultz Associate VP, Research and Graduate Studies, U of Winnipeg
52. John Service Executive Director, Canadian Psychological Association
53. Sue Sherwin Philosophy, Dalhousie
54. Ian Shugart ADM, Policy and Coordination, HC
55. Janet Storch Director, School of Nursing, U of Victoria (President, NCEHR; MRC Standing Ctte on Ethics)
56. Peter Sutefeld Psychology, UBC
57. Sandra Trehub Psychology, U of Toronto (TCAG)
58. George Wenzel Anthropology, McGill
59. Mark Wheeler Assistant Director, Health Policy and Information Directorate, HC
60. Ban Younghusband Medical Genetics, Memorial University of Newfoundland (TCAG)

Appendix 3

Summary of Interviews

The following represents a summary of the remarks and comments by interviewees without attribution. We have tried to organize the comments under various categories such as REBs, TCPS, NCEHR, conflict of interest, legislation, etc. Many of these comments are content-related and as such go beyond the scope of this Report. They are included here for the further information of the readers.

Raison d'être

- Who are we trying to protect and why?
- We are trying to protect people, protect good and ethical researchers, and protect institutions.
- Do good, don't do harm.

Values

- Academic freedom can and should be restrained by public interest.
- We need to privilege certain values.
- Our key value should be fairness and the appearance of fairness, first to the public and then to the researchers.
- There is a gap between the medical and non-medical communities. That imbalance is due to the pace of research and the development of knowledge in the biomedical fields. The social sciences and humanities are undergoing a cultural change with respect to ethics.
- We have an attitudinal problem in society in that truth and ethics are considered to be relative, and therefore ethics does not matter because there are no absolute values.
- If resources are going to be spent managing cultural differences, they should be done at the level of the Tri-Council.
- Ethics needs ongoing discussion and dialogue in order to incorporate changing values. Therefore encourage exchanges.
- Codifying ethics is pushing it into the realm of law.
- Ethical values in Canada are not uniform and ethicists themselves are few in number.
- The process should remain inclusive.
- We all agree that a publicly funded system should not trample the values of our citizens yet those same citizens contribute to non-publicly funded research operating with a different set of values. There is a certain hypocrisy in this.
- When we recognize that there are a variety of views then why should some views impose themselves on the views of others engaged in private research.
- Don't entrust ethical protection to either a government department or bureaucracy.

Assumptions

- Research subjects assume that the institution has vetted the researcher and the research protocol.
- Do we believe we are in crisis? Do we believe we must act now to save us all or do we yet have time to learn?
- What premise do we hold of researchers and institutions? Do we really believe that they are all just trying to get around the rules?
- If a conflict between subjects and researchers exists, who should compromise -- the researcher or the subject?
- Confrontation is not productive.
- Consensus eliminates the rich diversity of dynamic tension.
- If in general we don't trust the researchers or the institutions, can we really expect that we can trust the monitors? Who watches the watchers?
- How can you promote interdisciplinary research that has different rules for different disciplines?
- Processes are more important than content. We're dealing with moral questions within a cultural context.
- We are developing a dialogue among many players.
- We must develop the capacity to track scientific developments and make recommendations that are in harmony with the values of Canadians with researchers needs and the needs of our communities.
- There is no ethical disaster going on. Hence our focus should be on trying to do things better.
- Having the academic community take front rank responsibility for ethical research, as embodied in the TCPS, is an excellent idea. It is so much better than the U.S. regulatory case.
- We need to assume that the academic community can adequately take responsibility for ethics until they demonstrate such incompetence or untrustworthiness that we toss them out.

Scope of coverage

- Should our scope of coverage be only Tri-Council funded research, or should it include all publicly funded research, all research at public institutions, or all research -- affiliated and non-affiliated.
- Currently there is considerable unevenness across Canada in the application of research ethics.
- Is the goal to cover publicly funded research or the protection of human subjects in general?

Research

- We need to identify the features that are common to all research so we can apply an

ethical set of rules to that.

- Dealing with ethics in research is becoming more complex, more complicated, and more salient.
- Need to improve the service to researchers so that they have access to the appropriate knowledge and experience. This should be easy and convenient for researchers.
- What we're trying to achieve is an ongoing dialogue among the various disciplines of research.
- Between the Tri-Council and the researchers, there needs to be a series of honest brokers.
- The current structure encourages fragmentation and unevenness in the application of ethics.
- Research is now highly interdisciplinary and integrated.
- Where's the role for the public? There's a need for more public participation at the REB level and at the policy formation level
- Regulatory policy is becoming more entangled with research in general.
- What is reasonable to ask researchers to do to ensure that the public interest is not neglected?
- There are two ways of handling the biomedical/non-biomedical conflict. Either get them all to think the same way or have policies that recognize their differences.
- There are a number of urgent areas of science that are not covered under the TCPS document, like stem cell research.
- The issues that are of most concern occur outside the arena of publicly funded research.
- If ways are not found to level the playing field between university research and non-university research more and more research will be spun off into the private sector.
- The standard of care depends on what is published.

Models

- Alberta -- non-affiliated medical researchers are covered under the Alberta College of Physicians and Surgeons
- France – centralist
- UK -- decentralist
- Australia -- draft code on collectivities
- U.S. -- majority do not wish Canada to follow the U.S. model. Big teeth are applied unknowledgeably. Too adversarial.
- CCAC -- more confidence, more ownership, greater effectiveness, more inclusivity. Very effective in its advisory role.
- CBAC -- has independence, is broadly represented, and has shared funding commitments among its sponsors.
- Integrity policy model -- each discipline submits a draft policy.
- The U.S. is looking at our Canadian ethics processes, particularly the leadership by academia and volunteers, because it is cheaper and far less bureaucratic.

REBs

- REBs are central to this entire process.
- REB approval is essentially societal approval. Who then represents society?
- The responsibility of REBs should be to the universities as opposed to the granting agencies.
- REB should report to the president not to the VP of Research
- REB administrators need to be certified.
- The role of the REB is to protect people, and consequently it is an investment in research
- How expert are the REBs? Do they have the appropriate research and ethical expertise?
- The evaluation of REBs should involve experts external to the university. The university should know the researchers, their research and those who are participating in the REB.
- In the case of CCAC, the responsibility for REBs and for investigators lies with the specific institution and that institution has to sign an agreement to cover all types of research being conducted there.
- Clarify who can advise the REBs on issues of interpretation.
- Research ethics boards are stacked in favour of researchers leaving only limited impact for ethicists and the public.
- We need to revamp the composition of the REBs. We need to create a community of ethicists who can be brought to bear on specific cases as needed. In addition we need more disciplines involved. Maybe we could think of a staff function to deal with the 99% of applications that are routine while that problematic 1% can receive more quality attention.
- Participation in an REB panel should be paid, and by the university since it has a lot at stake.
- Don't lose the semi-autonomy of the REBs. They should not be second-guessed by some outside third party.
- Interpretation of the TCPS document should be done at the REB and institutional levels. Here NCEHR has an important consultative role.
- There's a lack of resources for REBs.
- Some institutions do not invite site visits and therefore there is an uneven application of the TCPS.
- The REB review system is amateurish and not professional.
- We need to involve more volunteer academics.
- The volume of clinical trials is increasing and the public wants closer scrutiny while Health Canada is shortening the time of the review process. This means an increased workload for REBs.
- How come when we do research there is money for the companies, money for the institutions, money for the departments but no money for the REBs?
- We need to see that when a research protocol is approved by one REB that this approval is recognized by other REBs. If the application of the TCPS is uniform there should not be a problem.

- We need certification of REBs so that we may know what is a good REB and have a stamp of approval.
- There should be some reward for REB members for their involvement, possibly real money to the chairs, but mainly professional recognition by Deans or the promotion of their research or conference opportunities. REBs are not recognized as a funding priority.
- I do not believe there is effective communication between REBs.
- I believe there is a crisis with REBs that is not understood at the top.
- The REB function should go well beyond the review process, in effect becoming a continuing mechanism for dealing with emerging dilemmas (a local think tank role) and creating intellectual capital.

TCPS

- Overwhelming support for a single statement covering all disciplines.
- Common principles and procedures but flexibility in their application in different disciplines (i.e. sets policies, not one)
- Increasingly the tendency is to treat TCPS as a code rather than as a policy statement.
- The TCPS should be seen as a set of minimum standards.
- There are no standards within the TCPS on obtaining or handling data on cultures.
- The TCPS needs work still in the areas of vulnerable populations and groups.
- Update and rewrite the TCPS every 18 months with input from the REBs.
- Ownership of the TCPS should be with the sponsors and any agency dealing with or funding research on humans. The document should also carry the names of its owners.
- NCEHR should/shouldn't be responsible for the TCPS.
- Having the TCPS as an open document leads to institutional and regional variance.
- We still could use a set of guiding principles or operational principles.
- The TCPS is setting the standard of practice. Institutions would be unwise not to follow the TCPS that is now the *de facto* standard of care.
- It is not ideal for the Tri-Council to be updating the TCPS because it doesn't help the perception of public trust. When those making changes to the document and those in the position of potentially being critical of the Tri-Council are members of the Tri-Council themselves, then the perception generated is distrustful.
- The TCPS document cannot deal with unaffiliated researchers. This will require something like the Alberta approach of governmental and professional intervention.
- Within the Department of National Defence, the government states specifically in the DAOD what can be done with research on humans. This overriding policy is consistent with the TCPS. As far as DND is concerned there is no other standard than the TCPS. "Why wouldn't we want to adhere to the TCPS. The best and brightest have already worked for years on its development".
- We need more local interpretation of the TCPS, not blind implementation.
- If nothing else, the TCPS has catalyzed discussion on ethical research. Extending and maintaining feedback on this discussion is important.
- I think we need some form of front piece for the TCPS that covers the nature of

research, the need of researchers, the working of REBs and principles. Then we need to have chapters that reflect the different traditions.

Living document

- the Tri-Council has a researcher, founder bias and therefore is not the best place to revise the TCPS
- There would be a conflict of interest if the Tri-Council updated the TCPS document.
- The TCPS is the product of the Tri-Council and therefore it should remain with them.
- With adequate transparency, the Councils can be trusted to set the proper benchmarks.
- The long-term focus of the TCPS should be resident with the Councils and not NCEHR.
- Update the TCPS from experience -- connoisseurship
- Emphasize the need for academic collegiality rather than administrators to manage policy.
- Avoid a politicized process for changing the TCPS document. We should create a system of feedback from all of the participants as a learning process through a broad circulation of ideas.
- Don't forget the concerns and exhaustive experience of the individual disciplines.
- The organization responsible for the interpretation and change function needs an effective mechanism for consulting with the social sciences, the humanities, researchers in general, and with the public. At present NCEHR does not have this capability.
- Don't forget about the professional codes that exist outside of the biomedical professions.
- Whoever owns the policy, they must take information from the REBs, researchers and the universities in order to update it.
- We need an ongoing working group to bring emerging issues forward.
- The TCPS document and its associated processes should reflect the diversity of conditions that exist. "One size, fits all" doesn't work.
- There was never any intention for the Tri-Council to retain control of the TCPS document on a permanent basis. The dual NCEHR/TCAG responsibility was only meant to be transitional.
- If the TCPS is to be a working document we can't wait five years to publish a new revision. What we might want to do is created in a loose leaf format and then changes could be made as we go by replacing pages.
- While information comes back to us through the surf and while NCEHR does respond to us it is not the final word. There is some confusion as to its authority for interpretation.

NCEHR

- Current relationships with NCEHR distort learning.
- Generally site visits have been popular.

- NCEHR needs more money in resources to carry out its current mandate.
- NCEHR lacks a breadth of expertise.
- NCEHR could evolve to perform a similar role to CCAC.
- NCEHR needs more independence.
- NCEHR lacks authority to enforce.
- NCEHR is too secretive, not sharing information widely enough either up to the Tri-Council or down to REBs and researchers.
- In a previous study problems were identified with 13 REBs and since then nothing has been done, what to say of the current portfolio of 65 REBs. NCEHR should not be expanding its mandate until it has successfully dealt with its previous mandate.
- NCEHR has no authority to deal with the problems that have already surfaced.
- Additional resources are needed for NCEHR to do both education and site visits.
- Clarify everyone's expectations with respect to NCEHR.
- Site visits are the key to building trust.
- We need more formal arrangements between the Tri-Council and NCEHR.
- NCEHR has not shifted from its biomedical focus.
- There is need to link NCEHR with the Canadian professional associations.
- The site visit panels should reflect the nature of the research going on in institution as well as the institutional characteristics.
- NCEHR is the place to clarify and to elaborate on the TCPS but not the place to interpret or to change the document. NCEHR doesn't have either the time or the resources. The 1% of the cases that require interpretation should go to the Tri-Council and the other 99 percent should go to NCEHR.
- NCEHR should see itself as a partner for local institutions.
- Decrease the micromanagement of NCEHR
- People may still be reacting to earlier versions of the TCPS and this gets transferred to NCEHR which didn't write that document
- Bring NCEHR closer to the Tri-Council with a three-year budgeting window and an increase in their resources to adequately cover their responsibilities
- If we need to alter the perception of NCEHR as an organization biased towards the medical fields, then we should put more attention on the selection process of NCEHR staff.
- NCEHR is now getting requests to do site visits for non-Council funded research. When we consider that only 10 to 15 percent of research is publicly funded, NCEHR does not have the resources to deal with non-publicly funded research.
- We have only begun to be aware of NCEHR, so how many other organizations remain unaware?
- Beyond the clarification of NCEHR's role, there is a discrepancy between its current roles and funding. NCEHR has responsibility but not the funding to do things.

Conflict of interest

- When the same people from the Councils fund the research, set the standards, monitor the standards, and impose sanctions there is a classic conflict of interest.
- Need to resolve the conflict of interest between the funders, the sponsors and the

decision-making

- Need to avoid even the perception of a conflict of interest in order to sustain public confidence in the system as a whole.
- NIH is both funder and standard setter. [*although OPPR has now moved out of NIH*]
- There is a conflict of interest between NCEHR and the Tri-Councils that builds cynicism and distrust in the structure of ethics.
- The idea of having policy development, education and policing in one place or in one organization is not a bad thing. It goes on in a University environment all the time.
- The U.S. decided recently that the NIH was in a conflict of interest position with respect to the OPPR so that the OPPR no longer reports to the NIH.

Reporting structures

- What is Health Canada's role? Why are they involved?
- Regulation by imposition vs. self-regulation.
- Where do we want to be in five years? Where are the benchmarks and milestones along the way?
- Where should the locus of control be? Institutional, local or national?
- What is the role of the Tri-Council Advisory Group?
- Need to create a learning forum.
- What are the roles of NCEHR staff and the NCEHR Council?
- What is the role of CIHR?
- An NCEHR-like body needs to be reconstituted so as to report to the Coordinating Committee not just the Councils themselves.
- How do we incorporate and address First Nations concerns?
- There's a need for a more long-term budgetary commitment
- There's not enough learning coming back to the Tri-Council from the experiences in the field.
- Don't have the policies dependent on any one particular leader.
- Public research is best served by cutting the stewardship function from the funding agencies.
- We need to do more with community members.
- Effective reporting to the Tri-Council is not there yet.
- Avoid centralization.
- A possible complex adaptive system might have local groups that feed new knowledge and experience into an expert panel that studies these issues and makes recommendations. They can then feed their recommendations to an *ad hoc* committee of the Tri-Council to prepare a form of change document.
- We need more direct exchanges on ethics between the universities than the Tri-Council.
- The expected feedback to the universities from NCEHR and the Tri-Council will be critical for the legitimacy of the current process.
- TCAG is at arm's-length from the Tri-Council.
- Currently, it is the institutions that advise the Tri-Council of research that may be problematic, however, NCEHR could easily perform this function to the Tri-Council.

- TCAG lacks ethicists and NCEHR can help with this expertise.
- We need to recognize that the current structure will not be permanent and may only be there for five years.
- We need to have a body that performs the three functions of policy development, education, and policing that is closer to the Tri-Council.
- We need more ethicists on TCAG. Right now there are none. We also need good writers and editors. We should keep the updating function within the Tri-Council.
- The reporting by NCEHR to the Councils should be direct to the Presidents and not to their assistants who tend to change very rapidly. The Presidents are the only ones who are there for a long time.
- It is odd that we have a representative from NCEHR on the standing committee of MRC but no representative from MRC on NCEHR

Subsidiarity

- Strong need to discourage the creation of extensive new bureaucracies in order to continue to encourage research.
- Our bias should be to the local level -- the REB first, then the institution, then some intermediary body, and then finally the Tri-Council.
- The community must be a partner in establishing the ethicalness of research.
- We need policies that can be unbundled at the local level.
- We need open and frequent communication with the public and with researchers.

Education

- What tools can be provided -- a web site, FAQ, casebook?
- Need to establish the competitive disadvantages and advantages of following the TCPS, i.e. develop metrics
- We need to encourage and develop new ways of thinking about research and ethics.
- Need to train universities to understand the sensitivities involved in facilitating community participation.
- The discussion of ethics is piecemeal in Canada. We need to put attention on developing more ethics courses in university programs.
- We need to link ethical research to the concept of good research.
- We need to change the perception that ethics is an administrative hurdle and not a value in and of itself.
- Allow more time for education and learning before embarking upon the path of enforcement.
- Education and regulation should be separate.
- There should be a universal focus on the next generation of researchers, i.e. graduate students.
- While you can do both education and enforcement, you can do better by separating them.
- The University of Victoria has developed an extremely good policy manual, one that could be a model for other institutions across the country.

Accountability

- The public does not understand how the stewardship function is deployed.
- If the Tri-Council does not act in response to the identification of an ethical problem, an NCEHR-like body should be prepared to make those problems public, but in NCEHR's case their staff and funding are tied to the Tri-Councils, making this option unlikely.
- The funding Councils need to be seen as standing up for the ethical standards Canadians expect. The system has to be seen as one that is set up to protect the public not to protect researchers or government.
- When research outcomes are not in the public interest, you need enough independence and enough people with "balls" threatening to go public.

Transparency

- The need for greater transparency came up again and again, i.e. transparency in decision-making at the REB level, at the institutional level, at the intermediary level, and at the Tri-Council level.
- Make all material public, giving access even to content for the sake of learning.
- From a university standpoint we're not sure what the community thinks. I don't know that lay people know much about ethics and research.
- Transparency is lacking in private settings. On or off site should not matter.

Learning loop

- Currently there's been no new learning since the TCPS document.
- Need to encourage a sense of a learning process at university level.
- We need to create a body of experts to call on.
- Get the public more involved
- If we cannot agree to common rules among the different disciplines then we need some form of intermediary steps in order for us to get there.
- Violations are not chronicled and as a result there is no learning.
- We need to have a list of projects that have been reviewed, so that we can learn from others.
- While cultural differences between the biomedical and non-biomedical disciplines do exist, they get resolved in the compromises that are reached at the REB level. This may suggest that the larger communities have to work together more.
- We need to create for ourselves a complex adaptive system.
- Having an expert panel that studies local input and makes recommendations in brief can contribute significantly to our collective learning.
- Don't crush a complex adaptive system with a heavy mandate.
- Stimulate grassroots thinking via roundtables to help focus ideas and prepare local recommendations.
- We need some form of research ethics clearinghouse. Currently the listserver is not

enough. It may be enough for the most effective REBs but it is not sufficient for those REBs there still trying to master the whole idea.

- We need more examples, more cases, and more accessibility of this knowledge for researchers and REBs alike. Also we need more examples for administrative personnel. We also need mentoring for those key university people involved with research ethics.
- We need more negotiation, fewer rules and less going for firm consensus.
- The one or two TCAG meetings per year are not enough for effective learning. Since the TCAG participants and site panel participants are all volunteers, there tends to be infrequent reporting. The suggestion is made to report every 10 visits.
- Failures are not effectively communicated. We need to impose regular and timely reporting, with the emphasis on timely.

Monitoring

- Who's paying attention to what goes on after a research project begins?
- Use selective monitoring where there is a demonstrated need.
- Ethics standards are applied only at a single point in time. It needs ongoing monitoring. But who will pay?
- Annual reporting of previously approved research is coming at some universities. We need to get away from long-term blanket approvals.
- Monitoring is not adequately described in the TCPS nor is it adequately resourced within institutions.

Accreditation/certification

- Who would audit? -- Tri-Council, NCEHR, the universities, some third party?
- Don't be in a rush to undertake enforcement when the TCPS is still emerging.
- We need an independent third party for auditing.
- We don't need an intermediary organization doing accreditation.
- There can be an accreditation role for NCEHR either in training or in ensuring minimum standards for the REBs.
- Accreditation should be separated from teaching as is done on the medical side.

Appeal process

- There is no clear process of appeal.
- Should the appeal process be focused on procedural or content-related issues?
- Focus on cooperation.
- The final appeal should be to the Tri-Council.
- Universities, researchers and REBs should be able to appeal as appropriate.

Compliance

- The self-regulatory approach is not good enough because researchers would be

- evaluating themselves and their own interests rather than the public interest.
- Obtaining REB and institutional compliance should be similar to the process of REBs themselves -- mainly collegial and advisory in nature, but if needed, application of authority.
- We need additional clarity in the process that covers the violation of standards.
- Must be willing to name those who are non-compliant.
- There is a conflict of interest (even if only apparent) for universities and the current set up of enforcement.
- Auditing should focus on the REB and university process, and not content.
- Sanctions should apply to any member of institution regardless of the source of funding for their research.
- The Tri-Council holds the money and therefore they should be the ones to regulate.
- There's no clear evidence that the Tri-Council can or will use the "big stick". There are universities that are not interested in complying and are not identified to the Tri-Council. NCEHR can identify problem institutions but cannot insist that the institutions fix their problems.

Liability

- Institutions have the responsibility to their human subjects.
- The Tri-Council is the organization that sets the standards.
- There are liabilities that involve "crown duty of care" and "ongoing duty of care". Of these the second is currently the most problematic and suggests a need for monitoring.

Statutory intervention

- To what extent should government be involved?
- We need to create a legislated, arm's-length body.
- Legislation is more possible in the case of research with human subjects than with research on animals where variable provincial legislation applies
- Need to have a national guiding policy or enabling legislation set out as law.
- In addition to some legal basis, have separate values documents and guidelines documents for resolving conflicts
- There is a need for regulation to control non-affiliated researchers.
- Need for some legislative basis for publicly funded research.
- We need to create a "risk gradient". We don't need new legislation or new laws but more of a piece of advertising or a light degree of government participation.
- Putting ethical codes into legal standards and trying to apply them across the board will have unintended consequences.
- Avoid legislation. Legislation can cripple research because it is too inflexible. We need to try and find a balance between the laws we need and the laws we can practically do.
- The push for legal protection often comes from wanting to avoid past mistakes without taking into consideration the sea change in societal values that has taken

place.

- If legislation is what it takes to get private REBs in compliance then that's what we should do.
- Once it is legal it is not ethical.
- We have to recognize that when, not if, we have a bad enough case involving ethics there will be legislative outcomes. All that we can do now is to forestall a total take-over in this area by government. We need to move now to get a credible process in place.
- We need to create some enabling legislation for a national council of volunteers and have a reporting mechanism to the Minister of Justice.
- The government will increasingly want indications of quality assurance with regard to the application of ethics in areas of human research.