

The Governance of Research Involving Human Participants in Canada

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Research involving humans has a long history, marked by both success and failure. It has become a vast and complex activity due to the multiple actors involved, its growing international implications and evolving context, the sustained attention from standard setting authorities, and finally, but not the least, the many underlying interests that sometimes compete or conflict.

This has resulted in increased public scrutiny over the past few decades in some countries like the United States and only more recently in others like Canada. In the midst of the repeated calls for increased public oversight of research activities, much attention has focussed on the development of social, ethical and legal norms. In addition, in many countries, ethics review committees (or research ethics boards (REBs) as they are called in Canada) were created to serve as the primary oversight mechanism of research involving humans primarily based in the institutional setting. These committees were created to review research protocols from a research ethics perspective that aims to promote ethical reflection and behaviour among those involved in research, with a particular focus on protecting and promoting the dignity and well-being of research participants. Ethics review committees have come under a lot of pressure and criticism in the past years and various national solutions proposed including, in some cases, in depth restructuring of the ethics review system that would include accreditation.¹

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¹See e.g. the most recent reports: Institute of Medicine of the National Academies, *Responsible Research: A Systems Approach to Protecting Research Participants* (Washington D.C.: National Academy Press, 2003); United States, National Bioethics Advisory Commission, *Ethical and Policy Issues in Research Involving Human Participants* (2001), online: National Bioethics Advisory Commission <<http://www.georgetown.edu/research/nrcbl/nbac/pubs.html>>; United Kingdom, Department of Health, *Governance Arrangements for NHS Research Ethics Committee* (2001), online: Department of Health <<http://www.dh.gov.uk/assetRoot/04/05/86/09/04058609.pdf>>; United Kingdom, Department of Health, *Research Governance Framework for Health and Social Care* (2001), online: Department of Health <<http://www.dh.gov.uk/assetRoot/04/01/47/57/04014757.pdf>>; France, Commission des Affaires sociales du Sénat, *Le fonctionnement des comités consultatifs de protection des personnes dans la recherche biomédicale. Rapport d'Information 267*, (Rapporteur, HURIET Claude), en ligne : Sénat <www.senat.fr/rap/r00-267/r00-267_mono.html#toc10>.

In Canada, ethics review committees have also come under review and many deficiencies, similar to those documented in other countries, identified.² Moreover, and as in other countries, the most recent reviews address research ethics issues from a broader governance approach in an attempt to tease out deficiencies in research participant protection that may be due to the environment within which ethics committees must operate as opposed to the committees themselves. Canadian reviews have primarily focussed on publicly funded research conducted in institutions and less attention has gone to the many other types of research involving humans: government research, charity or community based research, provincially-funded research and privately funded and conducted research. While there is agreement across the various reports that something has to be done to reinforce the ethics review function, relatively little ground has been covered towards reaching an agreement on the underlying issues and finding creative solutions and, eventually, implementing them. In fact, there appears to be a chronic inability to reach an agreement on what needs fixing and moving towards implementing possible solutions.

This paper analyses issues raised by the governance of research involving humans from the participants' perspective postulating that similar protections ought to exist irrespective of the source of funding for, or the location of the research. Carefully considering the various reports published to date, it attempts to clarify the global Canadian context for research involving human participants in order to shed light on the current governance mechanisms and move towards a common understanding of the core issues. To achieve this, two key questions continue to be explored here: First, how is research involving human subjects currently governed? And, second, how effective are the current governance arrangements and what common issues emerge?³ The aim of this paper is not so much to answer these questions, as it is first, to discuss the current governance context and, second, to identify eight significant or core issues that they raise, and provide guidance on developing a common understanding about them.

To address research ethics issues from the perspective of public governance is to focus on elements of good governance. These include accountability, oversight and transparency, clear government roles and responsibilities, clear relationships,

² See the following reports: Comité d'experts sur l'évaluation des mécanismes de contrôle en matière de recherche clinique, *Rapport sur l'évaluation des mécanismes de contrôle en matière de recherche clinique au Québec* par Pierre Deschamps, Patrick Vinay et Sylvia Cruess, 1995, en ligne : Fonds de la recherche en santé du Québec <http://www.frsq.gouv.qc.ca/ethique/documents_pdf/Deschamps.pdf>. ; Law Commission of Canada, *The Governance of Human Research Involving Human Subjects (HRIHS)* by Michael McDonald *et al.* (Ottawa: Law Commission of Canada, 2000), online: Law Commission of Canada <http://www.lcc.gc.ca/en/themes/gr/hrish/macdonald/macdonald_main.asp>; University of Ottawa, Centre for Governance, *Governance of the Ethical Process for Research Involving Human Subjects, Final Report* (2000); Québec, Vérificateur Général du Québec, *Rapport à L'Assemblée nationale pour l'année 2000-2001*, t.1, Québec, Publications du Québec, 2001 à la c. 4, en ligne : Vérificateur Général du Québec <http://www.vgq.gouv.qc.ca/publications/rapp_2001_1/Faits/Index.html>.

³ See McDonald *et al.*, *ibid.*

structures and standards, and public processes, mechanisms and participation.⁴ While this list is not exhaustive, two critical dynamics warrant particular attention. First, defining clear *roles* helps define clear *responsibilities* and clear *relationships* for public governance. Ambiguous or confused government roles seed ambiguity in government responsibilities and confusion in its relations. Second, good public governance depends on good *standards* and norms, good public *processes* to define them and good *public structures* to implement them. Public standards, processes and structures are intimately related. Identifying such elements and managing their relations is the basis for a comprehensive and coherent governance framework for research involving human participants. Accordingly, this paper describes, to the extent possible, the current governance framework in terms of roles and responsibilities of the various actors, relevant standards, existing structures and, finally, processes that support the whole framework.

The benchmark for assessing what constitutes “good” public governance is the promotion of ethical research. In turn, the ethical conduct of research implies the pursuance of socially beneficial research and the promotion and protection of the dignity and well-being of research subjects, both of which promote public trust.⁵

While precise information is lacking, it is apparent that research involving human subjects occurs in many fields, including the social sciences, natural sciences, fine arts, public health and biomedicine. Generally speaking, researchers, research hosts and sources of funding fall under the broad categories of academic, governmental, community-based and private. In turn, there are several kinds of REBs: institutional, governmental, regional or provincial⁶ and private for-hire or in-house REBs. It is not clear whether all researchers who conduct research involving humans have access to an REB. The creation of non-institutional private review committees may be providing some relief, although raising other concerns. All of these actors operate within a research environment that has evolved considerably in recent years, challenging the ethics review system.

There is no specific legislation that covers research involving humans in Canada. In fact, the Canadian regulatory approach to research involving humans,

⁴Based on the report submitted to Health Canada, *Issue Identification Paper: Governance of Research Involving Human Subjects*, by Derek J. Jones (14 August 2002) at Section 3.1.2. See also McDonald *et al.*, *ibid.* at Section B-1; University of Ottawa, *supra* note 2; Organisation for Economic Co-operation and Development, *Public Management Policy Brief No 9: Government of the Future* (OECD, 2001), online: OECD <<http://www.oecd.org/dataoecd/1/5/1917165.pdf>>; Organisation for Economic Co-operation and Development, *Governance Outreach Initiative: Report on High-Level Seminar Partnerships in Governance: Common Response to the Challenges of Globalisation* (A report from the High-Level Seminar, 9-10 May 2000), online: OECD <[http://www.oilis.oecd.org/olis/2000doc.nsf/4f7adc214b91a685c12569fa005d0ee7c12568d1006e03f7c12568f200411c41/\\$FILE/00078628.PDF](http://www.oilis.oecd.org/olis/2000doc.nsf/4f7adc214b91a685c12569fa005d0ee7c12568d1006e03f7c12568f200411c41/$FILE/00078628.PDF)>.

⁵McDonald *et al.*, *ibid.*

⁶For example, the Province of Newfoundland and Labrador is considering establishing a statutory-based provincial ethics review committee for all the province’s health research. In Québec, a provincial ethics committee, Fonds de la recherche en santé <www.frsq.gouv.qc.ca>, was created to review protocols that involve minors and incompetent adults and that cannot be submitted to a designated institutional REB.

including requirements for ethics review, is an incomplete mosaic of rules that range from formal legal regulations, to administrative policies and voluntary guidelines. Given Canada's constitutional division of powers, fourteen different governments (the federal, ten provincial and three territorial) have varying responsibilities on research activities. This has resulted in varying layers of protection for participants depending on various factors: first, the type of research including whether it implies a federally regulated product (such as experimental drugs or devices) or personal information; second, on the location of the research that is whether it is conducted within a public institution (university or hospital) or not and in which province or territory; third, on its source of funding with an important divide between public and private or community-based funding and in some cases funding received from US government sources (such as the National Institutes of Health); finally, and to a lesser degree, on the category of research participant since in some provinces particular rules apply to research with minors or incompetent adults. In some cases, there is confusion about which rules apply to which types of research as it is unclear how to handle, for example, trans-provincial research or research with funds from the United States.

Analysis of the governance framework for research involving human subjects revealed a concentration of structures for federally funded academic research. These structures primarily focus on standard setting⁷ and, increasingly, oversight activities⁸. When other research hosts and funders are involved, such as government or community-based or purely private research, few, if any, research ethics structures exist.

REBs are considered the core structure of ethics review systems and have come under review in various countries following a number of research scandals.⁹ Generally, REBs are expected to be independent, local, multi-disciplinary, competent, efficient, consistent and accountable. However, Canadian reports have mainly focussed on health research ethics review, was found serious deficiencies with Canadian REBs in terms of credibility, independence, expertise, capacity and accountability, among other things. The key concern is whether REBs have just become another layer of bureaucratic red tape or whether they have the credibility and independence required to conduct ethical evaluation that is sensitive to the interests of research subjects and that merits public trust. The paucity of information on how REBs in other fields of research involving human subjects function, as well as on other types of REBs (government, private or regional), makes any assessment

⁷The leading standard for research involving humans is the Tri-Council's (made up of the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada), *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* (Ottawa: Public Works and Government Services Canada, 2003), online: CIHR <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf> [TCPS].

⁸See e.g. the memorandum of understanding signed by institutions that receive Tri-Council funding, *infra* note 12.

⁹See *supra* note 1.

of their work difficult. However, in itself, this lack of transparency, although not necessarily intentional, is cause for concern.

In addition to clarifying roles and responsibilities, to identifying existing standards and structures, good public governance also depends on clear processes. The process used for the development of the leading Canadian guideline, the *Tri-Council Policy Statement* highlights some challenges and resistance faced during the standard development process, most notably from the social science researchers, as discussed below.¹⁰ More recently, the process used to interpret the *Tri-Council Policy Statement* has been described as being obscured by overlap and duplication. In parallel, there are a number of initiatives to review the *Tri-Council Policy Statement* or specific provisions thereof; how these relate to each other is not clear. Similar ambiguities also exist about the process for establishing structures to support research ethics. Ensuring that the process for adopting rules is transparent, credible and equitable is crucial to promoting their legitimacy, authority and effectiveness.

Most importantly, perhaps, are the processes for public oversight of the ethics review system, including REBs. In recent years, a number of factors have fuelled concerns about the ethics review function and have increased pressure for public oversight of REBs. Generally speaking, existing oversight mechanisms vary depending on the research host, since the current system of accountability primarily depends on the source of research funding or whether a regulated therapeutic product is under investigation. Some provinces (Alberta, British Columbia, Quebec) have introduced the notions of designated REBs for some types of research (with personal health information, by health care professionals and with minors or incompetent adults, respectively).¹¹ However, the designation process remains a largely static recognition of research ethics board regulatory compliance and qualitative evaluation criteria have not been developed. Workable evaluation criteria are considered difficult to develop given disparities between various regions.

The idea of introducing REB oversight through accreditation processes has been tossed back and forth in the past years without a clear vision emerging of what such a process would imply, of who would be responsible for its implementation and of standards against which accreditation would occur. Amidst discussions surrounding accreditation, the three federal research councils have required that academic institutions they fund sign into a *Memorandum of Understanding* that introduces a “controllership process” based on a contractual model.¹²

¹⁰ *TCPS*, *supra* note 7.

¹¹ See e.g. Alberta, *Health Information Act*, R.S.A. 2001, c. H-5; British Columbia, *Health Care (Consent) and Care Facility (Admission) Act*, R.S.B.C. 1996, c.181; Quebec, Art. 21 C.C.Q.

¹² *Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards* (Ottawa: Public Works and Government Services Canada, 2002), online: Natural Sciences and Engineering Research Council of Canada <www.nserc.ca/institution/mou_e.htm>.

Following this cursory review of the governance structure, the second goal pursued here is to clarify the state of the debate, to move towards a common understanding of the basic deficiencies of, or foundational issues raised by, the current framework for research involving humans. The conclusions of the various Canadian reports, sometimes in conflict, sometimes in agreement, have been carefully considered and serve as a template for the identification of eight key issues that, it is submitted, set the state of the debate.

First, there is a significant lack of data and evidence necessary for analysis and informed decision or policy-making. To date, the scope of Canadian reports has focussed on the governance of health research involving human subjects¹³ and on *biomedical research control mechanisms*, including REBs¹⁴. For other areas of research involving humans, the current governance context has yet to be documented and analysed in detail.

Assessing the governance needs in other fields of research, or in non-institutional sectors where research is conducted, is a daunting task since basic information is lacking on what kinds of research are ongoing, how the ethics of this research is being evaluated and who is responsible for the evaluation. For example, which organizations within the federal government are funding or conducting what type of research, and how is it being evaluated for ethical acceptability? Does research in the private sector in community-based research raise concerns and how are these being addressed? Given the multiple norms that are relevant to research involving humans, does this constitute a burden to those concerned with the ethical acceptability of research? While one dare not speak of a conspiracy of silence, the lack of transparency, or the lack of commitment or of opportunity to unveil research activities, could serve a severe blow to public trust.

Next there is a lack of Canadian research-based evidence on some key aspects of research involving humans.¹⁵ For example, little is known about the effects of

¹³ McDonald *et al.*, *supra* note 2; University of Ottawa, *supra* note 2; Vérificateur Général du Québec, *supra* note 2.

¹⁴ Ministère de la Santé et des Services Sociaux, Direction générale de la planification et de l'évaluation, *Rapport d'enquête concernant les activités des comités d'éthiques cliniques et des comités d'éthique de la Recherche au Québec* par Marie-Hélène Parizeau, Québec, Ministère de la Santé et des Services Sociaux, Direction générale de la planification et de l'évaluation, 1999, en ligne : Santé et des Services Sociaux du Québec <<http://ftp.msss.gouv.qc.ca/publications/acrobat/f/documentation/1999/99-727.pdf>>; Deschamps, Vinay et Cruess, *supra* note 2.

¹⁵ McDonald *et al.*, *supra* note 2 at 298-301. Such studies include for example, Nancy E. Kass & Jeremy Sugarman, "Are Research Subjects Adequately Protected? A Review and Discussion of Studies Conducted by the Advisory Committee on Human Radiation Experiments" (1996) 6:3 *Kennedy Institute of Ethics Journal* 271; Johane Patenaude et Julien Cabanac, «L'évaluation éthique des protocoles de recherche: Quelle recherche, quelle évaluation? Le cas de la distinction entre soin expérimental et soin innovateur» (2000) 2:2 *Éthique publique. Revue internationale d'éthique sociétale et gouvernementale* 89; Johane Patenaude, «L'évaluation du risque et ses paradigmes. Éthique préventive; Gérer les risques, devancer les crises» (2002) 4:2 *Éthique Publique. Revue internationale d'éthique sociétale et gouvernementale* 72.

research on participants and what motivates them to participate in trials especially when no benefits can be expected. Or, should the motivations of healthy volunteers of phase 1 clinical trials be questioned? We are equally ignorant about the effect of research on communities or groups or about the effect of regulations on the health of participants or the patients. At a higher level, little is known about the impact on society — in terms of the stigmatization of “marginal” groups or of our sense of humanity — of the setting of research priorities for government funding. Moreover:

...[s]tandard setters, be they in industry or in the public sector... ought to be intensely concerned about the effects of the research they sponsor on research subjects and in particular for ensuring that appropriate and effective standards are in place. In a broad sense, such information is vital to the public legitimacy of the conduct they regulate. To ask for this information and to act upon it would seem a basic and essential part of governance for standards setters.¹⁶

Finally, there is little research-based evidence — as opposed to anecdotal evidence — about how the new pressures on the ethics review system due to the changing research environment are affecting its independence, credibility and efficiency.

Second, Canada’s current governance framework is complex due to its “decentralized and multi-sourced arrangements”¹⁷, to the multiple actors involved and to the important differences among the various fields of research. The general context within which research is currently evolving influences how research is conducted in ways that are still unclear. There appears to be overlap, confusion and misconceptions, and sometimes competition, among the various actors, which leads to the motives behind certain decisions being questioned.¹⁸ To be certain, the current complexity and ambiguity is a serious impediment to transparency and could ultimately undermine public trust. Also of serious concern are the inevitable inefficiencies of the framework.

The system in Canada entertains a persistent confusion of roles. The recent regulatory development process for new clinical trial regulations provided a poignant example of the difficulties that can arise from the lack of clarity in the roles and responsibilities of various actors. The clinical trial regulatory development process highlighted that there are enduring differences between what some believe federal regulatory authorities review and approve in clinical trial applications and what is actually reviewed. Regulatory requirements clearly require regulatory authorities to review a number of safety aspects common to a full assessment of the scientific value of research. What is less clear is whether federal regulatory authorities also review clinical trial applications for overall scientific value — that is, whether

¹⁶McDonald *et al.*, *ibid* at 301.

¹⁷McDonald *et al.*, *ibid.* at vii; University of Ottawa, *supra* note 2.

¹⁸University of Ottawa, *ibid.* at 30.

clinical trials provide valuable new knowledge that justify the risk to humans¹⁹ — a crucial criteria for research to be considered ethical. Experience with both regulatory authorities and REBs reveals confusion, or rather misconceptions about, the role of federal regulatory authorities that have led to unfounded reliance by REBs on the federal review process to count as scientific review of protocols. In turn, if expected roles do not coincide with actual review, public trust in the system will suffer.

Continuing review of ongoing research is another area in which much confusion exists. While the importance of continuing review is widely accepted, the roles and responsibilities, and corresponding resources, have not been clearly attributed and translates into limited endeavours with continuing review. REBs are expected to assume a leading role and yet, little debate and discussion has focussed on the aspects of continuing review REBs can assume without adversely affecting their review and educational roles.

The third key issue questions the nature of the review being conducted by REBs: how much is actually ethical review? The 1998 introduction of the *Tri-Council Policy Statement* was a turning point for research ethics in Canada. Researchers' awareness of their ethical responsibilities for the research they conduct and of the boundaries of "acceptable research" increased. However, a common conclusion in reports and the literature is that research ethics is becoming a matter of following rules and procedures — a bureaucratic process — as required by funding agencies or regulators and implemented by REBs. After comparing the three central objectives of research ethics — promoting socially beneficial research, protecting and promoting human participants and maintaining public trust — to "what actually takes place in the name of ethical research," a prominent report concluded there was a narrowing of concerns or "ethical tunnel vision, in which the three ethical principles are given the most minimal instantiation."²⁰ The current governance framework reduces "research ethics to a dangerously simplistic concern for REB approval that is often functionally an approval of consent forms."²¹

Others have commented that evaluating the ethical acceptability of research by balancing the limits of the development of new knowledge against the human risk involved in such research (weighing the benefits for society against the risk to humans or the overall value) has been eclipsed to a large degree by the need to verify compliance with rules and procedures.²² If risk-benefit analysis remains one

¹⁹ Section C.05.006 (1)(b)(ii) of the Clinical Trial Regulations states the reasons for which a clinical trial application can be refused; *Food and Drug Regulations*, C.R.C. c. 870, s. C.05.006(1)(b)(ii).

²⁰ McDonald *et al.*, *supra* note 2 at 294.

²¹ *Ibid.*

²² Georges Legault, «Du souci moral à la saine gestion : l'enjeu des politiques de la recherche sur des humaines» (2000) 2:2 *Éthique publique. Revue internationale d'éthique sociétale et gouvernementale* 23; Hubert Doucet, «Les silences éthiques de l'éthique de la recherche» (2000) 2:2 *Éthique publique. Revue internationale d'éthique sociétale et gouvernementale* 31.

of the items to be evaluated by REBs, under the current model,²³ the items currently being balanced are limited to the risks and benefits to individuals who could serve as research subjects and their right to consent, and the potential benefits from new knowledge as assessed by a scientific peer review committee.²⁴ In other words, REBs now evaluate the acceptable level of risks to which potential participants can agree to expose themselves to instead of evaluating the ethical acceptability of research or its overall value.

Others have commented that the paradoxical effect of the *Tri-Council Policy Statement* has been the growing impression that if researchers abide by existing standards and procedures and obtain REB approval, then their research must be acceptable and, of even greater concern, then it is no longer necessary to debate the fundamental issues raised by their research.²⁵ The argument that standards can obviate the need for researchers to take ethical responsibility for their work can also be invoked when governments determine what research priorities they will be funding. For example, when governments are funding research in population genetics or stem cell research, there may be no need, in the eyes of the researcher, to question the acceptability of the research, since it is presumed to be acceptable because the government is supporting it.

This brings the impact of “ethical tunnel vision” to another level, the actors. There are many actors involved in research ethics in addition to REBs and researchers: public and private sponsors, research institutions and standard-setters, publishers and research participants. All of these actors have an important role to play in evaluating the overall acceptability of research and in engaging in a broader, more reflective view of research ethics. Tunnel vision also occurs when, in diagnosing problems and searching for solutions, only one or two of the multiple actors involved are the focus of attention.

It is also important to note that the ethical tunnel vision is also pervasive at the level of governance structures and the resources devoted to them, since ethics is often viewed “as a matter of efficiently processing applications for REB approval.”²⁶ In contrast with the scholarly quality of research, “the ethical quality of

²³ Legault, *ibid.* discusses three models that have, to date, underpinned REBs and the overall research ethics framework: moral, legal and administrative. While these are not mutually exclusive, the logic of one or another will dominate how REBs function at a given time. In Legault’s view, many of the problems of the current REB framework result from the focus on individual rights as proposed by the legal model and enforced by an administrative model. The effect is to make REBs focus on how to ensure the protection of individual rights, thus reducing ethical evaluation to the review of consent forms and, more recently, to the control and monitoring of researchers. Paperwork becomes the core of ethical evaluation.

²⁴ In turn, peer review committees can easily conclude that they do not have to evaluate the overall value of research, since they can assume that since sponsors have decided to award funding in this field it must be because they expect the overall value of research to be positive. See McDonald *et al.*, *supra* note 2 at 33-36.

²⁵ Guy Bourgeault, «Et si toutes les règles incitaient à la fraude...» (2000) 2:2 *Éthique publique*. *Revue internationale d’éthique sociétale et gouvernementale* 47.

²⁶ McDonald *et al.*, *supra* note 2 at 295.

research involving human subjects is given scant unsystematic attention."²⁷ This is also reflected in the limited ethics education available.

The fourth key issue concerns standards (legal, administrative, technical, ethical and professional) and whether they are appropriate and effective — that is, do they affect the behaviour of researchers in a way that is consistent with the promotion of socially beneficial research and the promotion and protection of the dignity and well-being of research participants. There is a lack of research-based evidence on what standards researchers refer to for guidance. Anecdotal information suggests that there is some resistance among researchers to adhere to existing standards notably the *Tri-Council Policy Statement*. This resistance should be more formally documented, and the underlying reasons explored, not only as means of understanding non-compliance or avoidance but also as an evaluation tool of the standards themselves. Otherwise the trend towards a stricter command-and-control approach may be difficult to avoid. In some cases, such as data protection legislation, requirements may not be well known by researchers and REBs, despite their widespread application.²⁸ The following more specific questions may assist in addressing these issues.

Where is the balance between uniformity and multiplicity of norms that apply to research involving humans? The *Tri-Council Policy Statement* provides uniform standards for all the types of research (biomedical, social and natural sciences) conducted in institutions that employ researchers who receive federal research councils' funding. In the field of clinical trials for investigational drugs, a similar process of adopting uniform standards, this time across countries, is well under way through the International Conference on Harmonisation and has produced the *Good Clinical Practice Guidelines*.²⁹ In contrast, many other types of research that are not funded through the three councils continue to function according to their own professional rules or to topic-specific rules that were not covered by the *Tri-Council Policy Statement*. For example, the National Research Council, that employs government researchers, has its own set of ethical guidelines³⁰ as do some fields of research such as research with aboriginal communities³¹ or population genetics³².

²⁷ *Ibid.*

²⁸ Personal Communication with David Flaherty (March 2002), comment provided during review of previous versions of this paper.

²⁹ Health Canada, Health Products and Food Branch, *TPD/ICH Tripartite Guideline — Good Clinical Practice: Consolidated Guideline* (Ottawa: Minister of Public Works and Government Services Canada, 1997).

³⁰ National Research Council Canada (NRC), *Research Involving Human Subjects: Guidelines for Institutes* (Ottawa: NRC, 1995).

³¹ See e.g. Association of Canadian Universities for Northern Studies, *Ethical Principles for the Conduct of Research in the North*, (28 November 1997), online: Yukon College <<http://www.yukoncollege.yk.ca/~agraham/ethics.htm>>.

³² See e.g. Quebec Network of Applied Genetic Medicine, *Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations* (Réseau de Médecine Génétique Appliquée, 2002), online: Réseau de Médecine Génétique Appliquée <<http://www.rmgq.qc.ca/en/index.htm>>.

To the federal mosaic, provincial and territorial rules and regulations must be added. The key issue is, given the very diverse fields of research involving humans, is there a need, and if so to what extent, for uniform standards to promote the goals of socially beneficial research and protection and promotion of subjects? This issue requires a careful balancing of clarity and transparency against the flexibility needed to meet the different research challenges.

A related question is the foundation by which to consider research standards as legitimate and effectively shaping behaviour. Generally, social norms can ground their legitimacy on one or a blend of factors such as: the participatory and democratic development process, the rational justification that underlies the norms³³ or the adopting authority. If ethics prevailed as a means for regulating research involving humans, then the development process and the rational justification should suffice to shape the behaviour of stakeholders. However, the leading model in Canada has rather been a focus on the standard-setting authority that must be recognized as legitimate by those whose behaviour is to be affected.³⁴ For example, professional groups have been recognized by the state as having “the power to control professional conduct privately.”³⁵ The fact that the state allows, albeit under state oversight, professional practice to be controlled within the profession is of significance for the governance of research involving humans. This is not to say that only professional groups should have authority to set standards that are relevant to research.³⁶ On the contrary, the leading standard for research ethics in Canada, the *Tri-Council Policy Statement*, was issued by administrative government authorities with input from professionals. However, following the bumpy development process, some stakeholders have questioned the *Tri-Council Policy Statement's* authority when research is not funded by one of the three Councils. For other standards, it is the lack government or public oversight or official recognition of standard-setting authority that undermines their legitimacy.³⁷

This brings us back to the difficult issue of assessing the legitimacy of standards integral to the current governance framework for research involving

³³ For example, according to one historian, Burgess, *infra* note 49, despite many changes that were made to preliminary drafts of the *Tri-Council Policy Statement*, many historians do not consider it to be relevant or useful.

³⁴ A discussion on legitimacy of standard-setting authority see Luc Bégin, «Les normativités dans les comités d'éthique clinique» dans Marie-Hélène Parizeau dir., *Hôpital et éthique: Rôles et défis des comités d'éthique clinique*, Québec, Les Presses de l'Université Laval, 1995, 32.

³⁵ Angela Campbell & Kathleen Cranley Glass, “The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research” (2001) 46 McGill L.J. 473 at 476.

³⁶ This position was rejected in the Nuremberg trials and the resulting *Nuremberg Code*. In fact, professional groups usually focus on professional conduct of their members in the research setting as opposed to regulating research as such.

³⁷ See for example, the critique by Québec, Conseil de la Santé et du Bien-être, *La santé et le bien-être à l'ère de l'information génétique : enjeux individuels et sociaux à gérer*, Québec, Publication du Québec, 2001 aux pp. 52 ff et 60 ff et s., en ligne : Conseil de la Santé et du Bien-être du Québec <http://www.csbe.gouv.qc.ca/fr/publications/avis/20010406_avis_cfr.pdf>.

humans. Concentrating on the legitimacy of standard setting authorities and highlighting their inevitable limits given the Canadian political system may have contributed to the current impression of deadlock. An alternative route is to give greater attention to other foundations of legitimacy that is the development process and the rational justification. This shift in focus may also highlight the importance of securing the legitimacy of standards not only in the eyes of investigators, but also in the eyes of the public in general and of those who decide to participate as subjects.

Another related question is whether the nature (ethical, legal, administrative, scientific or professional) of adopted standards and corresponding enforcement mechanisms appropriate. This issue is intimately linked to the legitimacy of standards and their standard-setting authority. For example, the *Tri-Council Policy Statement* is an administrative document adopted by funding agencies and intended for all the institutions that receive Tri-Council funding. This approach is based on the relationship between the funding agency and the institution receiving the funds, which is reinforced by the recent move towards signing contractual memoranda of understanding. Is an administrative model appropriate for what is closest to becoming the national standard for research in Canada or should other types of standards (ethical, legal, professional or scientific) be considered? This is not a purely theoretical question, since the system within which each type of norm is developed will have an impact on the governance structure, on the scope of the standard or which research subjects it will protect, for example. The current multiplicity of standards of all types that are not coordinated may be at the root of some of the confusion in the research community about which standards apply to which situation and what to do in case of conflicting requirements.

Lack of knowledge and understanding of standards certainly undermines their effectiveness. The prime example of this issues is with privacy protection legislation. As discussed by the previous Privacy Commissioner of British Columbia in a recent report:

More needs to be done to sensitize the research community to their privacy and data protection obligations. For example, in some provinces REBs are being given increasing authority under privacy legislation to rule on basic issues such as the need for informed consent for the use of identifiable personal information in health research. In other instances, the competent privacy authority (e.g. commissioner) can approve research with identifiable personal information under controlled circumstances. There is thus at least a partial commingling of legal and ethical obligations.³⁸

Fifth, the credibility and efficiency of various structures³⁹ that support research ethics in Canada have been questioned, as has the concentration of bodies⁴⁰

³⁸Health Canada, Ethics Division, *A Report on Privacy and Data Protection Issues Related to Research Involving Human Subjects* by David Flaherty (26 June 2002) at 3 [unpublished].

that are related to the Tri-Councils. According to the University of Ottawa report, the current governance structure, which involves both structures and processes, “has been described by observers as ‘a mess’, a reflection of overlaps and confusions that indicate a lack of trust in the partnership.”⁴¹ Moreover, it is “not a single group working out the kinks of a new system but rather a hodgepodge of individual groups constantly eyeing each other.”⁴² There lacks a spirit of cooperation and trust, and the current structure has “too many players intervening in an evolving system, resulting in a confusion of roles and overlap of responsibilities. ... No one (and no group) is responsible for the integrated management of the system.”⁴³ In addition, the underlying issue of whether agencies whose primary objective is funding research are in a conflict of interest position regarding the protection of research subjects still needs to be addressed⁴⁴ and debated.

³⁹ Various structures include, for example, at the federal level, the National Research Council in house REB; the Health Canada REB; the Canadian Biotechnology Advisory Committee; and several non-governmental bodies such as, the Canadian Association of University Research Administrators, the Humanities and Social Sciences Federation of Canada, the Canadian Association of Research Ethics Boards, Canada’s Research-Based Pharmaceutical Companies, and various professional organizations.

⁴⁰ See *e.g.*, the Canadian Institutes of Health Research Standing Committee on Ethics, Working Group on Ethics, and Ethics Office; the National Council on Ethics in Human Research and more recently, the Interagency Panel on Research Ethics.

⁴¹ For a visual representation of the governance structure see University of Ottawa, *supra* note 2 at 16-17.

⁴² *Ibid.* at 16.

⁴³ *Ibid.* at 16, 23-24.

⁴⁴ The University of Ottawa report rejected the idea that the three funding agencies were in a position of conflict of interest with respect to protecting human subjects, stating that in the past 25 years of effort 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. (*Ibid.* at 16).

In contrast, McDonald *et al.* wrote the following:

We think this response [University of Ottawa report] to the conflict of interest problem is quite unconvincing. For one thing, it would have been quite remarkable if Canada had not developed some sort of policy for the protection of research subjects given the world-wide push to this end. So the existence of policy is not on its own convincing evidence of sincere commitment. Even if ‘all the primary groups ... desire to promote ethical research,’ the central question is whether there is actually in place a system that is ‘both effective and fair.’

The primary question as we see it is not that of ‘good will’ or ‘good intentions.’ It is rather that of creating an effective system that balances the promotion of research and the protection of research subjects. In other words, we see the governance issues here as less about the stated intentions of institutional actors and much more about the design of those institutions and their performance. We take the problem of agency-risk seriously; professed good will — no matter how sincerely intended — is not enough. The institutions in question have been designed to promote research. REBs and ethics policies were put in place to counter-balance research promotion. Institutional commitment to ethical research is shown in large part by how much the institutional actors are willing to place effective constraints on the pursuit of primary objectives in order to protect innocent third parties. (McDonald *et al.*, *supra* note 2 at 313).

Since the University of Ottawa report, a new structure has been created: the Interagency Panel on Research Ethics (PRE). Together with its Secretariat, the PRE provides a new governance structure to steward the development, evolution, interpretation and implementation of the *Tri-Council Policy Statement*. Thus, while the PRE is a creation of the Tri-Councils, it is hoped that it will be guaranteed sufficient political and administrative independence and financial and human resources required to meet its mandate.

Sixth, many issues and concerns about the credibility and efficiency of institutional REBs have been raised including for example, REB expertise, training, independence, consistency, support, resources and timeliness. While some concerns are linked or are the result of systemic issues discussed here the cause of other deficiencies is less clear. It is clear that REBs are falling short of what had been expected of them. Some have called this “ethical tunnel vision”⁴⁵, since REBs focus too heavily on the consent form to the detriment of other important aspects of ethical evaluation. Others consider that our expectations of ethical review differ from the reality of their work that is closer to peer review to promote prudence and moderation.⁴⁶ In other words, what REBs do in the current context is verify compliance with standards, which is a control and surveillance role⁴⁷ short of ethical evaluation.

From a governance perspective, the challenge is to understand what is at the root of REB difficulties. Is it the model (legal, administrative or ethical) within which REBs are created?⁴⁸ Or is it a serious lack of human and financial resources? Or is it an implementation issue? Or is it ultimately the entire REB structure that needs to be reinvented? To be certain, discussions to develop a common understanding will have to integrate the complexity of the current context by considering the role and independence of REBs, their lack of accountability and ineffective functioning, in the institutional, governmental and private sector contexts and with the political reality of fourteen governments sharing responsibilities.

Seventh, the importance of adopting and following formal and transparent processes within the governance framework for research involving human subjects cannot be overemphasized. Such processes should address tasks such as the development and review of standards and the oversight of the governance process. In fact, much criticism about the basis of the leading framework, the *Tri-Council Policy Statement*, concerns the policy development process. As was recently reported, “the reaction from the social sciences and humanities (SSH) and natural sciences and engineering (NSE), was highly, perhaps even violently negative”⁴⁹

⁴⁵ McDonald *et al.*, *supra* note 2 at 294.

⁴⁶ “La tâche réelle des comités d’éthique de la recherche n’est pas d’ordre éthique mais une forme de contrôle par les pairs pour inciter à la prudence et la modération.” See Doucet, *supra* note 22 à la p. 35. This was also the conclusion of Parizeau, *supra* note 14 à la p. 28.

⁴⁷ Legault, *supra* note 22.

⁴⁸ For a discussion of these models, see Legault, *ibid.*

⁴⁹ University of Ottawa, *supra* note 2 at 14. This reaction is also reflected in a historian’s description,

and the governance processes for the administration of the *Tri-Council Policy Statement* were reported as deficient. The governance process 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.⁵⁰

An overarching concern related to governance of research is that while the *Tri-Council Policy Statement* is intended to be a living document open to review, there has been no formal and transparent review process but rather a multiplicity of ad hoc processes.⁵¹ A case-by-case approach may have the advantage of flexibility, but this may come at the cost of transparency, credibility and legitimacy. Should there be agreement on the need for a formal review process, the challenge will be to agree on what that process will be. Similar concerns over transparency, credibility and legitimacy also transpire from the lack of clear processes to establish new research ethics structures such as the Panel on Research Ethics. Since its creation, this Panel has, however, formalized to some extent the review process.

The implementation of the oversight mechanisms for the ethics review system should also follow a transparent process. Of particular importance will be determining what the goal of oversight processes should be, whether all types of research ethics review require the same level of public scrutiny, what mechanisms would be used, according to which standards, and who would conduct the oversight. For example, can concerns about REB independence be addressed by an oversight process, and if so, how?

Once more, the transparency and credibility of the process used to develop oversight mechanisms are crucial. Perhaps more important still is the need to carefully consider the legitimacy of any oversight mechanisms. Issues of “organizational” conflicts of interest also need to be addressed. For example, is there an inherent conflict of interest when research sponsors — governments, granting agencies or private organizations — are also the oversight bodies for the local ethics review system? Can an oversight body also provide education? Finally, whether

Joanne Burgess, «L'éthique et l'histoire» (2000) 2:2 *Éthique publique. Revue internationale d'éthique sociale et gouvernementale* 38, of how her profession lived through the 1996-1998 period of review and drafting of the Policy Statement, using words such as “combat against the code” and enduring hostility and mistrust even today.

⁵⁰ University of Ottawa, *ibid.* at 8.

⁵¹ See for example, the CIHR initiative on stem cell research, CIHR, *Human Pluripotent Stem Cell Research: Guidelines for CIHR Funded Research*, online: CIHR <[http://www.cihr-irsc.gc.ca/e/publications/1487.shtml#?>](http://www.cihr-irsc.gc.ca/e/publications/1487.shtml#?); and the Health Canada/CIHR initiative on placebos, Health Canada, Therapeutic Products Directorate, *The Appropriate Use of Placebos in Clinical Trials*, online: Therapeutic Products Directorate <http://www.hc-sc.gc.ca/hpfb-dgpsa/ocapi-bpcp/issue_placebo_e.html>.

and how to promote the involvement of the general public and of research participants at all levels of the governance process needs to come to the fore.

Eighth, but perhaps most importantly, the roles and responsibilities of researchers within a governance framework need to be addressed since they are the primary actors who can promote respect for the dignity and protection of humans participating in research. Should all those who conduct research on humans be considered “professionals” who should meet societal expectations of their conduct with research subjects? Are there outstanding concerns that need to be addressed with regard to scientific misconduct and conflicts of interest? Is the oversight process for scientific integrity appropriate considering the current context of research involving humans?⁵²

While Canadians continue to ponder over these concerns and propose solutions, let us hope that research ethics will find room to flourish in the realm of researchers and REBs alongside the flurry of legal, administrative and professional rules. This will require that as a society we accept that there will always be — because of the very nature of ethics review — inconsistencies in decision-making by research ethics boards and others involved in the oversight of research involving humans. Areas that deserve our attention will be those inconsistencies that are not grounded on solid ethical justifications but rather are due to failures, faults or voids in the research subject protection framework.

⁵² See *e.g.* one of the reports into the case of Dr. Nancy Olivieri, which highlights recent pressure on researchers and institutions. Committee of Inquiry, *Report of the Committee of Inquiry on the Case Involving Dr. Nancy Olivieri, the Hospital for Sick Children, the University of Toronto, and Apotex Inc.*, online: Canadian Association of University Teachers <www.caut.ca/english/issues/acadfreedom/olivieri.asp>.