Chapter 8
The Tunnel at the End of the Light? Development of the Tri Council Policy Statement in Canada

Jocelyn Downie and Cheluchi Onyemelukwe

Introduction

There have been several cases of unethical practices in research involving humans in different countries in which research subjects were harmed, beginning with research malpractice during the Second World War. The ensuing scandals resulted in the enunciation of several international ethical guidelines, such as the *Nuremberg Code* (1947, Article 1) the *Helsinki Declaration* (WMA 2000) the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Council for International Organizations of Medical Sciences 2002) the *ICH Harmonized Tripartite Guideline for Good Clinical Practice* (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use 1997), the *European Convention for Human Rights and Biomedicine* (*Convention on Human Rights and Biomedicine*, 1997, ETS No 164) and most recently, the UNESCO Declaration on Bioethics and Human Rights (UNESCO 2005). In Canada, the case of the LSD experiments conducted by Dr. Cameron and his colleagues without the consent of the participants in the 1950s, as well as the cases of *Halushka v University of Saskatchewan* (*Halushka v. University of Saskatchewan et al.* (1965), 53 D.L.R. (2d) 436, 52 W.W.R. 608) Sask. C.A.) and *Weiss V Solomon* (*Weiss c. Solomon*, [1989] A.Q. no. 312 (C.S. civ.)), where the research risks were not fully disclosed to the individuals involved, have been

Professor Bernard Dickens used the expression "the tunnel at the end of the light" in his presentation at the 1998 Canadian Bioethics Society Annual meeting in Toronto when he was reflecting on the process of the drafting and ultimate publication of the Tri-Council Policy Statement.

J. Downie (✉)
Faculties of Law and Medicine, Dalhousie University, Halifax, Canada
e-mail: jocelyn.downie@dal.ca

C. Onyemelukwe
School of Law, Babcock University, Ilishan-Remo, Nigeria

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documented. The more recent cases of Dr Olivieri and Apotex, which raised ethical questions about conflicts of interest and the duties of researchers to make available important information about studies in which they are involved,[1] and the death of James Dent in a gene transfer trial in Toronto (Downie 2003), emphasize the fact that research ethics remains a current and important issue in Canada.

The significance of research ethics in Canada was recognized by the three major funding agencies – the Social Sciences and Humanities Research Council, the Medical Research Council, and the Natural Sciences and Engineering Research Council–when they began a process of developing research ethics guidelines in 1994. That process culminated in the Tri-Council Policy Statement on Ethics in Human Research (TCPS) in 1998. The TCPS has since become the foremost policy guideline for the governance of research involving humans in Canada.

The establishment of the TCPS was thus an historic step in Canada's research ethics landscape, and thus deserves attention. As McDonald points out in the first treatment of this subject (McDonald 2009), it is important to have a sound historical understanding of Canada's research ethics history, not only for purposes of academic interest, but also to inform future policymaking. McDonald brings an insider's perspective to the process of creating the TCPS, having served as Deputy Chair of the Tri-Council Working Group—the group that drafted the document which evolved into the TCPS—from 1996 to 1998. In his paper, McDonald calls for more objective discussion and reflection on the process of bringing into being the TCPS (McDonald 2009, at 21).

In this paper, then, we answer that call. We investigate the motivation for this historic step. A decade after this historic process was completed we consider, also, with the possible clarity that retrospection can bring, the historical, legal and political context in which the process took place. We examine the extent to which the process of producing this policy demonstrated such important democratic concepts as legitimacy, transparency, accountability, representation and community engagement.

To secure public trust or citizen confidence, broad public consultation and civic engagement, which typically indicate a certain level of transparency and representation, are becoming an increasingly important part of the developing public policies in democracies such as Canada. The concepts of democratic legitimacy, transparency, accountability, representation and community engagement are essential in designing effective policy responses to public problems. This is no less so in an area such as research involving humans, where the issue of public trust and confidence is crucial to success. The objective of this paper is to highlight the extent to which these values have shaped research ethics policy in Canada and draw lessons for how future policies in this area and other areas that are possibly as contentious may profit from this experience. In this paper, we argue that efforts were made to ensure these basic democratic values in the process, but that these attempts should have been taken farther. In the following sections, we consider in more detail the process of

[1] For a description of the cases mentioned here, see Downie 2003.

developing the TCPS and critically examine the application of the concepts of democratic legitimacy, transparency, representation and accountability in that process.

The examination undertaken in this paper is particularly timely as the TCPS is currently under revision.[2] Although the process of drawing up a second edition is ongoing, we also consider, briefly, the direction in which that process appears headed, and what, if any, lessons can be drawn from the process of putting in place the current edition.

History and Background of Research Ethics in Canada up to Development of the Tri-Council Policy Statement

To understand the context in which the Tri-Council Policy Statement on Research Involving Humans was created, it is perhaps best to begin with a short history of research ethics guidelines in Canada. Below we recount briefly the history of research ethics guidelines in Canada, the motivation for creating the Tri-Council Policy Statement and describe the importance of the policy in research ethics and governance in Canada.

In the 1970s, the Canada Council, a federal agency which administered grants for research in the arts, social sciences and humanities established a Consultative Group on Ethics. This group was charged with developing general ethical principles for researchers. These principles were attached as appendices to the guidelines to be followed by applicants for Council grants, but they did not really serve as serious constraints to researchers since the Council management never ensured that they were adhered to (Rocher 1999; Adair 2001, 28–29). The Social Science and Humanities Research (SSHRC), after becoming independent of the Canada Council, also adopted its own set of guidelines in 1977, entitled: *Ethics: Guidelines for Research with Humans* (SSHRC 1979; McDonald 2000, 81). Rocher notes that these guidelines were basically a replication of the guidelines drawn up by the Consultative Group on Ethics. As he further notes, these guidelines arguably had little influence on researchers in the social sciences and humanities who, for the most part, showed little awareness of their existence (Rocher 1999). These guidelines were amended several times (The Feminist Health Care Ethics Network 1998, 257, note 2).

The Medical Research Council (MRC) also established ethics guidelines in 1978 (MRC 1978). These guidelines were subsequently revised in 1987 (MRC 1987).[3] The guidelines were used by researchers. However, they did not enjoy universal application, partly because of ambiguity in certain respects, as well as consultation by research ethics boards of other guidelines (Verdun-Jones and Weistubb 1996,

[2] The final draft of this revision prepared by the Interagency Advisory Panel on Research Ethics (PRE) is expected to be submitted to the funding agencies in February 2010. See Interagency Advisory Panel on Research Ethics (2008).

[3] See Starkman 1998, 272–3.

320). The Natural Sciences and Engineering Research Council (NSERC) had developed no research ethics guidelines, although it had the largest research budget of the three agencies (McDonald 2000, 82; Feminist Health Care Ethics Research Network 1998, 257, note 2). However, research funded by the NSERC was subject to the SSHRC or MRC guidelines, depending on which was most appropriate.[4]

With these guidelines in place, why was there a further move to implement a common ethics policy for research involving humans for the three Councils? Several controversies relating to research involving humans in the immediately preceding years appear to have been contributory. A 1992 incident, where a Concordia University professor murdered four of his colleagues after his complaints to his university of improper scientific conduct in research funded by the NSERC went unheeded, resulted in the Tri-Council Policy Statement on Integrity in Research and Scholarship in 1994 (MRC, NSERC, SSHRC DATE; Adair 2001, 28).[5] This policy required universities to develop procedures to deal with complaints of scientific misconduct (Adair 2001, 28, note 12). This policy paved the way for the three Councils to begin the process of developing a policy for research ethics (Adair 2001, 30). Other incidents of ethical misconduct which took place during this period, including falsifications of patients' records in a breast cancer study by Roger Poisson, a breast cancer researcher at St. Luc Hospital in Montreal, and other researchers' use of fraudulent data in several publications, may also have influenced the three Councils to seek a common solution with regards to ensuring high research ethics standards in Canada (Adair 2001, 29; Kinsella 2010; Altman 1994; Angell 1994). A 1994 report by the Royal Commission on New Reproductive Technologies, which recommended legislation to govern certain scientific activities, could also have motivated the decision by the three Councils to put in place a policy, in an attempt to preempt possible legislation on aspects of research involving humans (Kondro 1998, 1521).

In *The Governance of Health Research Involving Humans in Canada*, a report produced by the now defunct Law Commission of Canada, McDonald notes other specific reasons which necessitated the development of the Tri-Council Policy Statement. The process of developing the TCPS took place in an atmosphere of increasing changes in the types and complexity of research in Canada and around the world, including research into genetics and reproductive technologies. Thus the reasons for establishing a common ethics policy included that the existing guidelines were dated and thus did not cover new areas of research and recent technologi-

[4] Interagency Advisory Panel on Research Ethics. Introducing the TCPS: Development of Canadian Guidelines. http://pre.ethics.gc.ca/english/tutorial/00_intro_overview_context.cfm. Accessed 14 Apr 2008.

[5] Some commentators have also observed that the study undertaken by the National Council of Bioethics on Human Research (NBCHR) (now the National Council on Ethics in Human Research), which found that the MRC guidelines did not provide a functional environment for research ethics in Canada and that there existed a disarray in procedures and processes in Canadian REBs was motivated the establishment of the policy on integrity. The NBCHR recommended many procedural revisions, including increased regulation of REBs and research ethics in Canada. See Kinsella.

cal advances in the areas of biology and medicine. Further, the existing guidelines did not cover some disciplines implicated in research involving humans, including some interdisciplinary research and did not reflect newer thinking in the ethics of human research. The changes in international ethical guidelines in the norms in certain areas of research, particularly areas dealing with research involving collectivities, research involving women, and research in developing countries exposed inadequacies in the existing guidelines and served to highlight the need for developing new guidelines. Certainly these issues could have been taken care of by revising the existing guidelines.[6] However, it was also considered that to have separate guidelines for behavioural and biomedical research did not reflect the increasingly accepted ideas of the importance of integrated and interdisciplinary health research. Rocher notes that: "A growing number of social sciences researchers were involved in projects in the medical community as co-researchers or contributors: sociologists, anthropologists, demographers, researchers in administration. The disparity in ethical standards seemed blatant and was becoming particularly awkward" (Rocher 1999; Baer 1996). In addition, it became recognized that there were common moral values which govern all types of research, including such values as those found in the need to obtain informed consent and the avoidance of harm (McDonald 2000). Moreover, as the Councils pointed out, they had an obligation to the Canadian public to ensure that research supported by them met ethical standards (McDonald 2000) A set of guidelines which would have universal application and which would ameliorate the problems raised by employing different guidelines therefore appeared necessary.[7]

Although these reasons seemed clear enough, some in the research community raised issues with the need for one common ethics policy for all disciplines concerned with research involving humans. Fears were expressed that the policy would hinder research.[8] These concerns notwithstanding, the Presidents of the three funding Councils established the Tri-Council Working Group on Ethics in 1994, with a mandate to "to replace existing guidelines with regulations and policies" (Kinsella 2010). After several consultations and revisions, the final document–the Tri-Council Policy Statement–was published in 1998. The TCPS replaced the previous guidelines of the SSHRC and the MRC. It is an evolving document which means that it will undergo (and has already been undergoing) changes as new developments occur. These changes are administered by the Interagency Advisory Panel on Research Ethics (PRE) created in 2001, and which reports to the funding agencies.[9]

[6] This had been the initial task set by the Chair of the Working Group, that is, the revision of the MRC guidelines. See Working Group on Ethics Guidelines for Research with Human Subjects, Minutes of Meeting, Toronto, June 1994 at 7, cited in Feminist Health Care Ethics Research Network 1998, 234.

[7] See McDonald (2009) for an overview of the motivations for creating the TCPS.

[8] See for example, Scissons 1997.

[9] Interagency Advisory Panel on Research Ethics. About us: Mandate. http://pre.ethics.gc.ca/eng/panel-group/about-apropos/mandate-mandat/. Accessed 14 Apr 2008.

With respect to the significance of the Tri-Council Policy Statement (TCPS), it occupies a central place and plays a crucial role in research ethics and governance in Canada, both for historical and practical reasons. As an historical document, it was the first ethical guidelines produced in Canada which addressed all research involving humans. Thus McDonald notes that, "Where TCPS represents a major change from the former regime governing RIHS (research involving humans) at Canadian universities and hospitals is in its creation of a unified set of prescriptions for all research involving humans to replace the previously separate reviews for behavioural research governed by SSHRC Guidelines and biomedical research governed by MRC Guidelines" (McDonald 2000).

The historical and practical importance of the TCPS is further emphasized by the transformation of the Medical Research Council and the National Health Research Development Program (NHRDP) into the Canadian Institutes of Health Research (CIHR). This followed the 1998 work of the National Task Force, comprising leaders in Canadian health research, which found that the health research system was highly fragmented and that a more organized forum for promoting health research was required. It recommended that the government increase funding for health research, and create a modern organization consisting of networks which would fashion an integrated health agenda, bring together all fields of health research and encourage collaborations between these areas and multidisciplinary research (Prescott 1999). The CIHR was created in 2000 by an Act of Parliament (Canadian Institutes of Health Research Act 2000, c. 6), following the federal government's promise earlier in the 1999 federal budget (Health Canada 1999; Finance Canada 1999; Public Health Agency of Canada Health 1999). One of the main motivations for the creation of the CIHR, then, was to bring together different disciplines which deal with health research. It is also one of its mandates under the CIHR Act.[10] The efforts to enact the TCPS, with its focus on all types of research involving humans, seem therefore prescient. The increase in government funding of health research that has come with the creation of the CIHR also increases the need to ensure high ethical standards for such research. The TCPS provides a policy for the research funded by the CIHR.

Practically speaking, its broad scope ensures that protections are available for research participants in different kinds of research involving humans.[11] It requires all research institutions to subject research involving humans to ethical review (CIHR et al. 1998, Article 1.1). It provides for the structure, the composition and the authority of Research Ethics Boards (REBs) (CIHR et al. 1998, Articles 1.2 and 1.3). Further, the Councils which provide funding for many research projects in various institutions will only fund institutions which provide certification that they are in compliance with the TCPS (CIHR et al. 1998, 1).[12] This stipulation applies to all research involving humans in the institutions, not only to the portion of research

[10] See section 4 of the Act for other objectives of the CIHR.

[11] This has, however, been criticized by several researchers in the humanities.

[12] Even with increasing commercial funding of research, the three Councils remain, as Palys puts it, "an important and valued source of research funding in Canada." See Palys 1996a.

funded by the agencies. It thus applies, indirectly, to research which is funded by other sources, including by private or commercial organisations. The certification process requires the entering into a formal "Memorandum of Understanding" with any of the three funding agencies or all, as the case may be, which requires the institution to comply with the TCPS.[13] In addition, sanctions may be imposed on institutions and researchers who fail to comply with the requirements of the TCPS.[14] Moreover, other funding bodies, including provincial or federal funding bodies, require compliance with the TCPS. These include several Canadian federal government organizations such as the National Research Council Canada (NRC), the Canadian Space Agency, Health Canada and National Defence, provincial funding bodies such as the Nova Scotia Health Research Foundation and the Manitoba Health Research Council.[15]

But the impact of the TCPS goes beyond just funding issues and may have other practical implications. For instance, some professional organisations like the College of Physicians and Surgeons require physicians, to obtain approval from research ethics boards which comply with the TCPS, or any other research ethics review body that they deem fit. Failure to comply with this requirement could lead to disciplinary action against such physicians by such organisations.[16]

Also, it has legal implications for researchers and research participants. For example, many research institutions make compliance with the TCPS a condition of employment for their researchers (McDonald 2000, 80). In this regard, Dickens describes the legal impact of a policy statement like the TCPS on researchers: "If a research funding agency makes due observance of a code, guideline or policy statement a contractual condition of an award of funding, breach is enforceable by legal action against a party to the agreement for breach of contract. The same is true when, for instance, a university, hospital or other research centre engages research staff and supervisors with an express condition in their contracts of research employment that research will be conducted and supervised in accordance with relevant codes, guidelines and/or policy statements" (Dickens 2000, 98–99). Furthermore, although the TCPS is only a policy statement emanating from the three funding agencies and therefore not an authoritative legal instrument, there is also the possibility, in dealing with such matters as the legal liability of researchers to research participants, that courts in Canada may invoke standards set in it (Hadskis 2007, 263).

The TCPS is therefore a major policy document in Canada's research ethics landscape, having implications for research participants, researchers, research institutions and research funding. Hirtle notes that "the 1998 introduction of the Tri-Council Policy Statement was a turning point for research ethics in Canada.

[13] See the Memorandum of Understanding online at: http://www.nserc-crsng.gc.ca/institution/mou_e.htm. Accessed 20 Mar 2008.

[14] See for example, the CIHR 2010.

[15] See Panel on Research Ethics.2009. FAQs: About the TCPS. http://www.pre.ethics.gc.ca/eng/panel-group/faq/tcps-eptc/. Accessed 14 Oct 2009. See Hadskis 2007, 263.

[16] See Hadskis 2007, 263.

Researchers' awareness of their ethical responsibilities for the research they conduct and of the boundaries of "acceptable research" increased" (Hirtle 2003, 137).[17] As the primary policy for research ethics in Canada, it is necessary that it be recognised as legitimate not only by those whose behaviour it seeks to affect, that is the researchers, but more generally the citizens who are potential research participants.

It is a reasonable undertaking, therefore, to investigate the process by which the TCPS came into existence, especially in the light of the necessary consensus that must have been sought between the different stakeholders that were involved or interested in the process. It is also important to inquire into what lessons can be drawn from that process. Below we consider, then, the political and legal context in which the process took place.

The Canadian Political and Legal Context and the Process of Developing the TCPS

As discussed above, in 1994, at the initiative of the Ministry of Health, and the Ministry of Industry and Commerce, the three major funding bodies–the MRC, the SSHRC and the NSERC–set up the Tri-Council Policy Working Group on Ethics (hereafter, the Working Group). The Working Group consisted of researchers sponsored by the three funding bodies and the goal was to create a common set of ethics guidelines which would regulate research involving humans in Canada (The Feminist Health Care Ethics Research Network 1998, 23; McDonald 2000, 81). Although it was the intention to create a 'code,' the document that emerged became a 'policy statement,' which nonetheless serves the same purpose as a code in that it governs all research involving humans (Palys 2003). The political context in which the process of developing the TCPS occured is particularly important, especially given that the purpose of this paper is to investigate whether and how values such as democratic legitimacy, accountability and transparency, (values that are typically associated with the political context) affected the process.

Canada operates a democracy. Thus, not only should decision making by government entities be in the public interest, democratic processes in policymaking should accord with the values of Canadians. Dodds and Thomson rightly point out that:

> The legitimacy of policy in democracies depends, in large part, on the public deliberative processes that informed the policy: not on the substance of the policy, but on the process of public reasoning used to determine it….people who will be affected by policies should have the opportunity to express their views about the matter in the process of policy debate, and their contribution to the debate should not be artificially constrained by that process (for

[17] The author notes, however, that 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. See also McDonald 2000.

> example, an imposed limit on the range of ethical issues that can be considered as part of the policy debate, or constraints on the form of submissions to the policy-makers). The ideal is to ensure that individuals have an authentic and effective voice in participating in public deliberation about topics that affect them. Policy makers draw on that public debate and engagement in setting the policy: the policy is thus informed by the public deliberations of the people affected by the policy. (Dodds and Thomson 2006, 331–332)

Barnes and others also note that: "Opening up decision making systems to wider influence is seen as a means of improving the legitimacy of decisions and enhancing the responsiveness of the services that are provided" (Barnes et al. 2004). Legitimacy, then, does not only affect the acceptability of the policy but also its usefulness to those who would utilize it.

Although writing specifically about legitimacy in governance, Montpetit's description of two understandings of legitimacy is useful in the context of the development of the TCPS. According to him, legitimacy could be said to consist of output-oriented legitimacy and input-oriented legitimacy. Output-oriented legitimacy is conferred on public policies by virtue of their promotion of the public good, regardless of who has conceived them. This sort of legitimacy relies on policymaking by experts. With input-oriented legitimacy, on the other hand, legitimacy is bestowed upon public policies when the public is conferred with. These two kinds of legitimacy are, however, not necessarily mutually exclusive and may work best together, resulting in experts and the public acting together to create effective policies (Montpetit 2003, 97). The creation of the TCPS appears to portray this kind of unity between input-oriented and output-oriented legitimacy. The Working Group, consisting ostensibly of experts, charged with drafting the guidelines by the three Councils invited input from the research community and the general public. Such public consultation demonstrated the desire for the guidelines which would emerge to be a result of a transparent, democratic process which would foster inclusiveness by addressing the concerns of different groups within Canadian society, and result in a legitimate document which would be widely applicable. The question, however, is the extent to which this aspiration was met.

Further, the Councils which sought to put in place the TCPS are government entities, disbursing government monies, raised from taxation dollars paid by the general populace, for the purpose of ensuring the conduct of research projects that would be of eventual benefit to Canadians. It is therefore a reasonable assumption that the process of putting in place the TCPS would be sensitive to, and take into cognizance the democratic values accepted in such a country. Such values include transparency, which involves an open process which takes into consideration the views of the stakeholders, that is, those who may be affected by the eventual policy which would be the result of a democratic process. The stakeholders in the process of making the TCPS included the funding bodies, that is, the three Councils who had a responsibility to ensure that research funded by them was conducted in an ethical manner, universities and teaching hospitals where much research is conducted and which employ the researchers, the researchers whose conduct the TCPS was put in place to regulate, research subjects or participants whose interests and safety the TCPS is meant to protect, and consumers of researchers who have a right

to safe products of research conducted in an ethical fashion. Were these stakeholders sufficiently represented and consulted with, in the process? How much input did these stakeholders have in the process of enacting the TCPS? Did the process thus exhibit sufficient democratic legitimacy, transparency, community engagement and representation?

Aside from the political context in which the development of the TCPS took place, the legal context is also important because in a society ostensibly governed by the rule of law such as Canada, the legal foundations of any important venture such as research involving humans affecting Canadians remain powerful. The legal context for research involving humans in Canada was, and continues to be, complex. At the time of the creation of the TCPS, Canada had no national or overarching legislation that governed all research involving humans. That is still the position today (Hirtle 2003, 137). When the process of developing the TCPS began, there was (and there still is) a variety of institutions, and legal and less formal rules, which govern research involving humans including clinical research. There are, however, various provincial statutes which deal with aspects of research involving human participants.[18]

There was no legislation or other legal rule which mandated the Councils to establish the TCPS or which dictated the process for the development of a statute. The legal basis for engaging in the process of developing the TCPS is therefore not readily apparent. As Dickens has noted elsewhere, "the law applies almost inadvertently to the enterprise of biomedical research" Dickens 2000, 93). Many have noted the complexity and ambiguity that is a result of the mosaic of rules and policies forming the basis of the governance of research involving humans. This mosaic may be considered an impediment to transparency which could adversely affect public trust (Hirtle 2003, 137). Also, considering the central importance of the TCPS to research, the research community, and the general public, it is arguable that a clear legal basis for the policy would have been very desirable.

It was within this political context of democratic values and unclear legal background that the Working Group developed the TCPS. It was an extensive process, which included soliciting of reactions from the research community, the principal parties that would be affected. This included the publication of an issues discussion paper by the Working Group in November 1994. A draft of the Code of Ethics was published in April 1996, which was distributed for comments from the academic community (Tri-Council Working Group on Ethics 1996). This draft elicited over 250 comments from the academic community (Dinsdale 1998). A final draft Code of Ethics was prepared in light of the comments received by the Working Group and was published in July 1997 (Tri-Council Working Group on Ethics 1997). Broad

[18] Quebec's Civil Code has provisions on research involving humans. Other provinces have legislation which impact research involving humans in several respects, including Newfoundland which has recently passed a legislation making ethics review a law. Also, Health Canada, in its role as the federal health regulator regulating drugs and medical devices under the *Food and Drugs Act* has introduced regulations governing the conduct of clinical trials for drugs, the *Regulations Amending the Food and Drug Regulations (1024 - Clinical Trials) (Clinical Trials Regulations)*.

formal and informal consultation, extensive discussion, and analysis followed each of these publications (Rocher 1999; Christie et al. 2004, 67). In addition, the Working Group consulted other guidelines and codes of ethics for research involving humans, disciplinary and professional codes, as well as the work of scholars on the ethics of research involving humans from different fields, including law, philosophy, religious studies, social sciences, engineering, and health sciences (Tri-Council Working Group on Ethics 1996). After the third document was published in 1997, the Working Group revised the document and submitted it to the Councils. The Councils made several revisions to the Working Group version and published the final version of the TCPS in May 1998.

Evaluation of the Process of Developing the TCPS

To evaluate how well the Working Group succeeded in satisfying the aspiration for democratic legitimacy, transparency, accountability, representation, and community engagement it is necessary to consider several issues. In terms of legitimacy, was there an inherent conflict of interest issue raised by the creation of an ethics guideline by Councils whose major purpose is to promote research? In terms of accountability and representation, what was the composition of the Working Group? Did its membership reflect a broad range, or diversity, of persons? Apart from representation on the Working Group, broad-based consultation of the public would also be necessary to meet the criterion of community engagement. As stated above, such a body must solicit the perspectives of stakeholders and affected parties during the data-gathering and policy formation process (Weijer 1997). What was the nature of public participation in the development of the TCPS? How broad was the consultation?[19] Further, it is also essential to determine how the consultations were carried out, and the level of transparency, including whether or not there were open meetings to which the public were invited. Finally, it should also be considered whether the input received from various groups and the concerns expressed therein were duly considered. Did such input reasonably influence the outcome of the consultations, and to what extent was such input reflected in the final document, the TCPS? Each of these issues are considered respectively below.

Some commentators on the development of the TCPS observed early what they considered to be a conflict of interest arising from the role of the Councils as research funders and therefore promoters as well as ethical guidelines sponsors.[20] There is a strong argument that a conflict of interest exists. However, given that the Councils acknowledged their responsibility to ensure that the research funded by them is conducted in an ethical manner, it was not necessarily a bad idea to put in place the TCPS given the vacuum that existed at that point. In addition, a conflict of

[19] In this respect, Montpetit observes that: "Input-oriented legitimacy emerges not just when people are listened to and heard but when more people are listened to and heard" (Montpetit 2003, 102).

[20] See for example, Palys 1996a.

interest situation could be counterbalanced by taking extra steps to ensure the independence of the process. In other words, the desire to ensure that federally-funded research meets the highest possible ethical standards was appropriate, and the meeting of this desire would require further steps including ensuring the independence of the drafters of the ethical guidelines from the Councils.

Beyond a conflict of interest issue, the view of Working Group regarding the breadth of their mandate, would also influence the degree to which the concepts of democratic legitimacy, transparency, accountability and representation, and community engagement were utilized in the process. It would, for instance, affect how much time was given for communications to be received and how broad the consultations would be. In their article outlining the formal and informal process by which they sought to influence the Working Group, the Feminist Network, a group of interested feminists which made representations to the Working Group observed generally that:

> It was very clear from the beginning that our vision of the appropriate task for the Working Group was much broader than the one it has envisioned for itself. The specific questions asked, the time line set, and private conversations with some members of the Working Group all indicated that initially the Working Group was planning simply to tinker with the existing MRC Guidelines, making minor correction here and there and broadening the scope of the Guidelines to make them relevant to the other two granting agencies. (Baylis et al. 1999, 247)

Assuming this to be a correct picture of the mandate that the Working Group initially envisioned,[21] it is easy to see that the values of democratic legitimacy, transparency and community engagement could not fully have been realised in the process of developing the TCPS. The final product from the Working Group involved far more than tinkering and reflected a much broader interpretation of their mandate. The scope of the mandate would, for instance, have affected how much time was given for communications to be received, how broad the consultations were, and how well any comments received would be reflected in the resulting policy. As the discussions that follow indicate, there were problems in these areas, possibly arising in part from the Working Group's initial narrow view of the scope of its mandate. Confusion over mandate threatened, at the very least, the realization of the value of community engagement.

What was the composition of the Working Group? What was the process of appointing these members? What were the rationales for choosing them? In this regard, as Weijer et al, observe, "As a matter of democratic legitimacy, guidelines written to govern research involving a particular community should include community members in the guideline-writing committee" (Weijer et al. 1999, 277). Broadly speaking, then, it may prove useful, for democratic legitimacy and transparency purposes, that the Working Group include representation from different communities involved as potential participants in the research process. Information is not readily available in the public domain regarding the manner or rationale for choosing members of the Working Group. It would appear that members, who were

[21] And this would appear to be the case, see McDonald 2009, 13.

considered to be experts in areas considered relevant, mainly from the university research community, were chosen by the Councils and appointed individually. Thus, as is clear from the drafts of the Code available publicly, members of the group were drawn from different backgrounds and disciplines. They included doctors, lawyers, philosophers, psychologists and ethicists.[22] The composition changed several times before the last draft was produced. Palys criticised the process, noting that the members of the Working Group did not adequately represent the diversity in the research community. Representatives of socially and scientifically marginalized groups including, Aboriginal, Black, Third World, or radical Feminist academics and groups were not included as part of the Working Group (Palys 1996a). The Feminist Network also observed that their efforts to influence the committee were hampered in part by the lack of a gender balance in the composition of the committee, as well as a lack of sufficient numbers of feminists on the Working Group (Baylis et al. 1997, 8). It has also been suggested that a non-researcher from a vulnerable community may have been a valuable addition to the Working Group (Palys 1996a). Perhaps, at the inception of the process, there was an assumption that consultation of various groups rather than representation in the group would suffice to bring the required diversity into the resulting document. It would appear therefore that the composition of the Working Group left much to be desired, from the process of choosing experts to serve, to the diversity of the experts chosen to serve. In our view, although the Working Group should not have been too large in order to allow for meaningful exchange of ideas, there could and should have been greater diversity. In order to realize the goal of representation of those directly affected by the policy being developed, it would have been appropriate to include not only experts in the Working Group but also lay persons who had previously participated or were currently participating in research, and also members of different communities (for example, there were no individuals from Aboriginal communities nor any past or present research participants) and, only one third of the members of the Working Group were women. Greater diversity and better gender balance would have been more appropriate.

The second issue that arises for discussion is that of community engagement. In this respect, how broad were the consultations leading towards what eventually became the TCPS? Were the different stakeholders sufficiently consulted, and adequate time given for their input to be received? McDonald points out that "The Working Group received over 2000 pages of comments from over 250 respondents – almost all the respondents were from the research community – individual researchers, disciplinary groups, university and hospital administrators, research ethics boards, university departments and research institutions as such. In light of those comments and further discussions, the Working Group produced a final version of the Code and submitted it to the Councils in May 1997" (McDonald 2000, 82). Despite the seeming breadth of these consultations and the many comments

[22] They also included ex-officio members plus two ex officio members, the Honourable Mr. Justice T. David Marshall, chair of the MRC's Standing Committee on Ethics, and Dr. Abbyann Lynch, president of the National Council on Bioethics in Human Research. See Squires 1994.

received by the Working Group, several criticisms of inadequate consultation were leveled against the Working Group. One of main sections that received criticism for failure to seek sufficient consultation was the section on collectivities, which was originally to include aboriginal communities as well as groups such Ashkenazi Jews and others. The aboriginal communities were not formally consulted.[23] The section on aboriginal communities was eventually eliminated from the TCPS because there had been no formal consultation with the communities.[24] The CIHR has now established specific guidelines for health research involving humans in aboriginal communities after wide consultation with these communities (CIHR 2007). Other criticisms were also leveled by different groups at the time regarding insufficient dissemination of various drafts to the research community and inadequate time to comment on the drafts (The Feminist Health Care Ethics Network 1998, 247). The Working Group refuted these accusations.

Although it is important that the process include broad consultations of stakeholders in the research process, this would be meaningless if the results of such consultations did not influence the resulting document in significant and positive ways. Another important issue to examine, therefore, is whether, and the extent to which the comments solicited by the Working Group affected the outcome. Rocher notes that the results of the consultations by the Working Group and the comments received resulted in three broad changes to the final document. According to him the document "initially strongly marked by philosophical reflection, it became much more pragmatic; efforts were made to eliminate as much of the overly legalistic wording of the *Code* as possible; attempts were made to make it a document which, while unique, could be adapted for diverse applications" (Rocher 1999). Despite these changes, however, criticisms about the process have come from areas such as research involving communities (discussed above), research in the humanities, and research involving women. With research in the humanities, there has been much criticism about the TCPS by those who use different theories and methods than are typical in medical research protocols. The biomedical model of ethics review draws in part from the history of research ethics, beginning mainly with scandals in biomedical research and the reactions of different organisations and governments to them. The application of ethics, and the use of the biomedical model of ethics review has therefore attracted criticism from researchers in the social sciences and humanities (McDonald 2000, 82; Guillemin 2004).[25] Whatever the merits or lack

[23] Information from conversation with Prof. Bernard Dickens (May 8, 2008).

[24] Indeed in Section 6 of the TCPS, it is pointed out that: "During the drafting of this Policy Statement, suggestions were made to create a section dealing with research involving Aboriginal Peoples. The Agencies, however, have not held sufficient discussions with representatives of the affected peoples or groups, or with the various organizations or researchers involved. The Agencies have therefore decided that it is not yet appropriate to establish policies in this area. The text of Section 6, which builds on the extensive literature on research involving Aboriginal Peoples, is intended to serve as a starting point for such discussions" (TCPS, 1998, Section 6). See also, McDonald 2000, 82.

[25] Another essay however suggests that the criticisms may not stand under scrutiny. See Ells and Gutfreund 2001.

thereof of such criticism, one wonders, if, and how much of such criticisms, were made and attended to prior to the process of establishing the TCPS. With reference to research involving women and the TCPS process, one could draw from the experience of the Feminist Network. They sent comments to the Working Group pointing out that adopting alongside other perspectives, a feminist viewpoint, would allow greater fairness to women who were or would become involved in research as subjects. The issues they sought to address in their communications with the Working Group included the exclusion and underrepresentation of women in research even where the research goals were directly related to women's issues, the risk of exploitation of women subjects in research and research priorities and agendas which reflected oppressive views and attitudes. They noted that that their efforts to influence the process met with some success - initial drafts of the Working Group's guidelines were "sensitive to many of the issues we had raised in our first submission", but that they did not go nearly far enough in addressing the issues raised in their communications (The Feminist Health Care Ethics Network 1998, 251). More importantly, the last Policy which eventually emerged after revisions by the Councils did not reflect many of these changes. As is discussed below, these omissions were not peculiar to this particular group.

In any event, the Feminist Network made a specific point which has significance for the subject of this paper. In the areas in which they did not meet with much success with the Working Group, they concluded that they failed to take into consideration the political implications of the changes that they sought to bring about in the ethics guidelines under preparation and that more active political lobbying of the Working Group and, even more importantly, the Councils to which the Working Group was accountable would have been more effective.[26] While this argument has merit and is no doubt a realistic view, it is arguable that if the Councils truly recognized the value of democratic legitimacy, transparency, accountability, representation, and community engagement, there would be little need for the academic community and other groups to take cognizance of, and focus on such external factors as politics. Instead the focus would be on the most inclusive and ethical arguments which, despite the differing perspectives necessarily held by different stakeholders, place the research subjects at the centre. The ideal and the real are, however, different matters. It would appear that implicit in a discussion of the degree of difference made by the comments submitted by different persons, groups and communities is a question of power, politics and access. While some, like the Feminist Network, had difficulty in having certain sections amended or added, others may perhaps have been more successful because of greater access to, or more intense political lobbying of the Working Group or the Councils. For instance, the Canadian Association of University Teachers (CAUT) and other interested parties succeeded in "securing the deletion of the section on research involving collectivities and its replacement by a section limited to research involving Aboriginal peoples" because of their view that the section on collectivities would also limit research

[26] See generally, Baylis et al 1997.

on public entities and, consequently, academic freedom (McDonald 2001, 17).[27] There was therefore a certain degree of public participation, but perhaps not enough consideration of the issues raised in the consultations. Because there were no open meetings to which the public was invited,[28] and not all the documents submitted as part of the consultation are in the public domain, and with a decade having now passed, it is difficult to ascertain precisely how much public participation there was, how broad the consultations were, and how much the input affected the outcome of the deliberations of the Working Group. But from the examples used here, it is arguable that more could have been done in terms of improving participation, community engagement and transparency.

In addition, there were significant deficiencies with respect to transparency about the consultation process. A website with a record of the consultations held, the time periods for comments, and the comments received, would have been helpful in promoting transparency and addressing any issues regarding the adequacy of the consultations or time given for receipt of comments.

Finally, the evaluation must touch upon whether or not the input received from various groups and the concerns expressed therein were duly considered, and whether or not such input reasonably influenced the outcome of the consultations and to what extent was such input reflected in the final document, the TCPS. The issue of the final control over the content of the guidelines is perhaps the most significant with respect to the democratic values at stake in the TCPS development process; so many of the values were implicated and the steps taken by the Councils were so corrosive to the values. The Working Group finished their last draft and submitted it to the Councils. In the final analysis, the Councils had the last word on the guidelines. Indeed, Palys critiquing the first draft of the Code had noted that:

> Though there is mention made that the members of the Working Group will engage in revision of the document during the fall of 1996, the TCWG gives itself no obligations regarding the extent to which commentaries by members of the academic community will be considered, nor is there any indication that the research community will ever have an opportunity to express its consent to be governed by the principles espoused in the TCWG's final draft. Quite the contrary, the only persons to be consulted regarding the final document are "the Councils", who will offer their "ultimate approval", apparently on behalf of those they command. Such a choice hardly seems to embody the spirit of power-equality and emphasis on "human dignity and respect" that the TCWG's draft Code espouses as an ideal. One can only wonder why those on the Councils are not subject to the same high standards that are expected of researchers. (Palys 1996a)

McDonald, expressed similar fears, noting towards the end of the process that:

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[27] Ted Palys, for instance, in his criticism of the 1997 draft of the Working Group's Code notes a change of a tone in the document different from the tone employed in the previous drafts. This must have been a result of the consultations and communications received by the Working Group. See Palys 1997 and Palys 1996b. See Adair 2001, 30–31 describing his partial success with having several wordings changed at the Council level. He had been a member of the Working Group.

[28] Open meetings, it must be noted, are not necessarily always the best option in all policymaking situations. As Weijer notes, "openness is a clear expression of commitment to democratic process, but closed meetings may allow for greater consensus building" Weijer 1997.

> The code was a complex undertaking. Many difficult, agonizing choices were made during the process. My concern, especially with the three-person committee's short deadline, is that the enormous learning experience of Working Group members will be lost at this point and that, inadvertently, through lack of knowledge of these complexities, e.g., the 2500 pages of correspondence in the 1996 consultations and verbal communications from data reviews, their work will endanger the document's integrity. There is a real danger that they will not give back to the community something which is recognizably a result of the Tri-Council Group's final draft and the consultation process. The councils have to make some decisions about how to minimize those dangers, while moving the document forward quickly. (Canadians for Health Research 1997)

Others like Lowy even suggested that pressure was being put at the time on the Councils to water down the earlier Working Group's version of the Code or even block their approval of the Code entirely because it was considered unduly restrictive (Lowy 1997).

These comments appeared to foreshadow what did eventually occur at the end of the Working Group's mandate, when the document which ostensibly had received input from the research community went to the Councils. A number of significant changes were made to the draft at the Councils' stage. The introduction to the final version of the TCPS stated that it was "prepared by the Councils by revision of the Working Group's Final Report in light of consultations between mid-1997 and May 1998" (CIHR et al. 1998). However, it will be noted that the Councils did not invite more input from the research community, or even from the Working Group as a body, but merely revised the document themselves (McDonald 2000, 82). In this way, much of the value received from consultations of the Working Group and the helpful communications that they received may have been lost. An accusation of lack of transparency was therefore made against the Councils. In this regard, McDonald, points out that:

> The Councils have been criticized for a behind the doors revision process and a lack of public consultations – especially compared to the very open process used by the Working Group in revising the 1996 draft *Code*. (McDonald 2000, 82)[29]

He adds that: "Members of the former Tri-Council Working Group have publicly and privately expressed concerns about the quality and coherence of the revisions made to the 1997 draft *Code*" (McDonald 2000, 82). Some of the substantial changes made at the Councils stage included changes related to research involving women already discussed above. Although the Working Group had, following comments submitted to it, expounded on the role of, and protection of women involved in research, and there was a discussion of the complexities surrounding the setting of a fair and inclusive research agenda, this section was eliminated by the Councils. In this respect, McDonald noted that the Working Group did not believe that mere tinkering with the ethics review process provided enough protection for the interests of women in research (McDonald 2001, 2, footnote 21). However, for reasons best known to the Councils, this section was completely removed (Baylis et al. 1999, 253). In McDonald's words, this replacement was "the most tepid of statements in

[29] See also Baylis et al. 1999.

regard to the just distribution of the benefits of health research to men and women" (McDonald 2001).

Another area in which there was substantial difference is the difference in approach to the issue of public health research. Public health research was dealt with under the Privacy and Confidentiality Section in the Working Group's draft Code, but according to Joly, the Chair of the Working Group, was not addressed in the final version of the TCPS leaving "this area of research …in a grey zone and the nature of the regulations to be applied are almost totally undefined."[30] There were other more minor amendments as well, including the use of the term "research subject" in place of the term "research participants" used by the Working Group (McDonald 2001, 2, footnote 2).[31]

One could therefore argue that, particularly at the Councils' stage, much of the consideration formally or informally given to the concepts of democratic legitimacy, transparency, accountability, representation, and community engagement at the Working Group stage of drafting the policy guidelines was lost. Arguably, therefore, although significant attention had been given to criticisms of the TCPS at the draft stage (Palys 2003), at the final Councils' stage it became almost a dictatorial process in which the Councils had the last word on what constituted ethical standards for research involving humans in Canada, with insufficient consideration given to the wishes of other stakeholders in the process at the final but perhaps most crucial stage. Needless to say, it is difficult and perhaps even impossible to accommodate every viewpoint in developing an ethical policy guideline as wide-ranging as the TCPS, and that in seeking consensus on areas in which there may be major differences of opinion, certain standards may have to be sacrificed. However, one would have expected more attention to be paid to these very important concepts which affect not only the process but also the substance of such an important policy.

The Development of a Second Edition of the Tri-Council Policy Statement

When the TCPS was adopted in 1998, the Councils agreed to make it an evolving document, accommodating changes in the field of ethics and research and making amendments accordingly over time. The Interagency Panel on Research Ethics

[30] See Joly 2001, 155. The Code stated: "Public health officers may be mandated by law to undertake research and in such cases REB approval is not required; this does not, however, exempt public health officers from seeking REB approval when the research is outside their mandate. In such case, REB approval is mandatory and, in all cases, respect for persons must be observed." The TCPS has no equivalent provision.

[31] See also, for instance, Flagel 2000. In the area of psychological research, the word "deception" which was allowed in the Working Group's draft code was eliminated in order to ensure that it would pass through the scrutiny of the Department of Justice. See Adair 2001, 31. See also, McDonald 2009, 18.

(PRE) was therefore created in 2001 to administer these changes and to support the development of the TCPS.[32] In addition, PRE also provides advisory opinions on issues in the TCPS, answering written queries from researchers, research ethics committees, and administrators.[33] It consists of 12 volunteer members who are experts in different research areas.[34] Since its creation, the PRE has been engaged in several consultations on different aspects of the TCPS. More recently, they have been engaged in the process of preparing a second edition of the TCPS, which is expected to be ready sometime in 2010.

The PRE in December 2008 presented a Second Edition of the TCPS (PRE 2008) for public comment. A final draft is due to be submitted in 2010 (PRE 2008). Given that consultations on the new draft are currently ongoing, it is perhaps too early to analyse with much depth the differences in the processes of development of the two editions. However, it is apposite to consider what may be different thus far.

In what way, then, does the process of drawing up the second and forthcoming edition of the TCPS differ from the first? And what lessons have been drawn or should be drawn, from the first edition? In trying to answer these questions, we seek to raise again questions relating to legitimacy and the inherent conflict of interest issue raised by the creation of an ethics guideline by Councils whose major purpose is to promote research. In terms of accountability and representation, what was the composition of the PRE and the Working Committees? Does its membership reflect a broad range, or diversity, of persons? Has there been sufficient broad-based consultation of the public necessary to meet the criterion of community engagement? It should also be considered whether the input received from various groups and the concerns expressed therein are being duly considered. Will such input reasonably influence the outcome of the consultations, and to what extent will such input be reflected in the final document? These are not easy questions to answer, particularly in light of the fact that the second edition is still in the process of being finalized and will not be so until the Fall of 2010. And yet, they are questions that need to be asked in order to address the concerns that arose in the process of creating the current edition of the TCPS. Some of the answers attempted here are obviously only speculative and preliminary, given that the process is still continuing. Below, we reflect on that ongoing process and consider the lessons that may have been, and should be, learned from the process of developing the current edition. We begin with a brief consideration of the political and legal context in which the development of the second edition is taking place. We then consider some of the new content of the draft second edition. Finally, we examine the process and what, if any, lessons could be learned from the process of drawing up the current edition.

First, it is important to note that the political landscape remains largely unchanged and that the legal landscape has changed somewhat, but not drastically. Other federal legislation which have an impact on research ethics governance such as, the

[32] Interagency Advisory Panel on Research Ethics. About Us: Mandate. http://pre.ethics.gc.ca/eng/panel-group/about-apropos/mandate-mandat/. Accessed 14 Oct 2009.

[33] Ibid. See for instance, Jones 2007.

[34] Ibid.

Canadian Institutes of Health Research Act enacted in 2000, *Personal Information Protection and Electronic Documents Act* (PIPEDA) enacted in 2000, and the *Assisted Human Reproduction Act* which was enacted in 2004, all of which contain several research-related provisions, have been developed since. What this means is that there is more legislation which has implications for the conduct of research in addition to guidelines.

The forthcoming edition[35] has benefited from the current edition in different ways. In terms of content, the new edition has adopted some of the content that featured in the Working Group's draft Code. An obvious example is the use of different terminology such as the adoption of the term "research participant." The term "research participant" had earlier been proposed by the Working Group and was used in its Code.

Apart from provisions which have their roots in the Working Group's Code, many revisions are also the product of consultations and comments received by various working groups since the PRE was established in 2001. Other areas have therefore benefited from the insight of working groups, expert panels, and interpretations provided by the PRE since its establishment. One of the areas in which work has been done by the PRE is in the area of social sciences and humanities research, an area in which concerns were raised during the process developing the TCPS, and even afterwards. One of the main concerns, pointed out above, was the concern raised by social science and humanities researchers about the TCPS and how it affected the kinds of research in which they engage. Accordingly, in 2003, the PRE created the Social Science and Humanities Special Working Committee on Research Ethics (SSHWC). The SSHWC was charged with advising the PRE on the development of the TCPS in relation to the social science and humanities research communities. In 2004, after consultation with the social science and humanities research community, they made public a report: *Giving Voice to the Spectrum* (PRE 2004), which addresses the concerns raised in social science and humanities research in contrast to biomedical research. A very clear effort is made to include issues in social sciences and humanities, using specific examples, and clearly pointing out when any discussion relates only to biomedical research in the second edition. There has been an effort to use more illustrations and identify more applications of such research in the later edition. Even more explicitly, there is a separate chapter on qualitative research.[36]

Also, areas such as biomedical research involving placebos in the context of randomised clinical trials (RCTs), and research involving Aboriginal peoples have been given an extended treatment. In laying out when placebos could be considered acceptable,[37] the first (and current) edition of the TCPS, was considered to be more

[35] Comments made here are based on the provisions of the forthcoming edition as at October 2009.

[36] Chapter 10 of TCPS (PRE 2008).

[37] Generally, a placebo control is considered appropriate when there is no proven treatment for the study condition. Where established treatment exists, placebos should not be used, except in extraordinary circumstances, in keeping with the principle of clinical equipoise. See Freedman 1987, 141.

restrictive than the ICH-GCP, which had been adopted by Health Canada (Sampson et al. 2009).[38] An initiative, the National Placebo Initiative, was then established in 2001 to find common ground on that specific issue. The forthcoming edition merges the provisions of the first edition with the guidelines.

Research involving Aboriginals had not been given extensive coverage in the current edition because, as was pointed out above, the communities had not been involved in extensive discussions. Since then, the CIHR had established an Aboriginal Ethics Working Group in 2004, which created the *CIHR Guidelines for Health Research Involving Aboriginal People* (CIHR 2007).[39] These guidelines, which came into effect in 2007, cover research funded by CIHR.[40] They are reflected in the extended chapter on Research Involving Aboriginal Peoples. These guidelines were developed following extensive discussions and engagement with aboriginal communities and researchers engaged in research with these communities.[41] Apart from these, there are other differences in content.[42] The content may still change as the policy remains under development.

The process of developing the second edition of the TCPS has been significantly different because of the presence and activity of the PRE. Instead of a transitory Working Group, the PRE is a permanent body which has a specific mandate to assist

[38] See also, National Placebo Working Committee 2004.

[39] See AREI PRE 2008.

[40] CIHR. Aboriginal Ethics Policy Development. http://www.cihr-irsc.gc.ca/e/29339.html. Accessed 14 Oct 2009.

[41] CIHR. Aboriginal Ethics Policy Development. http://www.cihr-irsc.gc.ca/e/29339.html. Accessed 14 Oct 2009.

[42] For example, distilling of ethical principles which numbered seven in the TCPS One (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, Maximizing Benefit into three, namely: Concern for welfare; Respect for autonomy; and Respect for the equal moral status of all humans); Article 2.1 of TCPS Two: Change of definition of "research;" from systematic investigation which produces generalisable knowledge as stated in TCPS One p.1.1; Allowing for the use of deception in clearer terms (taking into consideration the concerns of researchers in the social sciences like psychologists); A more exhaustive list of types of research exempt from REB review (research using information exclusively from publicly available information, creative practices, public policy research, quality assurance and quality improvement studies, program evaluation, and performance reviews or testing within normal educational requirements. Article 6.4 - Composition – TCPS Two – community member must have relevant training and experience; Composition – TCPS Two – member knowledgeable in law (not risk manager or legal counsel, and not restricted to biomedical research as in TCPS One); Article 6.2 (see Application) Conflict of interest – senior administrators not to serve on REBs, A fuller section on conflict of interest in TCPS Two, Chapter Seven; Provisions on privacy and confidentiality in the context of internet research in TCPS Two, Article 10.3 has no equivalent in TCPS One; Ad hoc appeal boards not allowed in TCPS Two (Art. 1.11), but may be allowed under TCPS Two (Article 6.19, application); A fuller section on multi-centre research, including choice of model of REB; More details on research in public health emergencies, Article 6.21 in TCPS Two; More details on international research; Article 11.12 – New requirement for Clinical trial registries; and so on. See also PRE. What's New in the TCPS. http://www.pre.ethics.gc.ca/policy-politique/initiatives/docs/What's%20New%20in%20the%20TCPS.pdf. Accessed 12 Oct 2009.

the development of the TCPS. The concepts of democratic legitimacy, transparency, representation and community engagement may be argued to have been employed in some fashion in the work of the PRE. Comments are invited regularly from the general public and the research community on several areas that may require amendment. Several working committees have been established over the years to offer considered opinions on several areas, with comments from the research community. Responses to interpretation questions developed in the past several years, and the reports emanating from these committees, based on public consultations have been used extensively in revising the new version of the TCPS.[43] In the process of drafting the second edition, various consultations have taken place and many comments have been received by the PRE.[44]

It could be argued that the process of developing the second edition has the potential to be more democratic and encompass the necessary democratic values because of the existence of the PRE, which did not exist back in 1998. The PRE now serves as a middleman between the public and the research community and the Councils, replacing the Working Group. It may also be argued that this time will be different because the PRE advises the Councils, but has also been working with the public and the research community in the process of developing comprehensive guidelines based on consensus. Unlike the Working Group, it remains a more or less permanent advisory body that can take on board the opinions of members of the research community and the general public on a continuing basis. The PRE has been engaged in the process of revising the TCPS, and developing interpretations for nearly a decade now. Also, the mandate of the PRE is clear, possibly clearer than the mandate of the Working Group, which, at first, set out to revise the MRC Guidelines.[45]

Arguably, however, despite these positive arguments, these democratic concepts have been applied in a limited fashion and can be extended. First, in terms of the conflict of interest issues and the related issues of legitimacy, challenges clearly remain in this area. The PRE is a creation of the funding Agencies and reports to them. In fact, it could be argued that the Working Group may have had more independence than the PRE currently does, being beholden to its creator, the Councils. In this respect, several commentators have noted that it remains problematic for the funders of research to be the regulators of research, even as it puts in place guidelines which aim to address conflicts of interest in research involving humans (McDonald 2009, 20; Sampson et al. 2009). Downie summarises these concerns aptly:

> We must also be concerned about conflicts of interest and research funders. National funding councils currently set the standards for research ethics and are responsible for enforcement of these standards and yet their mandate is the promotion of research. The presidents

[43] What's New in the TCPS. http://www.pre.ethics.gc.ca/policy-politique/initiatives/docs/What's%20New%20in%20the%20TCPS.pdf. Accessed 12 Oct 2009, 2. For a list of these reports, see PRE 2009a, b, c.

[44] Some of these comments are publicly available online. See for example, Palys and Lowman 2009; Sherwin 2009; Halperin et al. 2009.

[45] See Baylis et al 1999. See also, McDonald 2009.

> of the three national funding councils recently named an interagency Panel on Research Ethics (PRE) with responsibility for interpreting and revising the TCPS. Many in the research ethics community called for this responsibility to be given to a group outside the councils rather than one appointed by and reporting to the presidents of the councils (Downie 2003, 14).

This is clearly not an optimal situation. It is, however, a situation that requires ongoing national discussion. Until a national solution can be found and that lacuna filled, it appears likely, unfortunately, that the Councils will continue to regulate research funded by them. However, in these circumstances and in the situation that the Councils will not remove the revision of the TCPS from the mandate of the PRE, the Councils must be prepared to take extra steps to show how this conflict of interest is being managed, including how much independence the PRE can exercise in this respect. Extra steps must be taken to show transparency at all stages of the processes.

In terms of accountability and representation, we raise the question, as we did in the context of the current edition: What is the composition of the PRE, and the various Working Committees that have made a significant input in the process of developing the second edition? The composition of the Working Committees varies. However, the PRE is composed of 12 members who serve on a voluntary basis.[46] They are experts and researchers drawn from various disciplines and institutions. There is greater public participation also, with the members of the public participating in the process of nominating the panel members. However, such public participation is clearly limited as the Councils have the final say, and it is not clear if the different perspectives (for instance, Aboriginal, Black, Third World, or Feminist perspectives) are a consideration. Unlike the Working Group, there appears to be a better gender balance, although this could stand for some improvement.[47] It is hoped that this allows for better representation of a diversity of views on the panel. Unfortunately, it is not clear, as some commentators have suggested, that there is specifically, a representation of past or current research participants on the PRE to represent the views of the very persons that the TCPS is established to protect.[48] This is an area worth considering as the PRE continues its work, both with respect to the PRE itself and the various working committees.

Further, it must be noted that several problems arise with respect to the seeming ad-hoc processes adopted in putting together the new edition. Hirtle summarises some of these concerns, which include the degree of transparency, credibility and legitimacy attached to the processes noting that:

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[46] The past and current members of the Panel are listed on the website. PRE. About Us: Panel Members Interagency Panel on Research Ethics. http://pre.ethics.gc.ca/eng/panel-group/about-apropos/members-membres/. Accessed 12 Oct 2009.

[47] There are currently four women on the Panel, not including the Executive Director of the Secretariat on Research Ethics. See PRE. About Us: Panel Members Interagency Panel on Research Ethics. http://pre.ethics.gc.ca/eng/panel-group/about-apropos/members-membres/. Accessed 12 Oct 2009. It will be recalled that the Feminist Network complained of the gross gender imbalance on the Working Group. See Baylis et al. 1997 and accompanying text.

[48] See McDonald 2009; Palys 1996a.

> 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. 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. (Hirtle 2003, 151)

Others, like Palys in his comment on the second edition, for instance, allege that the PRE ignored some of the recommendations of some of its working committees (Palys and Lowman 2009, 17). Palys calls for further consultation on the draft second edition on the grounds that:

> PRE's strategy is that of an ethics deity imposing its own "right answers" rather than fulfilling its mandate to educate, promote discussion, respect disciplinary and methodological diversity, build consensus, and cultivate a culture of research ethics in Canada.
>
> 2) Draft TCPS-2 contains no annotations explaining PRE's rationale for the policy changes it proposes, as might be expected of a body that claims it operates according to the principles of "openness, transparency and accountability." (Palys and Lowman 2009, 20)

Still others, like Baylis, have also observed the conflicting ideas about how to formally incorporate previously existing guidance in different areas, such as stem cell research, use of placebos, or research involving aboriginal peoples into the second edition of the TCPS. Should this be by inclusion in the body of the TCPS; or by inclusion as an appendix to the TCPS; or by reference in the TCPS to the specific guidelines in question? (Baylis 2009). What is the status of these guidelines, after the second edition comes into force?

There are therefore concerns about the balance and diversity of perspectives with respect to the composition of the working committees and expert panels. These different committees and panels have had significant input into the revised edition, in a more or less makeshift fashion, raising legitimacy issues. On the other hand, there appear to be concerns that the recommendations of the working committees and expert panels are not being adopted. A different but related concern is how to incorporate other guidance into the TCPS. Such concerns raise questions of legitimacy, and about how standardized and stable the process of drafting the policy is. Going forward, a clearer and more transparent method of revision for the TCPS may be appropriate, as is the definition of the status of different guidance documents by the Councils.

In terms of community engagement, how broad have the consultations been? Are the different stakeholders being sufficiently consulted and adequate time being given for their input to be received? Since it first began work, the PRE has regularly called for comments from the public and the research community on different aspects of the TCPS. The PRE presented the draft second edition in December 2008, and has since engaged in regional consultations, visiting different institutions at the country, as well as national conferences, and receiving input (PRE 2009b).[49] The

[49] See also PRE. Conference Presentations. http://www.pre.ethics.gc.ca/eng/activities-activites/events-actualites/conferences/. Accessed 29 Sept 2009.

consultation period was to have ended in March 2009 but was extended to the end of June 2009, possibly to accommodate requests for more time to comment on the draft by persons and communities who believed that the 3 month period of comment initially provided was insufficient.[50] A final draft will be released to the public for final comments in December 2009 for a period of 60 days after which the final version will be prepared and presented to the Councils (PRE 2009c). There have, however, been complaints about the concentration of consultations in, and engagement with, academic institutions, with inadequate engagement with community-research partners. There have also been complaints that the Aboriginal community has not been sufficiently included in consultations with respect to the preparation of the second edition.[51]

Needless to say, it will be difficult, if not impossible, to accommodate every viewpoint in such a value-oriented policy as that contained in the draft second edition. But flexibility in consultation periods and broad inclusion in consultation processes will allow more feedback from the communities to be affected by the draft policy, the possibility of broader assessments of issues from sundry perspectives, high levels of awareness of the draft, broader support of the policy from those whom the draft may affect and the least negative repercussions later in the policy process.[52] There appears to be clear recognition that the engagement with the public is necessary to the success of the second edition (Beaudet et al. 2008). Hopefully, the PRE and the Councils will remain open to flexibility in allowing more time, if need be, for more consultations and in extending consultations to different interested communities. As yet, it is difficult to estimate how far the consultations undertaken, and comments received are influencing the direction of the document. However, it would certainly be beneficial for adequate consideration to be given to these comments in order to enhance not only the process, but also the moral support, acceptability and legitimacy of the resulting document.

As was clearly the case in the development of the current edition, the PRE, like the Working Group, will pass the draft second edition to the Councils. The Councils, as with the current edition, have the final say on the version of the edition that goes into effect. As such, the same issues that arose at the end of the process of making the TCPS are also likely to be present, with the Agencies able to make or to decide not to undertake any amendments without any consultations. Given the major accusation leveled against the process of the first edition that the Councils undertook a major revision without consultations, thus eliminating to a large extent the

[50] Several comments available online requested an extended period for comment. See for example, Palys and Lowman 2009, 21. See also, Sherry Ann Chapman, Letter to the PRE by Community-Partnerships for Health : RE: Extension of consultation time period and engagement strategy for community feedback. http://www.noveltechethics.ca/pictures/File/Health_Policy_Private/TCPS%20Documents/CCPH-Letter-031809.pdf. Accessed 21 Sept 2009.

[51] Sherry Ann Chapman, Letter to the PRE by Community-Partnerships for Health : RE: Extension of consultation time period and engagement strategy for community feedback. http://www.noveltechethics.ca/pictures/File/Health_Policy_Private/TCPS%20Documents/CCPH-Letter-031809.pdf. Accessed 21 Sept 2009, 2.

[52] Ibid.

democratic values that had earlier on been established, it can only be hoped that this will not be the case with this new edition. It makes little sense to engage in expensive consultations at the expense of the Canadian taxpayer, and then to undertake a revision process that does not take those consultations and comments into account. Apart from the financial resources expended, policymaking in which the democratic values discussed herein are not ensured risk losing essential support by the very entities that are required to apply it, thus jeopardizing its legitimacy and adequate implementation. Transparency and openness remain key in the success of this more recent process.

Conclusion

In 1998, the three major government funding Councils put in place the TCPS to regulate all research involving humans in Canada funded by them. In this paper, we have sought to examine the process of developing the TCPS, an historic and very important document in Canada's research ethics landscape and the application of the concepts of democratic legitimacy, transparency, representation, accountability and community engagement in that process. This exercise, important as it is, has received insufficient attention in the literature in the past. We have also considered the on-going process of putting in place a second edition of the TCPS.

Although process is quite different from substance, substance may be positively or adversely affected by the process of putting together the substance of important policies such as research ethics policy in democratic societies. As Hirtle rightly observes that, "Ensuring that the process for adopting rules is transparent, credible and equitable is crucial to promoting their legitimacy, authority and effectiveness" (Hirtle 2003, 141). It would appear from our discussion that there were several flaws in the process of developing the TCPS relating to the democratic values of democratic legitimacy, transparency, representation, accountability and community engagement. The TCPS, as previously discussed, remains the foremost ethics policy in Canada, and is widely used in research institutions. One could therefore think that the flaws in the process were perhaps not so severe as to damage the utility and effectiveness of the policy. One could also argue that the funding powers of the Agencies could also mean that, no matter how unacceptable the process, the policy would still have been effective and that the need for such a policy at the time of its creation would have outweighed other misgivings about the process. It is not debatable, however, that more could certainly have been done in terms of imbuing the process with democratic values, and this doubtless would have meant less need for revising the document afterwards, and more importantly, more respect being shown to the document (thus more protection of human subjects).

There are certainly lessons to be learnt for future policymaking efforts in the area of research ethics and in other important policy areas. Indeed, as we discuss in this paper, the work currently being done in terms of preparing a second edition of the TCPS could benefit from these lessons. Given where things stand at this stage of the

process, some of these lessons may appear to be belated, (for example, the Councils' conflict of interest in creating the TCPS), but others may still be timely (for instance, preparation of the final version and reflection of consultations). It can only be hoped that the PRE and the Councils will not repeat the mistakes of the past. Time will tell.

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