The Tunnel at the End of the Light? A Critical Analysis of the Development of the Tri-Council Policy Statement

Cheluchi Onyemelukwe
and Jocelyn Downie *

1. Introduction

In 1994, the Social Sciences and Humanities Research Council (SSHRC), the Medical Research Council (MRC), and the Natural Sciences and Engineering Research Council (NSERC) began a process to develop research ethics guidelines. That process culminated in the *Tri-Council Policy Statement on Ethics in Human Research* (TCPS) in 1998.[1] The TCPS has since become the foremost policy guideline for the governance of research involving humans in Canada. Its establishment therefore deserves particular attention. The deputy chair of the Tri-Council Working Group on the Ethics of Research with Human Participants, Michael McDonald, recently called for more objective discussion and reflection on the process of establishing the TCPS, to inform future policy making;[2] this call is particularly timely in view of the ongoing process of developing a second edition.

In this article, we seek to answer McDonald's call. Specifically, we examine the process of developing the current edition of the TCPS and critically evaluate the application of the democratic values of legitimacy, accountability, representation, and community engagement in that process. We argue that some efforts were made to reflect these values in the process of developing the current edition of the TCPS but that a better job could and should have been done. In addition, as the process of drafting the second edition is underway, we also reflect briefly upon the direction in which that process appears to be headed in light of the lessons learned from the first.

---

1 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: Ethical Conduct for Research Involving Humans* (1998) [TCPS 1998].

2 Michael McDonald, "From Code to Policy Statement: Creating Canadian Policy for Ethical Research Involving Humans," *Health Law Review* 17, 2–3 (2009), 12.

The objective of this article is to highlight the extent to which the democratic values of legitimacy, transparency, accountability, representation, and community engagement have shaped research ethics policy in Canada thus far and to draw lessons for how future policies in this area, and other areas that are similarly contentious, may profit from this experience.

2. Democratic Values for Research Ethics Policy Development

At the core of the idea of democracy is the right to participate in making decisions that may ultimately affect one.[3] Various theories of democracy, including deliberative democracy theory,[4] recognize the importance of this right to participation in decision making in society. Democratic values such as legitimacy, transparency, representation, accountability, and community engagement are mutually reinforcing corollaries of the right to participate; participation promotes the legitimacy and transparency of policy decisions, encourages the representation of broad perspectives on public issues, and promotes accountability for decisions and engagement in decision-making processes.

Given Canada's political system and commitments, democratic values must be given expression in the manner in which Canada develops major policies. Further, the councils that sought to put the TCPS in place are agents of the government, disbursing government monies, raised via taxation from the general population, for the purpose of ensuring the conduct of research projects of eventual benefit to Canadians. It is therefore reasonable to assume that the process of developing the TCPS should reflect the democratic values accepted in Canada.[5]

The development of research ethics policies such as the TCPS requires broad engagement with the public, because it is a value-laden policy matter around which there tend to be opposing values, contentious views, and a strong need for consensus. Areas such as social or biomedical research involving minorities or collectivities, clinical research involving human tissues, and stem-cell research raise important questions to which there are no easy answers.[6] Consensus on such matters cannot be arrived at without deliberate

---

[3]   Laura B. Perry, "Education for Democracy: Some Basic Definitions, Concepts, Clarifications," in *International Handbook on Globalisation, Education and Policy Research*, ed. J. Zajda (Dordrecht: Springer, 2005), 687. There are other key concepts, such as equality and choice, but all of these are linked fundamentally to the right to participate in decision making.

[4]   Samuel Chambers, "Deliberative Democratic Theory," *Annual Review of Political Science* 6 (2003), 307; S. Freeman, "Deliberative Democracy: A Sympathetic Comment," *Philosophy and Public Affairs* 29 (2000), 371; J. Elster, *Deliberative Democracy* (New York: Cambridge University Press, 1998); J.S. Fishkin, *The Voice of the People* (New Haven, CT: Yale University Press, 1997).

[5]   Obviously there is much debate as to what these are. Given space constraints, we can hope neither to do justice to that debate nor to present a full defense of the values we use in our analysis. Rather, we stipulate the values of legitimacy, transparency, representation, accountability, and community engagement and refer the reader to the literature cited in the article for the defence.

[6]   For examples of some issues on which consensus has emerged and on which there are still conflicting opinions in clinical research see Baruch A. Brody, Laurence B. McCullough, and

recognition of, and transparent and broad engagement with, a wide array of perspectives, including those of minorities or hitherto disadvantaged groups. Such engagement requires adequate representation, including drawing members of policy-drafting committees from groups likely to be affected by the policy, sufficient and transparent public consultations, and reflection of such consultations in the final policy. It is reasonable to claim that persons who may be affected by a policy should be consulted and that representatives of a committee should be drawn widely and reflect both the population of persons who may be affected by the policy and those who are experts in the specific policy area.

Legitimacy would be lacking in any policy that does not result from broad and transparent engagement and representation. Legitimacy affects not only the acceptability of the policy but also its usefulness to those who would utilize it.[7] Opening up policy making to public involvement does not mean that policy makers will not have tough decisions to make or that consensus will always be achieved.[8] Nevertheless, stakeholders who will be affected by policies should have the opportunity to express their views about the matter in the policy-making process and, in effect, confer greater legitimacy on that process.

Although written specifically about legitimacy in governance, Eric Montpetit's description of two understandings of legitimacy is useful in the context of the development of the TCPS. According to Monpetit, legitimacy can 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 policy making by experts. *Input-oriented legitimacy*, on the other hand, is bestowed on public policies through consultation with the public. These two kinds of legitimacy are not necessarily mutually exclusive, however, and may work best together, such that experts and the public, including major stakeholders and minority groups, act together to create effective policies.[9]

The process of developing the TCPS aspired to reflect a unity between input-oriented and output-oriented legitimacy. The working group, consisting ostensibly of experts, was charged by the three councils with drafting

---

Richard R. Sharp, "Consensus and Controversy in Clinical Research Ethics," (*Journal of the American Medical Association* 294 (2005), 1411. See generally Miriam Brouillet and Leigh Turner, "Bioethics, Religion, and Democratic Deliberation: Policy Formation and Embryonic Stem Cell Research," *HEC Forum* 17, 1 (2005), 49; S. Kim et al., "Assessing the Public's Views in Research Ethics Controversies: Deliberative Democracy and Bioethics as Natural Allies," *Journal of Empirical Research on Human Research Ethics* 4, 4 (2009), 3.

[7] Marian Barnes et al., "Recent Research: The Micro-Politics of Deliberation: Case Studies in Public Participation," *Contemporary Politics* 10, 2 (2004), 93.

[8] Susan Dodds and Colin Thomson, "Bioethics and Democracy: Competing Roles of National Bioethics Organisations," *Bioethics* 20 (2006), 326. See also J. Cohen, "Deliberation and Democratic Legitimacy," in *The Good Polity: Normative Analysis of the State*, ed. A. Hamlin and P. Pettit, 17–34 (Oxford: Basil Blackwell, 1989), 21.

[9] Éric Montpetit, "Public Consultations in Policy Environments: The Case of Assisted Reproductive Technology in Canada," *Canadian Public Policy* 29 (2003), 97.

the guidelines and invited input from the research community and the general public. Such public consultation demonstrated the desire for the guidelines that would emerge to be a result of a transparent, participatory process that would foster inclusiveness by addressing the concerns of different groups within Canadian society and produce a legitimate document that would be widely applicable. The question, however, is the extent to which this aspiration was met. We investigate this in the next section of this article.

Apart from legitimacy, democratic values such as transparency, community engagement, and representation require an open process that takes into consideration the views of the stakeholders, that is, those who may be affected by the policy that will eventually result from a democratic process. The stakeholders in the process of making the TCPS included the funding bodies, that is, the three councils, which 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 many of the researchers who conduct research and who should seek to do so in an ethical manner; and, perhaps most importantly, research participants, whose interests and safety the TCPS is meant to protect, and consumers of research, who have a right to safe products of research conducted in an ethical fashion. Were all these stakeholders sufficiently represented and consulted with in the process of creating the current edition of the TCPS? How much input did these stakeholders have in that process? Did the process sufficiently exhibit the democratic values under discussion? All these questions are addressed in the next section.

3. The Process of Developing the TCPS

In 1994, at the initiative of the Ministry of Health and the Ministry of Industry and Commerce, the three major research funding bodies—MRC (now CIHR), SSHRC, and NSERC—set up the Tri-Council Policy Working Group on Ethics. The working group's goal was to create a common set of ethics guidelines that would regulate research involving humans in Canada.[10]

The process of developing the TCPS included soliciting input from the research community, publishing an issues discussion paper in November 1994, publishing a draft of the Code of Ethics in April 1996, and publishing a final draft Code of Ethics in July 1997.[11] Formal and informal consultations, extensive discussion, and analysis followed each of these publications.[12] The working group submitted the final draft code to the councils, which made

---

[10]   Feminist Health Care Ethics Network, *The Politics of Women's Health: Exploring Agency and Autonomy* (Philadelphia: Temple University Press, 1998), 234. Although it was the intention to create a "code," the document that emerged became a "policy statement." For the reasons see McDonald, "From Code to Policy Statement," 17.

[11]   Tri-Council Working Group on Ethics, *Code of Conduct for Research Involving Humans* [final version] (Ottawa: Minister of Supply and Services, 1997), http://www.ethics.ubc.ca/code/july97/j97-1.pdf [*Working Group Code*]

[12]   Guy Rocher, "Origin and Development of the Tri-Council Policy Statement on the Ethics of Research Involving Humans," *NCEHR Communique* 9, 2/10, 1 (1999), http://www.ncehr-cnerh.org/uploads/editor/file/communique/english/communique4-5/proceedings.html.

several significant revisions to the working group's version and published the final version of the TCPS in May 1998.

To evaluate the process through the lens of the democratic values set out in the previous section, we consider a number of contentious issues: the source of the guidelines; the scope of the working group's mandate; the composition of the working group; various features of the consultations; and the final control over the content of the guidelines. In doing so, we draw from and analyse the experiences of individuals and groups writing during the process a decade ago. Most of them were not writing specifically on the expression (or lack thereof) of democratic values in the TCPS process, but their comments during and after that process provide helpful insights.

We begin with the source of the guidelines (i.e., the three councils). Some commentators, early on, noted what they considered to be a conflict of interest arising from the roles of the councils as research funders and research promoters as well as promulgators of ethical guidelines.[13] In our opinion, a clear conflict of interest existed (and exists) in the councils' adoption of these multiple roles. The tension between the goals of providing funds for research and regulating research may create problems in developing and enforcing appropriate research ethics policies. Moreover, the councils may align their interests with other research sponsors whose main interests do not necessarily include the protection of research participants.[14] The competing obligations of the councils posed a threat to the output-oriented legitimacy (promotion of the public good) of the policy-making process.

However, given the vacuum that existed at that time, and the councils' acknowledgement of their responsibility to ensure the ethical conduct of research funded by them, it was a reasonably defensible idea for them to put in place the TCPS. That said, the problematic conflict-of-interest situation should have been dealt with by, at the very least, taking extra steps to maximize the independence of the process. In other words, the desire to ensure that federally funded research meets the highest possible ethical standards was laudable, but significant steps should have been taken to maximize the ultimate meaningful independence of the drafters of the ethical guidelines from the councils and the independence of the emanating policy. Some small measure of response to the conflict-of-interest situation can be seen in the fact that the councils appointed a working group; however, the effectiveness of this response was limited by the fact that the working group reported to the councils and that the councils retained ultimate authority

---

[13]   See, e.g., Ted S. Palys, "The Ethics of Ethics: Comments Regarding the Tri-Council Working Group's March 1996 Draft *Code of Conduct for Research Involving Humans*" (1996), http://www.sfu.ca/~palys/codecomm.htm.

[14]   Indeed, they have explicitly done so. For instance, in December 2009, the president of CIHR publicly expressed the position that CIHR should align its agenda and vision with industry: Alain Beaudet, Testimony before the federal Standing Committee on Health, 40th Parl, 2nd Sess (30 November 2009), http://www2.parl.gc.ca/HousePublications/Publication.aspx?DocId=4275165&Language=E&Mode=1&Parl=40&Ses=2#Int-2984056. See Steven Lewis, "Neoliberalism, Conflict of Interest, and the Governance of Health Research in Canada," *Open Medicine* 4, 1 (2010), http://www.openmedicine.ca/article/view/379/302.

over the content of the TCPS and exercised it in the end. As we discuss further below, the final product of the working group was revised by the councils. Thus, an inadequately managed conflict of interest on the part of the councils in developing the TCPS adversely affected the policy's legitimacy.

Beyond the conflict-of-interest issue, the working group's views as to the scope of its mandate also influenced the degree to which the democratic values at stake were reflected in the process. The working group's mandate was "to develop new policies and regulation to replace the Councils' existing guidelines for research involving humans."[15] However, the working group was not clear on this mandate, at least initially. For instance, as noted by the Feminist Network (a group of interested feminist academics that made representations to the working group), there were indications that the working group had initially planned "to tinker with the existing MRC Guidelines, making minor corrections here and there and broadening the scope of the Guidelines to make them relevant to the other two granting agencies."[16] This view is confirmed by McDonald.[17] 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 were reflected in the resulting policy. As the discussions that follow indicate, there were problems in all these areas, possibly arising in part from the working group's initial narrow view of the scope of its mandate. Confusion over the mandate threatened, at the very least, the realization of the value of community engagement.

The composition of the working group is another crucial issue. Information is not readily available in the public domain on the manner of or rationale for choosing the particular members of the working group. It would appear that individuals considered to be experts in areas considered relevant, mainly from the university research community, were chosen by the councils and appointed as individuals rather than representatives. Members of the working group were drawn from different disciplines and, although the composition changed several times before the final draft was produced, included doctors, lawyers, philosophers, psychologists, and ethicists.[18]

The challenge of developing a policy for many disciplines certainly required that members be drawn from various disciplines. The multidisciplinary background of the members of the working group was therefore a positive feature. At the time, however, Ted Palys rightly criticised the process for the

15   McDonald, "From Code to Policy Statement," 14.
16   F. Baylis et al., "Women and Health Research: From Theory, to Practice, to Policy," in *Embodying Bioethics: Recent Feminist Advances*, ed. A. Donchin and L. Purdy (Lanham, MD: Rowman & Littlefield, 1999), 247.
17   McDonald, "From Code to Policy Statement," 13.
18   See Members of the Tri-Council Working Group on Ethics, Appendix A of Tri-Council Working Group, *Draft Code of Conduct for Research Involving Humans* (July 1997), http://www.ethics.ubc.ca/code/july97/app-abc.doc.

narrowness of its composition, noting that the working group did not adequately represent the diversity of the research community. Representatives of socially and scientifically marginalized groups, including Aboriginal, black, Third World, and feminist academics and groups, were not included in the working group.[19] The Feminist Network also observed a lack of a gender balance and an insufficient number of feminists in the membership of the working group.[20]

In our view, although the working group should not have been too large for meaningful exchange of ideas, it could and should have included greater diversity. In order to realize the goal of representation for those directly affected by the policy being developed, it would have been appropriate to include not only experts but also lay people who had previously participated or were currently participating in research, as well as members of different communities (no individuals from Aboriginal communities were involved, for example, nor any past or present research participants); furthermore, only one-third of the members of the working group were women. Greater diversity and better gender balance would have been more appropriate.

A further set of concerns arises with respect to the consultations engaged in by the working group. The value of community engagement is obviously implicated here. It is important to reflect upon how broad the consultations leading to what eventually became the TCPS were, whether the many different stakeholders were sufficiently consulted, and whether they were given adequate time to provide their input. McDonald points out that the working group received and catalogued many comments in its preparation of different drafts of the code.[21] However, some considered the consultations inadequate and the dissemination of the drafts insufficient. Criticisms were also levelled by different groups at the time with respect to a lack of transparency in the circulation process and inadequate time to comment on the drafts.[22]

The lack of adequate consultation had serious effects, resulting in serious deficiencies in the TCPS and requiring corrective measures by the councils. Because of the lack of formal consultation with Aboriginal communities, the section on collectivities created by the working group was eventually eliminated from the final draft that became the TCPS.[23] CIHR ultimately established separate specific guidelines for health research involving

---

[19] Palys, "The Ethics of Ethics."

[20] Françoise Baylis, Jocelyn Downie, and Susan Sherwin, "Ensuring Proper Attention to Gender in Health-Related Research: One Group's Story" (Paper presented at the Gender and Health Conference, Halifax, July 4–5, 1997), 8.

[21] McDonald, "From Code to Policy Statement," 16.

[22] Feminist Health Care Ethics Network, *The Politics of Women's Health*, 247. See also John Furedy, "SAFS and the Proposed Canadian Tri-Council Code of Ethical Conduct for Research Involving Humans: Ethical Humility But Epistemological Arrogance" (Handout for SFN Symposium: Social Policy Masked as Ethics Hurts Science: Some Perspectives from Working Scientists, October 1997), http://www.psych.utoronto.ca/users/furedy/bioethic.htm.

[23] See TCPS, s. 6. McDonald notes, however, that the working group had anticipated this criticism and opted not to create a section specifically on research with Aboriginal communities. See McDonald, "From Code to Policy Statement," 16.

humans in Aboriginal communities, after wide consultation with these communities.[24] In addition, a Social Science and Humanities Special Working Committee on Research Ethics was required to revisit the issues raised by researchers in the social sciences and humanities during the TCPS development consultations.[25]

Moreover, in terms of ensuring that their comments influenced the direction of the policy, some groups may have had greater success thanks to more intense lobbying of the working group. For example, the Canadian Association of University Teachers (CAUT), vehemently opposed to the inclusion of a section on collectivities on the grounds that the section limited academic freedom,[26] actively lobbied and succeeded in "securing the deletion of the section on research involving collectivities and its replacement by a section limited to research involving Aboriginal peoples."[27] Conversely, the Feminist Network, a group that made representations on inclusion of women in research, has noted that it had only limited success[28] because of its less intensive lobbying of the working group and the councils.[29]

It would appear, then, 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. Some groups were better able to make their views count than others. In our view, however, if the working group and 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 be cognizant of and focus on such external factors as politics. Certainly not all perspectives or viewpoints can be accommodated, but a truly democratic process would have ensured not only that were comments solicited but that reasonable attention was paid to such comments. Such reasonable attention would depend not upon how powerful the stakeholders might be, or how intensive the lobbying, but on the value of the perspective to the policy matter at hand—in this case, the protection of research participants and the promotion of socially responsible research.

---

[24]   *CIHR Guidelines for Health Research Involving Aboriginal People* (Ottawa: CIHR, 2007), http://www.cihr-irsc.gc.ca/e/documents/ethics_aboriginal_guidelines_e.pdf. See Interagency Panel on Research Ethics [PRE], *Draft 2nd Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* (December 2009), http://www.pre.ethics.gc.ca/pdf/eng/Revised%20Draft%202nd%20Ed%20PDFs/Revised%20Draft%202nd%20Edition%20TCPS_EN.pdf, chapter 9 [PRE, "Draft 2nd Edition"].
[25]   Social Science and Humanities Special Working Committee on Research Ethics, *Giving Voice to the Spectrum* (Ottawa: PRE, 2004).
[26]   McDonald, "From Code to Policy Statement," 16.
[27]   Michael McDonald, "Canadian Governance of Health Research Involving Human Subjects: Is Anyone Minding the Store?" *Health Law Journal* 9, 1 (2001), 17. See Ted Palys, "Bulldozers in the Garden: Comments Regarding the Tri-Council Working Group's July 1997 Draft *Code of Ethical Conduct for Research Involving Humans*" (n.d.), http://www.sfu.ca/~palys/tcwg97.htm.
[28]   Feminist Health Care Ethics Network, *The Politics of Women's Health*, 251.
[29]   See generally Baylis et al. "Ensuring Proper Attention to Gender in Health-Related Research."

In addition, there were significant deficiencies with respect to transparency about the consultation process. A Web site with a record of the consultations held, the time periods for comments, and the comments received would have been (and would continue to be) helpful in promoting transparency and addressing any issues relating to the adequacy of the consultations or of the time allowed for receipt of comments.

The issue of 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, as so many of those values were implicated and the steps taken by the councils were so corrosive to them.

The working group submitted its last draft to the councils in 1997. Some, including McDonald, expressed fears that the councils might not "give back to the community something which is recognizably a result of the Tri-Council Group's final draft and the consultation process."[30] Others, such as Frederick Lowy, suggested that pressure had been put on the councils to water down the earlier working group's version of the Code of Ethics, or even to block their approval entirely because the draft's provisions were considered unduly restrictive.[31]

These fears appear to have foreshadowed what did eventually occur after the working group's document went to the councils. A number of significant changes were made to the working group's document. The introduction to the TCPS states 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."[32] The councils did not invite more input from the research community, however, or even from the working group as a body. Instead, they commissioned consultants to revise parts of the document,[33] thus eliminating a considerable degree of the transparency that had characterized the process up to that point.[34] Members of the working group expressed concerns about the quality and coherence of the revisions made to the policy.[35] Some of the substantial changes made at the councils' stage related, for instance, to research involving women: although the working group had, following the submission of comments, expounded on the role and the 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 of the document was eliminated by the councils.[36] The

---

30 Canadians for Health Research, "What's Right, What's Missing, What's Next?—Discussion" (1997), http://www.chrcrm.org/main/modules/pageworks/index.php?page=015&id=249 (accessed October 14, 2009).
31 Frederick Lowy, "Research Ethics Boards: Potential Conflicts of Interest for Institutions" (1997), http://www.chrcrm.org/main/modules/pageworks/index.php?page=015&id=235 (accessed October 14, 2009).
32 TCPS 1998, Introduction.
33 See McDonald, "From Code to Policy Statement," 18.
34 Ibid.; see also Baylis et al., "Women and Health Research," 253.
35 McDonald, "From Code to Policy Statement."
36 See Michael McDonald, "The Current Context of HRIHS," in *The Governance of Health Research Involving Human Subjects*, by Michael McDonald et al. (Ottawa: Law Commission of Canada, 2000), 81.

working group's section on research involving women expressly required the inclusion of women from disadvantaged social, ethnic, racial, and mentally or physically disabled groups and a specific statement that no woman should be automatically excluded from relevant research.[37] For reasons known only to the councils, however, this section was completely removed.[38] It was replaced with a section requiring that women not be excluded only on the grounds of sex or reproductive capacity,[39] which Michael McDonald subsequently described as "the most tepid of statements in regard to the just distribution of the benefits of health research to men and women."[40]

Public-health research is another area in which there was substantial change. Public-health research was dealt with under the Privacy and Confidentiality cection in the working group's draft code, but it is not addressed in the TCPS, which leaves "this area of research ... in a grey zone and the nature of the regulations to be applied ... almost totally undefined."[41] In addition, the Working Group's term "research participant(s)" was replaced by "research subject(s)."[42] In the area of psychological research, the word "deception" (a term of art in psychology-related research), which was allowed in the working group's draft code, was eliminated.[43]

Thus, when the councils took over, even the limited reflection of democratic values seen at the working group stage of drafting was largely lost. The action of the councils in commissioning consultants to revise the documents after the lengthy drafting process was undemocratic and detracted from positive features of the process up to that point. This action, in our view, undermined the legitimacy of the document and the accountability, representation, and community engagement that should have been an essential part of the process.

Further, the revision of the working group's draft code by the councils also illustrates the point made earlier about the councils' conflict of interest in developing the policy and the effect of that conflict on legitimacy and accountability. The manner in which the councils carried out the revisions did not maximize the independence of the process, and thus did not manage the conflict of interest. At the councils' stage, the process became a far less democratic one as the conflicted councils took the last word on what constituted ethical standards for research involving humans in Canada.

---

37   "Research Involving Women," ss 6.3–6.4, subsection A of *Working Group Code*, http://www.ethics.ubc.ca/code/july97/.
38   See Baylis et al., "Women and Health Research," 253.
39   TCPS 1998, art 5.2.
40   McDonald, "Canadian Governance," 2 n21.
41   Jean Joly, "Public Health Research and Public Health Non-research: Who Governs What?" in McDonald et al., *Governance of Health Research*, 155.
42   See McDonald, "Canadian Governance of Health Research," note 2, for a discussion of the significance of this change. See also, e.g., David C. Flagel, "Children as Research Subjects: New Guidelines for Canadian IRBs," *IRB: A Review of Human Subjects Research* 22, 5 (2000), 1.
43   See John G. Adair, "Ethics of Psychological Research: New Policies, Continuing Issues, New Concerns," *Canadian Psychology* 42, 1 (2001), 31. See also McDonald, "From Code to Policy Statement," 18. This term has been restored in the new TCPS, as it is clearly a method that is essential in most psychological research.

In sum, there were clearly efforts made to ensure that the process of developing the current edition of the TCPS would reflect democratic values. These efforts could, however, have been taken further. For instance, appointing more members from different communities outside the academic community would have resulted in greater representation and community engagement. Similarly, ensuring that no final revisions were made without input from the stakeholders would have shown greater accountability and transparency and would have improved the legitimacy of the resulting policy.

We turn now to consider the ongoing process of developing the second edition of the TCPS and reflect on the lessons that should be drawn from the process of developing the current edition.

4. The Process of Developing the TCPS (2nd ed.)

When the TCPS was adopted in 1998, the councils agreed to make the policy an evolving document, accommodating changes in the field of ethics and research and making amendments accordingly over time. The Interagency Panel on Research Ethics (PRE) was created in 2001 to administer these changes and to support the development of the TCPS. The PRE also provides advisory opinions on issues in the TCPS, answering some written queries from researchers, research ethics boards, and administrators. It consists of 12 volunteer members who are experts in different research areas.[44] Since its creation, the PRE has engaged in several consultations on different aspects of the TCPS.[45]

More recently, the PRE has been engaged in the process of preparing a second edition of the TCPS, which was published in December 2010. In December 2008, the PRE presented a draft second edition of the TCPS[46] for public comment.[47] A revised version of this draft was published in December 2009,[48] and comments were accepted until March 2010. Given that no new edition has yet been promulgated, it is too early to analyse in much depth the differences in the processes of development of the two editions. Some of the analyses attempted here are thus necessarily only speculative and preliminary, given that the process is ongoing. Nonetheless, it is apposite to consider what may be different thus far and what lessons may still be learned from the past to improve the current process.

---

[44] Panel on Research Ethics, "About Us: Mandate," http://pre.ethics.gc.ca/eng/panel-group/about-apropos/mandate-mandat/.

[45] One example of this is research in the social sciences and humanities. In 2003, the PRE created the Social Science and Humanities Special Working Committee on Research Ethics (SSHWC); in 2004, after consultation with the social science and humanities research community, SSHWC submitted the report *Giving Voice to the Spectrum* (see note 25 above).

[46] "Draft 2nd Edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*" (Ottawa: PRE, 2008), http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/draft-preliminaire/ (accessed June 20, 2009).

[47] Ibid.

[48] PRE, "Draft 2nd Edition."

There have been significant differences between the process of developing the first (and current) edition and the process for the draft second edition because of the presence and activity of the PRE. Instead of a transitory working group, the PRE is a somewhat permanent body with a specific mandate to assist in the development of the TCPS. The PRE now serves as an intermediary between the public, the research community, and the councils. Comments are regularly invited from the general public and the research community on areas that may require amendment. Several working committees have been established over the years to offer considered opinions on several areas, and their work has been commented upon by the research community. Responses to issues requiring interpretation, 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.[49]

Unlike the working group, the PRE 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. Also, PRE's mandate is clear, certainly clearer than the mandate of the working group, which set out to "tinker with" the MRC Guidelines and ended up dramatically revising them.[50] And, importantly in terms of the content, the PRE has been involved in and can continue to revise the TCPS in response to concerns raised over the past decade.[51]

In the process of drafting the second edition, various consultations have taken place and many comments have been received by the PRE. The PRE's decision to publish comments received on the last draft of the second edition (as well as the posting of submissions online by their authors[52]) has also allowed for greater transparency.[53]

It could be argued, therefore, that the process of developing the second edition has the potential to be more democratic and to better reflect the values of legitimacy, transparency, accountability, representation, and community engagement because of the presence of the PRE, which did not exist back in 1998. It could also be argued that the policy-development process has been different this time because the PRE advises the councils and has also been working with the public and the research community in the process of trying to develop comprehensive guidelines.

---

[49]   See 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 October 12. 2009), 2. For a list of these reports see PRE, "Policy Initiative" (2009), http://pre.ethics.gc.ca/ eng/policy-politique/initiatives/reports-rapports/.
[50]   See McDonald, "From Code to Policy Statement."
[51]   See, e.g., Nancy Walton, "The New Draft Canadian Federal Guidelines: Is There More to Say?" Research Ethics Blog (February 2, 2009), http://researchethicsblog.com/2009/02/ 07/the-new-draft-canadian-federal-guidelines-is-there-more-to-say/.
[52]   See http://www.noveltechethics.ca, for example, for some comments on the TCPS.
[53]   PRE, "Public Participation: Public Comments on the Revised Draft 2nd Edition of the TCPS (December   2009)," http://www.pre.ethics.gc.ca/eng/policy-politique/participation/ comments-commentaires2009/> (accessed June 26, 2010).

Despite these positive developments, however, democratic values have so far been applied in a limited fashion in the second-edition process, and there remains room for improvement. First, challenges clearly remain in terms of the conflict-of-interest issues and the related issues of legitimacy. The PRE is a creation of the funding councils and reports to them; in fact, it could be argued that the working group had more independence than the PRE currently does, since the latter is even more beholden to the councils (a standing rather than ad hoc structure is at stake, and this includes jobs). Some questions posed to the PRE about the second-edition process have been answered by a vice president at CIHR rather than by the PRE Secretariat, the executive director of the PRE, or the PRE chair, which suggests a decreasing rather than increasing degree of independence. It remains problematic for the funders and promoters of research to be the regulators of research, even as the funders put in place guidelines which aim to address conflicts of interest in research involving humans.[54] This situation is clearly not optimal and requires further national discussion. The discussion that has already occurred, including, for instance, that contained in the report of the Experts Committee for Human Participant Protection in Canada, indicates a need for an independent body to develop research ethics policy in Canada.[55] This suggestion must be carefully considered, and steps taken by the councils toward ensuring that the creation of such a body occurs.

Until a national solution can be found, however, it appears likely that the councils will continue to regulate the research they fund. In these circumstances—and if the councils will not remove the revision of the TCPS from the mandate of the PRE—the councils must be prepared to take steps to manage this conflict of interest, including maximizing the PRE's independence in this respect. Further, as one of us suggested in the comments on the last revision of the draft second edition, this forthcoming edition "should not be released without at least a concurrent announcement of an endorsement of the Experts Committee recommendation that an independent body be established with responsibility for the development, implementation, and interpretation of national policy on research involving humans."[56] It would help with the legitimacy of the second edition if the councils were to endorse the establishment of an independent body to develop research ethics policy in Canada and take active steps to ensure that this occurs.

In terms of accountability and representation, it is important to examine the composition of the PRE and of the various working committees that have had significant input during the process of developing the second edition. The composition of the working committees varies, but the PRE is composed of

---

[54] McDonald, "From Code to Policy Statement," 20.
[55] Experts Committee for Human Research Participant Protection in Canada, *Moving Ahead: Final Report* (Ottawa, 2008), http://www.hrppc-pphrc.ca/english/movingaheadfinalreport2008.pdf.
[56] Jocelyn Downie, Letter to the Interagency Panel on Research Ethics (March 1, 2010), http://www.pre.ethics.gc.ca/pdf/eng/Comments2009/114_%20Downie,%20Jocelyn.pdf.

12 members,[57] experts and researchers drawn from various disciplines and institutions. There is greater public participation also, as members of the public participate in the process of nominating PRE members. However, it is not clear whether differing perspectives (e.g., Aboriginal, black, Third World, or feminist perspectives) are represented at the PRE table. It is also not clear whether there is specific representation for past or current research participants on the PRE to bring the views of the very persons that the TCPS was established to protect.

Further, several problems have arisen that may be due to the seemingly ad hoc processes adopted in putting together the new edition, a combination of the interpretations given by the PRE, previous consultations, and provisions from other ethics guidelines.[58] Some, including Ted Palys in his comment on the draft second edition, allege that the PRE has ignored recommendations by some of its own working committees.[59] Others, such as Françoise Baylis, have observed inconsistent approaches to the issue of formally incorporating into the second edition pre-existing guidance in different areas, such as stem-cell research and research involving Aboriginal peoples. Should this be done by inclusion in the body of the TCPS, or by inclusion as an appendix to the TCPS, or by means of references in the TCPS to the specific guidelines in question?[60] Evidence of inconsistency remains in the revised draft second edition. For instance, the CIHR Guidelines on Research with Aboriginal Communities have been incorporated (with significant, but unacknowledged, amendments) into a chapter in the revised draft second edition; the CIHR Guidelines for Human Pluripotent Stem Cell Research,[61] however, are merely referenced.[62] Commenting on the revised draft second edition, both Downie and Baylis point out that merely referencing the stem-cell guidelines permits an unjustified, unjustifiable, and inconsistent differential treatment.[63] Furthermore, if any of these guidelines are not incorporated into the final text of the second edition, it is unclear what their status will be after the second edition comes into force; and leaving guidelines outside the TCPS even after a process of updating the TCPS creates a

---

57   For past and current members see PRE, "About Us: Panel Members Interagency Panel on Research Ethics," http://pre.ethics.gc.ca/eng/panel-group/about-apropos/members-membres/.

58   See Marie Hirtle, "The Governance of Research Involving Human Participants in Canada," *Health Law Journal* 11 (2003), 151.

59   Ted Palys and John Lowman, "One Step Forward, Two Steps Back: Draft TCPS 2's Assault on Academic Freedom" (March 15, 2009), http://www.sfu.ca/~palys/Palys-LowmanComments OnDraftTCPS2.pdf, 17.

60   Françoise Baylis, "Formal Incorporation of the *Updated Guidelines for Pluripotent Stem Cell Research* into the Revised *TCPS*" (March 31, 2009), http://www.noveltechethics.ca/pictures/File/ Health_Policy_Private/TCPS%20Documents/Incorporation_of_Stem_Cell_Guidelines.pdf.

61   *Canadian Institutes of Health Research Guidelines for Human Pluripotent Stem Cell Research* (2008).

62   Revised Draft Second Edition, art 12.10.

63   Downie, Letter to the PRE (March 1, 2010); Françoise Baylis, Letter to the Interagency Panel on Research Ethics (February 25, 2010), http://www.pre.ethics.gc.ca/pdf/eng/ Comments2009/45_Baylis,%20Francoise.pdf.

dangerous precedent. A confusing multiplicity of governing documents may proliferate.

In terms of community engagement, concerns can be raised about the sufficiency of the consultations—for example, whether adequate time has been allotted for stakeholder input to be generated, received, and absorbed. 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 and national conferences to receive input.[64] The 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 three-month period of comment initially provided was insufficient.[65] A further draft was released to the public for comment in December 2009, with a comment period of 75 days. The final version is currently being prepared for presentation to the councils.[66] There have, however, been complaints about the concentration of consultations in, and engagement with, academic institutions and about inadequate engagement with community research partners. There have also been complaints that Aboriginal communities have not been sufficiently included in consultations with respect to the preparation of the second edition.[67]

Certainly it is difficult to accommodate every perspective in such a values-laden policy. But flexibility in consultation periods and broad inclusion in consultation processes allow more feedback from the communities to affect the draft policy, the possibility of broader assessments of issues from sundry perspectives, greater awareness of the draft, broader support of the policy from those who may be affected, and fewer negative repercussions later in the policy process.[68] There appears to have been clear recognition that engagement with the public is a necessary element of the process of developing the second edition.[69] But more time could have been allowed for response to the last revised draft of the second edition. Particularly given the fact that it was supposed to be the last draft, perhaps a period of 120 days, instead of the actual 75 days (which, moreover, included the

---

[64] PRE, "TCPS Regional Consultation Tour Schedule 2009" (2009), http://www.pre.ethics.gc.ca/policy-politique/initiatives/docs/CONSULTATION_TOUR_SCHEDULE_2009_ENG.pdf; see also PRE, "Conference Presentations," http://www.pre.ethics.gc.ca/eng/activities-activites/events-actualites/conferences/.

[65] Several comments available online requested an extended period for comment. See, e.g., Sherry Ann Chapman, Letter to the PRE by Community-Campus Partnerships for Health (March 18, 2009), http://www.noveltechethics.ca/pictures/File/Health_Policy_Private/TCPS%20 Documents/CCPH-Letter-031809.pdf.

[66] PRE, "Extension of Release Date and Expanded Opportunities to Comment on Revised Draft 2nd Edition of the TCPS," http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/revised-revisee/Default// (accessed October 10, 2009).

[67] Chapman, Letter to the PRE, 2.

[68] Ibid.

[69] Alain Beaudet, Suzanne Fortier, and Chad Gaffield, "Invitation to Participate in the Consultations on the Draft Second Edition of the TCPS" (News release, December 2008), http://www.nserc-crsng.gc.ca/Media-Media/NewsRelease-CommuniqueDePresse_eng.asp?ID=108.

December holiday season), should have been allowed for comments on the draft, to ensure that all who wished to comment had the opportunity to reflect on the draft and to submit their comments.

As yet, we cannot tell how far the consultations undertaken and the comments received have influenced the final document. A major improvement over the previous process, however, is that the comments on the last draft of the second edition have been posted publicly on the PRE's Web site.[70] This allows for greater transparency and will make it easier to determine, at the end of the process, whether these comments had any impact on the final document. Unfortunately, these and other apparently positive developments with respect to transparency have recently been severely undermined by reports that individuals and groups have been consulted by the PRE outside the public comment window and without any disclosure of the fact or the content of the consultations. Further, there appear to be no plans to make public the version of the second edition of the TCPS submitted by PRE to the councils. There will therefore be no way for observers to determine what effect these supplementary private consultations had.

Finally, the PRE plans to pass its final draft of the second edition to the councils, who will have the final say on the content of the official second edition. Therefore, the same issues that arose at the end of the process of creating the current TCPS are likely to recur, with the councils, despite their conflict of interests, able to make amendments without any public consultations. Indeed, these issues are likely to be exacerbated if the plan stands to keep the version submitted by the PRE to the councils secret, as there will then be no way for observers to determine what changes were made by the councils. With the current edition of the TCPS, the councils undertook a major revision without consultations, thus eliminating to a large extent the commitment to democratic values that had earlier been manifest. It can only be hoped that they will not repeat (and compound) that error in producing this second edition. While at the moment the latter outcome seems likely, there is still time for the Councils to learn from the past and to avoid undermining the democratic values that they should be upholding.

5. Conclusion

In 1998, the three major government funding councils established the TCPS, a historic document in Canada's research ethics landscape. In this article we have sought to assess the process of developing the TCPS through the lens of a set of democratic values. We have also considered the ongoing process of establishing a second edition of the TCPS. We have demonstrated that, in a number of ways, democratic values were manifest in the process of developing the current TCPS and even more so in the process of developing the second edition. However, there were also some serious deficiencies with respect to these values in the process of developing the current

---

[70] PRE, "Public Participation."

edition, and these deficiencies seem to have been exacerbated in the process of developing the second edition, putting the democratic values in even more peril.

There are certainly lessons to be learned from the story of the development of the current TCPS, and the preparation of a second edition of the TCPS could benefit from these lessons. Given where things stand at this stage of the latest process, some of these lessons may be moot (e.g., the councils' conflict of interest in creating the TCPS and the failure to include research participants in the process). But other lessons may still be timely (e.g., transparency around the last phases, reflection of consultations in the substance, and an endorsement of the creation of an independent entity to develop research ethics policy). It can only be hoped that the PRE and the councils will not repeat the mistakes of the past. Time will tell.

Abstract

In 1998, the three major government funding councils put in place the *Tri-Council Policy Statement* (TCPS) to regulate all research involving humans in Canada conducted at institutions funded by the councils. This article examines the process of developing the TCPS, a historic and very important document in Canada's research ethics landscape, and the application of the democratic values of legitimacy, transparency, representation, accountability, and community engagement in that process. The authors argue that efforts were made to ensure basic democratic values in the process but that these attempts should have been taken farther. This examination is a timely exercise in light of the new draft now being prepared to replace the current version of the TCPS. The authors also consider this ongoing process of establishing a new edition and reflect on lessons to be learned.

Keywords: democracy, democratic values, research ethics policy, policy-making process, Tri-Council Policy Statement

Résumé

En 1998, les trois conseils subventionnaires fédéraux publiaient l'*Énoncé de politique des trois Conseils* (EPTC) afin de réglementer toute recherche canadienne avec des sujets humains effectuée dans des institutions financées par ces organismes. Dans cet article, nous examinons le processus d'élaboration de l'EPTC, un document historique très important en matière d'éthique de la recherche au Canada, ainsi que l'application de certaines valeurs démocratiques dans ce processus, à savoir la légitimité, la transparence, la représentativité, l'obligation de rendre compte et l'engagement communautaire. Bien que des mesures ont été prises afin d'assurer la présence de certaines valeurs démocratiques fondamentales dans ce processus, de telles valeurs auraient put être présentes davantage au sein de l'EPTC. Cette constatation est importante, d'autant plus qu'une nouvelle ébauche de l'EPTC viendra bientôt remplacer la version actuelle. De plus, nous examinons le processus d'élaboration d'une nouvelle version et soulignons les leçons à retenir.

Cheluchi Onyemelukwe
Schulich School of Law
Dalhousie University
Halifax, NS B3H 4H9
Canada
E-mail: conyemel@dal.ca

Jocelyn Downie
Schulich School of Law
Dalhousie University
Halifax, NS B3H 4H9
Canada