

Article: "Research Ethics Governance and Political Science in Canada"
Author: Tony Porter
Issue: July 2008
Journal: *PS: Political Science & Politics*



This journal is published by the American Political Science Association. All rights reserved.

APSA is posting this article for public view on its website. APSA journals are fully accessible to APSA members and institutional subscribers. To view the table of contents or abstracts from this or any of APSA's journals, please go to the website of our publisher Cambridge University Press (<http://journals.cambridge.org>).

This article may only be used for personal, non-commercial, or limited classroom use. For permissions for all other uses of this article should be directed to Cambridge University Press at permissions@cup.org.

Research Ethics Governance and Political Science in Canada

The governance of research ethics in Canada, including its research ethics boards (REBs), which correspond to the institutional review boards in the U.S., often is portrayed as an exemplary model of cross-disciplinary cooperation and consultation that is altruistically striving to protect research subjects from abuses in biomedical, social sciences, and humanities research. While there is indeed a great deal of altruism and good intention among those involved in this governance, power and interests also play a role that is of particular concern for political scientists. Governance arrangements have been driven by biomedical research, which is vastly better funded than social sciences and humanities (SSH) research. These arrangements have been imposed on the SSH research community with little sensitivity to the distinctive problems of SSH research, despite concerns about such problems that political scientists and other SSH researchers have expressed for a decade. A recent proposal initiated by major research funders to dramatically

strengthen research ethics governance has generated even more alarm.¹

In Canada research ethics governance is organized around a Tri-

Council Policy Statement (TCPS) that was released in 1998 by the three federal research funding agencies, the Medical Research Council (replaced in 2000 by the Canadian Institutes of Health Research, CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) (CIHR, NSERC, and SSHRC, 1998). These three granting agencies are publicly funded by the federal government and report to it but are governed by councils in which the majority of members are academics or academic administrators, thus providing the agencies considerable autonomy in setting policy. The three councils have required universities to sign memoranda of understanding as a condition of receiving funding. To implement the TCPS universities have established research ethics boards to review and authorize all research involving human participants whether funded by the granting councils or not. While there are other federal rules on research ethics, such as the clinical trial regulations established under the Food and Drugs Act, these tend to be oriented towards health research and it is the

TCPS and its associated institutions that are most important for most SSH research.

In addition to the three granting councils and universities, other important actors in the regime organized around the TCPS include the Interagency Advisory Panel on Research Ethics (PRE), a body of external experts established in 2001 to support the development of the TCPS; the National Council on Ethics in Human Research (NCEHR), a nongovernmental organization that aims to assist REBs in interpreting guidelines, resolving contentious issues, and other similar matters; and the Canadian Association of Research Ethics Boards (CAREB), which represents REBs. NCEHR maintains a database of Canadian REBs that includes 147 university or college REBs. Of these, 85 handle all types of research, 31 focus on biomedical research, and 31 focus on other types of research. NCEHR also lists 111 REBs associated with hospital or other health care institutions and 32 others, most of which are agencies that provide both health and social services.²

Many actors and institutions involved in the management of the TCPS have spoken of it with pride, emphasizing the collaboration between the three councils and their associated research communities that they see it as representing and the flexibility that it provides relative to a set of rules established by legislation. For instance on the release of the TCPS the president of the Medical Research Council stated: "Canada is the first country to produce a comprehensive ethical policy statement for research involving humans in all academic disciplines" (Dr. Henry Friesen, quoted in Chaiton, Paquet, and Wilson 2000, 1).

Contrary to this rosy picture, the history of research ethics governance in Canada reveals recurrent concerns expressed by political scientists and other SSH researchers that indicate the inappropriateness of the regime for SSH research, and that also create the impression that the regime is a juggernaut that continues on its trajectory, relatively impervious to criticism. Even back in 1996, when a draft code was released for consultation, as one history of the process notes, "the reaction from the social sciences and humanities (SSH) and natural sciences and engineering (NSE), was highly, perhaps even violently negative. Generally they criticized the document for being biased to a biomedical perspective" (Chaiton, Paquet, and Wilson 2000, 14). The Canadian Association of University Teachers organized a strong

by

Tony Porter,

McMaster University

campaign against the code's perceived negative implications for academic freedom and critical research (McDonald 2000, 83). Although the draft code was revised substantially in response to these concerns before being issued as a less legalistic TCPS, the types of concerns that had been expressed in 1996 did not disappear.

For instance a 2002 report on a consultation held by the PRE that Professor Grant Amyot made to the Canadian Political Science Association (CPSA) noted, "members of the Panel and other speakers mentioned several problems with the TCPS. They were very well aware of the 'resistance' to the document on the part of researchers in the humanities and social sciences, who see it as imposing a clinical model on their very different research project." Professor Amyot's report documents concerns with the unclear exemption in the TCPS for "public policy issues," inconsistency and conservatism in the application of the TCPS by REBs, the inappropriateness of written consent and preapproved set questions for much political science research, the "ethics review chill" on graduate student empirical research, and questions about the appropriateness of the TCPS guidelines for research in aboriginal communities (Amyot 2002).

Concerns such as these led the PRE to establish in 2003 a Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC), which called for further consultation. Then in 2004 it issued a report, *Giving Voice to the Spectrum*, which was strongly critical of the TCPS and its impact on qualitative SSH researchers, highlighting the types of concerns mentioned above. As the report noted, "stated simply, the TCPS does not 'speak' to their experience, leaving REBs that may lack appropriate breadth of expertise free to impose default assumptions that threaten free inquiry for no ethical gain" (SSHWC 2004). After yet another round of consultations the SSHWC issued a second document, *Qualitative Research in the Context of the TCPS*, for which the consultative period ended in April 2007. The goal of the SSHWC was then to propose specific revisions to the TCPS based on this most recent consultation.

In addition to the concerns about qualitative research documented by the SSHWC there are further concerns that are especially relevant for political scientists. The SSHWC report did not devote much attention to the problems in applying arrangements originally designed to protect vulnerable subjects in clinical trials to powerful figures who in being interviewed by political scientists are also treated as research subjects who must be protected. Ostensibly the TCPS is sensitive to this problem, stating that

REBs should recognize that certain types of research—particularly biographies, artistic criticism or public policy research—may legitimately have a negative effect on organizations or on public figures in, for example, politics, the arts or business. Such research does not require the consent of the subject, and the research should not be blocked merely on the grounds of harms-benefits analysis because of the potentially negative nature of the findings. (CIHR, NSERC, and SSHRC 1998, i9)

However in practice REBs continue to subject public policy research to review, including requiring informed consent.

For instance, in preparing this article I was required to obtain research ethics authorization from my REB before being allowed to interview people involved in the governance of research ethics, including members of my REB who were providing the authorization and other academics who I might wish to ask for their assessment of research ethics governance. While a signed consent form was not required, I was instructed

to document consent with a log, and to make explicit to interviewees their right to withdraw from the research. I was advised to inform interviewees of a plan for destroying the interview data. My proposed interview questions (which I was required to submit but was permitted to alter in the course of interviewing) were carefully scrutinized. My responses to the questions on the application form together with follow-up e-mail correspondence exceeded 4,000 words, within the target word length for the article I was conducting research for.

Although my REB authorized my research in less than two weeks, not all REBs are equally speedy or sensitive to public policy research, and given the time pressures experienced by most scholars the burden of even this relatively expedited review can deter research. Current arrangements mandating informed consent and destruction of data can also be problematic for survey research conducted by political scientists. The destruction of data can have negative consequences for the historical record and for the investigation of problems with academic integrity. In general the part played by SSH research in democracy, which includes contributing to the public's ability to express itself and holding powerful figures accountable, has not been balanced against the overwhelming emphasis of the arrangements on the protection of vulnerable participants from the type of abuses that are much more common in biomedical research.

In 2007, before the revisions to the TCPS that the SSHWC was preparing could be finalized, a new process for reworking the governance of research ethics in Canada took center stage. This new process was initiated by a Sponsors' Table for Human Research Participant Protection. It included members such as the Alberta Ministry of Health and Wellness, the Association of Canadian Academic Healthcare Organizations, and Canada's Research-Based Pharmaceutical Companies, a total of 14 sponsors, 10 of which are health related. The other four included the Canadian Federation for the Humanities and Social Sciences, the Association of Universities and Colleges of Canada, the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council. The Sponsors' Table is chaired by Dr. Michel Brazeau, former CEO of the Royal College of Physicians and Surgeons of Canada. To many observers the biomedical representation on this body heavily outweighed representatives of SSH research. The Sponsors' Table created an Experts Committee that in 2007 issued a draft report, *Moving Ahead*. This report proposed the replacement of the TCPS with a drastically reworked and strengthened set of governance arrangements.

Central to the *Moving Ahead* proposal was the creation of a new body, a Canadian Council for the Protection of Human Research Participants (CCPHRP), a nongovernmental organization to be established under the *Corporations Act*. The CCPHRP would have a board of up to 15 directors, appointed for their expertise in research ethics. These directors would be accountable to and appointed by members, who would initially be chosen by the Sponsors' Table and in the longer run, be "drawn from organizations committed to fostering human research participant protection in Canada" (Experts Committee for Human Research Participant Protection 2007, 47)—probably in practice a set of organizations quite similar to the existing membership of the Sponsors' Table. The annual cost of this new council was estimated at CAN \$9–10 million, supporting a staff of 51. *Moving Ahead* also proposed that a system of accreditation be put in place. The benefits it envisioned resulting from these changes included greater consistency in implementation and education, more efficient review of multi-site research projects, wider coverage to include research not presently covered by the TCPS, and a greatly strengthened capacity for monitoring and compliance, "including issuing

warnings, mandating education programs, and, ultimately, withdrawing accreditation. Other penalties and enforcement mechanisms should be developed and clearly identified" (59). The report called for a single system applicable to all research, noting, "Not only is there high risk biomedical research and low risk social science and humanities research, there is also low risk biomedical research and high risk social science and humanities research. Therefore, while it is reasonable to argue that the level of scrutiny applied to research should vary by level of risk, it is not reasonable to argue that it should vary by type or discipline" (40).

While not all the responses to the *Moving Ahead* report have been made public, some are harshly critical. The SSHWC, noting the hundreds of submissions from SSH researchers that they had received "that document the imposition of a biomedical framework on their work and their objections to this imposition," posted on the web site of one of their members:

we believe that this structure will actually entrench—rather than reverse—the problems that social sciences and humanities (SSH) scholars face in this country . . . We have worked tirelessly to identify the problems with the imposition of just this type of biomedical ethics model on the SSH in Canada, so we are saddened and frustrated that this is the model presented here for "solving" our existing problems (Blackstone et al. 2007).

The Association of Universities and Colleges of Canada's (AUCC) response, a copy of which AUCC provided me, was also critical of the *Moving Ahead* proposal. It noted:

In the report, we do not see evidence of specific problems justifying the need for accreditation, or proof that accreditation adds significant value in dealing with such problems, or proof that accreditation needs to apply to all research, not just high-risk research . . . Universities are concerned that a new council would involve new controls and bureaucracy, adding considerably to the compliance burden and the expense of the system, raising the prospect of "regulatory creep," and creating problems from the viewpoint of accountability.

The response questioned the implication in the *Moving Ahead* report that a change of this scale was needed, pointing out that universities had already made very substantial investments in research ethics governance.

At present it is not at all clear what will happen with these developments in the governance of research ethics in Canada and their impact on political scientists and other SSH researchers. In June 2007 the board of directors of the CPSA decided to initiate a working group chaired by Professor Jacqueline Best to consider the implications for political scientists of the governance of research ethics, and later in that year it agreed to host a research ethics section of its web site, to send a letter to its membership setting out concerns about research ethics governance, and to approve a response to the *Moving Ahead* report that also included such concerns.³

How best can we understand this ongoing history of research ethics governance in Canada? How do we reconcile the enthusiasm of some for a single regime that covers biomedical and SSH research and the hostility of others to this idea? How did accreditation make its way so prominently onto the agenda despite the lack of strong support for it on the part of universities?

One possible explanation is that those promoting the strengthening of a single unified research ethics regime are farsighted and principled in their recognition of the ethical need for safeguards in all research and the efficiency that can accompany a strong unified system. As one report characterized the origins of the process, "it was generally recognized that there are common

moral values which govern all types of research involving humans" (McDonald 2000, 81). Certainly there are legitimate ethical concerns about risks to research subjects that can accompany political science and other SSH research, such as publishing information that could harm users of illegal drugs or critics of authoritarian governments.

Anyone who becomes involved in research ethics governance will encounter remarkably committed and caring individuals who devote large amounts of uncompensated time, without which the present regime could not survive, who contend with harsh criticisms from colleagues angry at the experience of submitting research ethics applications. They often add to the burden of their research ethics governance responsibilities by engaging in extensive consultation and training with researchers. Professor Vincent Sacco, a sociologist on the Sponsors' Table's Experts Committee, told me in an e-mail on March 6, 2008, that the committee took the issue of the impact of its proposals on SSH research very seriously:

In many ways, this was the most vexing issue with which we dealt and the one which probably consumed the greatest amount of time. I think at the outset, many of us would have reasoned that there really was a need for formal disciplinary distinctions with respect to the assessment of risk or with respect to the construction of assessment protocols. However, months of discussion led many of us to the view that while such a distinction seems reasonable in a priori way, it was really not defensible.

Moreover, in response to concerns about the dominance of biomedical approaches in the process, he stated, "I can say with complete confidence, that the members of the committee were well aware of the complexities of the situation and made every effort to move beyond traditional modes of disciplinary defensiveness and promotion."

While these positive characterizations of Canadian research ethics governance should be part of the story, our understanding of the serious problems with the regime can be improved by considering the political economy of the regime. There are numerous indications of the preeminent role played by biomedical actors in the regime. In addition to the heavy health orientation of the Sponsors' Table membership that was noted above, this is evident in NCEHR, the agency responsible for advising REBs, which was initiated by the Medical Research Council, and which had previously been named the National Council on Bioethics in Human Research (Chaiton, Paquet, and Wilson 2000, 12–15). The NCEHR is sponsored by four organizations, three of which are health related. In 2008, of the 13 members of the Panel on Research Ethics, which is responsible for developing the content of the TCPS, 10 have some institutionalized health connection, such as being on staff at a hospital, teaching in or being appointed to a medical or health program, representing patients, or sitting on the advisory board of CIHR.⁴ CAREB, which represents REBs, was initiated during discussions at the Medical Research Council (MRC) Task Force on Monitoring in February 2000, and Dr. Raphael Saginur of Ottawa Hospital chaired the Interim Working Group that launched CAREB and became its first board of directors.⁵ The much more active role Health Canada has played as compared to other government departments can also be noted. Of the 290 REBs that the NCEHR database lists, 111 are associated with hospitals or other health care institutions and there is no comparable set of SSH-oriented REBs outside the universities and colleges.

While some of this greater involvement of biomedical actors can be interpreted as an appropriately ethical response to the greater severity of ethical problems in biomedical research, it also reflects a familiar problem in the literature on collective

action. The intense concern of biomedical researchers with ethical issues, especially when supplemented by the tendency of such research to be carried out in teams, enhances their capacity and willingness to invest time and resources in research ethics governance. In contrast ethical concerns about the impact of research ethics on research subjects for individual SSH researchers are less common, more complex, and more dispersed, reducing the probability that SSH researchers will devote time and resources to research ethics governance, and increasing the probability that where the interests of biomedical and SSH researchers diverge the former will win out. The political economy of risk management exacerbates this. Universities and REBs are well-integrated institutions that can be exposed to the negative reputational consequences and legal liabilities associated with the very visible errors that might result from research, even if individual REB members endeavor to not allow these to influence their judgment. Indeed the TCPS (CIHR, NSERC, and SSHRC 1998, 1.9) states, “the maintenance of satisfactory records and documentation is essential. Failure to do so may expose researchers and institutions to legal liability.” Thus it is not surprising that the regime tends to devote more attention to preventing the types of problems that might be associated with such risks than to the less visible costs associated with research that is abandoned in anticipation of the burden of ethics review or the time that is spent by researchers in preparing applications, costs that primarily fall on dispersed and harried individual researchers (Zywicki 2007).

The political economy of clinical trials and health research funding is closely related to these collective action problems. Caulfield (2005, 58) cites industry research that documents severe problems in recruiting participants in clinical trials, with the resulting delays in bringing drugs to market that are estimated to cost from \$600,000 to \$8 million per day of delay. Efficient research ethics governance is important for universities and political jurisdictions as they compete in a global market for health research dollars. In a 2006 Health Canada consultation on its regulations of clinical trials involving human subjects, a majority of respondents indicated that they were considering conducting research in other countries due to Canadian regulatory costs, the difficulty of running multi-site trials in Canada, and the potential for higher enrollment rates in trials elsewhere. Accreditation was seen by 71% of respondents as a desirable way to address challenges to the system (Health Canada 2006). Low cost or laxity is not likely to be the sole consideration in evaluating the attractiveness of research ethics regimes for health research since recruitment of research subjects will be facilitated by credible signaling that these subjects’ interests will be protected. Moreover governments are unlikely to allow clinical trials without some assurance that citizens will be protected. Features of research ethics governance such as standardization, centralization, multi-site applicability, and trans-jurisdictional credibility and recognition are all likely to be important. The revenues at stake in clinical research provide substantial incentive and capacity to produce research ethics arrangements with these attributes. The *Moving Ahead* proposals would very significantly enhance these attributes in the Canadian regime.

More broadly, public and private health research has been rapidly growing in importance, has attracted increasingly impressive amounts of funding, and has become increasingly cross-disciplinary. Health R&D as a percent of gross domestic expenditures on R&D in Canada increased from 14% in 1989 to 23% in 2006 (Statistics Canada 2007, Table 1-1). During this same period the share of funding of health R&D from business sources increased from 18% to 25% and the share from foreign sources from 2% to 14%, while the share of funding from higher education sources decreased from 39% to

28% (Statistics Canada 2007, Table 1-2). In 2006 total health R&D expenditures were \$6.6 billion (Statistics Canada 2007, 4), while R&D expenditures on social sciences and humanities in the higher education sector totaled \$2.2 billion (Statistics Canada 2008). In 2006–2007 CIHR’s grants and awards expenses totaled \$810 million, while SSHRC’s expenditures on SSH research totaled just under \$306 million (CIHR 2006–2007, 54; SSHRC 2006–2007, 9). Health costs consume a huge proportion of government budgets and health concerns preoccupy citizens and consumers. A great many health problems have social or policy dimensions that involve biomedical researchers conducting SSH research or SSH researchers conducting health research. In Canada the transformation of the Medical Research Council into the CIHR reflected these changes. Having a unified research ethics regime will complement these changes as well.

Given these political economy considerations it is not surprising that the growth of a biomedically oriented but unified research ethics regime has appeared as a seemingly unstoppable trend in Canada. Given the integration of U.S. and Canadian markets and research communities it is also not surprising that research ethics governance should be more influenced by U.S. models than by other jurisdictions, such as the United Kingdom, where the Economic and Social Research Council’s *Research Ethics Framework* states, “Other ethical frameworks for research on human subjects, such as that which addresses biomedical research, may not be appropriate, which is why a framework specific to social science is necessary” (2006, 1). While the ethical motivations of those involved in research ethics governance who have promoted the unified model are undoubtedly important, these alone cannot plausibly account for the recurrent failure of the regime to act on the concerns of SSH researchers. Unfortunately these ethical motivations have tended to complement the political economy factors rather than challenging them.

The fate of research ethics governance in Canada remains unclear. It is certainly possible that the TCPS will be altered to reflect the concerns of SSH researchers that have been identified by the SSHWC. However the ongoing history of the regime suggests that those interested in the type of strong unified model set out in the *Moving Ahead* report will press ahead, which for SSH researchers will drastically increase the burden of research ethics governance with no significant offsetting benefits, further reducing flexibility, including making a strategy of noncompliance impossible. REBs are under considerable strain and probably are at the limit of the capacity of their reliance on voluntarism to handle the large volume of research authorizations that the regime directs to them. While it may seem to some advocates of the strong unified model that their support base in biomedical researchers and funders is powerful enough to push ahead despite resistance, it is likely that at a certain point opposition on the part of SSH researchers will increase and the legitimacy of the arrangements will be damaged, as will the ability of the regime to elicit the degree of voluntarism and acceptance that is needed to sustain it.

Hopefully before that occurs political scientists and other SSH researchers, drawing on their own experiences and that of colleagues in the U.S. and other countries, finally will be able to elicit a meaningful response from the current regime and to obtain arrangements that achieve the appropriate balance between protecting vulnerable research subjects and facilitating research, including the types of political research that help hold powerful figures accountable or provide opportunities for weaker citizens to express their identities and interests, both of which are crucial contributions to democracy that research ethics governance in Canada has so far failed to adequately recognize.

Notes

1. I sit on a working group on research ethics of the Canadian Political Science Association and the Ethics Committee of the Canadian Federation for the Humanities and Social Sciences. The views expressed in this article do not necessarily reflect the views of those bodies.
2. The database is at www.ncehr-cnerh.org.

3. The CPSA's web site, with its pages on research ethics, is at www.cpsa-acsp.ca.
4. <http://pre.ethics.gc.ca/english/aboutus/panelmembers.cfm>.
5. See "Frequently Asked Questions," www.careb-accr.ca/?q=node/4.

References

- Amyot, Grant. 2002. "Report on Consultation Meeting on the Tri-Council Policy Statement on Ethical Conduct for Research Involving Human Subjects." Canadian Political Science Association, May 29. www.cpsa-acsp.ca/template_e.cfm?folder=about&page_name=ethics_amyot_e.htm (April 18, 2008).
- Blackstone, Mary, Lisa Given, Bernard Keating, Joseph Levy, Michelle McGinn, Ted Palys, and Will van den Hoonaard. 2007. Comments on the Draft Report of the Experts Committee for Human Research Protection in Canada. Social Sciences and Humanities Working Committee. www.sfu.ca/~palys/SSHWCResponseToMovingAhead-final.pdf (April 23, 2008).
- Canadian Institutes of Health Research (CIHR). 2006–2007. *Touching Lives*. Annual Report. www.cihr-irsc.gc.ca/e/34768.html (April 18, 2008).
- Caulfield, Timothy. 2005. "Legal and Ethical Issues Associated with Patient Recruitment in Clinical Trials: The Case of Competitive Enrolment." *Health Law Review* 13 (2–3): 58–61.
- Chaiton, Alf, Gilles Paquet, and Christopher Wilson. 2000. "Governance of the Ethical Process for Research Involving Human Subjects." Centre on Governance, March 15. www.christopherwilson.ca/papers/final_ethics_report.pdf (April 10, 2008).
- CIHR, NSERC, and SSHRC. 1998. "Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans." With 2000, 2002, and 2005 amendments. www.ncehr-cnerh.org/english/code_2/ (April 18, 2008).
- Economic and Social Research Council. 2006. *Research Ethics Framework*. www.esrcsocietytoday.ac.uk (April 1, 2008).
- Experts Committee for Human Research Participant Protection in Canada. 2007. *Moving Ahead*. Draft Report, August 15. www.hrppc-pphrc.ca/english/consultation.html (April 1, 2008).
- Health Canada. 2006. "Clinical Trials Regulatory Framework Review: Results of 2006 E-Consultation." Health Products and Food Branch, December. www.hc-sc.gc.ca (April 9, 2008).
- McDonald, Michael. 2000. "The Current Context of HRIHS." In *The Governance of Health Research Involving Human Subjects (HRIHS)*, ed. Michael McDonald et al. Ottawa: Law Commission of Canada.
- Sciences and Humanities Research Council of Canada (SSHRC). 2006–2007. *Annual Report*.
- Social Sciences and Humanities Research Ethics Special Working Committee (SSHWC). 2004. *Giving Voice to the Spectrum*. pre.ethics.gc.ca/english/workgroups/sshwc/SSHWCVoiceReportJune2004.pdf (April 23, 2008).
- Statistics Canada. 2007. *Science Statistics*. Catalogue 88-001-XIE, March.
- Statistics Canada. 2008. "Gross Domestic Expenditures on Research and Development." Table 358-0001, CANSIM database.
- Zywicki, Todd J. 2007. "Institutional Review Boards as Academic Bureaucracies: An Economic and Experiential Analysis." Special Issue, *Northwestern University Law Review* 101 (2): 861–95.