

# *From Code to Policy Statement: Creating Canadian Policy for Ethical Research Involving Humans<sup>1</sup>*

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## **Introduction**

While the history of U.S. and international research ethics is well documented, little has been written on the formation of Canadian policy and practice.<sup>2</sup> Most commentary on Canadian policy has centred on content, particularly on gaps and shortcomings.<sup>3</sup> This is an unfortunate situation with both practical and intellectual implications. If Canadians are to understand and assess our policies and practices in this area, it is vital to have a sound historical understanding of our situation. Otherwise policy-making is likely to be erratic and ineffective. Intellectually the history of research ethics has become a subject in its own right. Beyond Canada the lack of a good Canadian history adds to the misperception that all national policies are clones of Belmont. It is vital, then, to have a sound intellectual history of key periods in Canadian research ethics policy.

My intention is to provide a sketch of the formation of the 1998 *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS)*.<sup>4</sup> My primary focus will be on process and contextual elements with less emphasis on content issues. This is in part due to space limitations – each of the multiple content issues deserve detailed treatment in their own right. However, I also believe that what is most lacking at this stage is a discussion of process and context.

I have several reasons for focussing on *TCPS*. The *TCPS* is now Canada's policy for research ethics in most of

the public research sector even though other policies (particularly *ICH-GCP*) are also relevant.<sup>5</sup> Moreover, issues arising during the *TCPS* process continue to this day. This history may also have particular relevance as a new formulation of the *TCPS* is being advanced for fall 2008,<sup>6</sup> and the Sponsors' Table continues its deliberations on research governance.<sup>7</sup>

The formation of any policy for advancing ethical practice is a complex matter requiring a context sensitive balancing of matters of principle with practical considerations. The challenge is to balance these in a realistic and ethical way. Locating our situation historically helps answer the question of whether a good balance has been struck. In this paper I will first address two questions: what were the circumstances that led to the creation of the *TCPS* and how was the *TCPS* created? In the final section I will draw some lessons from this history.

This paper draws on my experience as a member and deputy chair of the Tri-Council Working Group on Ethics (TCWG) – the group that drafted the document (the "Code") that led to the *TCPS*. I draw also on the subsequent work that my colleagues and I did for the Law Commission of Canada (LCC) and on a CIHR-sponsored study on Canadian governance of ethical health research involving humans and a comparison of US and Canadian governance.<sup>8</sup>

As part of the latter, Dr. Fern Brunger (MUN) interviewed key participants (n=9) in the formation of *TCPS*. I have



also drawn on documentation from the TCWG period and afterwards.

## 1. Circumstances Leading to the TCWG

Prior to the *TCPS*, the key Canadian policies for governing research involving humans were the 1987 *Medical Research Council Guidelines on Research Involving Human Subjects*<sup>9</sup> and the 1979 *Social Sciences and Humanities Research Council Guidelines*<sup>10</sup> which originated with Canada Council in 1976. Guy Rocher, who was involved in the Canada Council process, says that the SSHRC Guidelines “did not have much influence on social sciences and humanities researchers, the majority of whom were unaware of their existence, including members of the research ethics committees of Canadian universities.”<sup>11</sup> The third federal research council, the Natural Sciences and Engineering Research Council (NSERC), had no guidelines in this area even though it funded research in such sensitive areas as experimental psychology and biomedical devices.<sup>12</sup>

Closely connected to the MRC and its *Guidelines* was the National Council on Bioethics in Human Research (NCBHR). NCBHR was an expert group of bioethicists, REB members, and health researchers sponsored by the Royal College of Physicians and Surgeons and the MRC.<sup>13</sup> As will be seen shortly, some members had aspirations to play leadership roles in the creation of national policy, which led to important tensions later. Suffice it to say that MRC tended to view the NCBHR as a support and service organization assisting biomedical REBs. Whereas bioethics members of the NCBHR took the view that they were a national ethics body primarily charged with formulating national policy. The NCBHR did perform both roles including conducting site visits to REBs and producing policy statements on such issues as informed consent and research with children.<sup>14</sup>

Four sets of factors favoured establishing a single unified policy rather than continuing with separate area-specific policies. First, there were contextual factors that remain relevant today. These include growing global competition in research and development (R & D) with R & D being increasingly seen as a major driver of economic growth and community well-being. As well, there were important new areas of research. For example, within two years of the adoption of the 1987 *MRC Guidelines* a new set of guidelines had to be created to cover somatic cell gene therapy research.<sup>15</sup> New

research tools including computers and biobanks raised important questions about privacy and consent to future unspecifiable use of data. In addition there were new modes of interdisciplinary research that transcended the medical-behavioural divide. This raised the question of whether the MRC or the SSHRC *Guidelines* were applicable and the prospect that such research would be stymied by discordant rules and REBs.<sup>16</sup>

Second, there were significant changes in ethical perspectives around human subjects research. In the period following the 1966 publication of Henry Beecher’s landmark paper in *NEJM*, the main task was seen as protecting actual and potential subjects from excessive research risks.<sup>17</sup> By the late 1980s, activists, including feminists and people with HIV or breast cancer, pushed strongly to include disease-specific groups as well as women and children in research so that they might reap the benefits.<sup>18</sup> As well, norms in some areas of research were seen as unsatisfactory or unsettled (e.g., emergency room research and research involving Aboriginal people).

Third, various international developments favoured a comprehensive re-evaluation of national policy. The US model with the Common Rule based on the Belmont Report had spread world wide. Canada was the largest foreign recipient of NIH funding.<sup>19</sup> Since institutions receiving NIH funding had to provide assurance that US standards were met for NIH projects, there was pressure for harmonizing standards. Indeed, one informant noted that in the 1980s there were informal discussions about bringing Canada’s medical research under the US Federal assurance system. This would have involved using the Office for Protection from Research Risks (OPRR). This however raised the acutely embarrassing question of why Canada lacked a domestic system of assurance and how, without one, could the MRC assure the OPRR of Canadian compliance with US rules. There were also important ethical challenges with regard to research in developing countries represented in the 1991 CIOMS *Guidelines*.<sup>20</sup>

The fourth set of factors was domestic. The MRC was launched on a trajectory that would eventually lead in 2000 to the establishment of the CIHR - moving from a model supporting basic biomedical research towards one of supporting health research broadly conceived. In 1993 there was the important report of the Royal Commission on New Reproductive Technologies that



highlighted ethical and social challenges in a major area of medical research.<sup>21</sup> In 1990 an NCBHR task force headed by T.D. (Douglas) Kinsella revealed significant deficits in human research protection in Canadian medical faculties.<sup>22</sup> The 1986 Supreme Court decision in *Eve* also raised important question about whether more than minimal risk paediatric research was legally permissible.<sup>23</sup>

Moreover, by the early 1990s universities were developing a patchwork quilt of local human research protection policies which created new obstacles to multi-site research. It also raised a challenge to Canada's three councils – whether researchers at funded institutions would be expected to play by local or national rules. The absence of NSERC from human research protection provisions was clearly anomalous. Finally in the early 1990s, the three councils had developed a uniform policy on research integrity.<sup>24</sup> The moment seemed ripe for the development of a common policy on the ethical conduct of research involving humans.

Thus, in 1994 the three Council Presidents created the Tri-Council Working Group on Ethics (TCWG) to address these issues. Informants report that at the start there was ambiguity about whether the mandate was to update *MRC Guidelines* or to do something wider in scope covering research in non-medical as well as medical areas. The group formed was quite interdisciplinary with members drawn from medicine, law, bioethics, biomedical engineering, and the social sciences.<sup>25</sup> The TCWG had the "...mandate to develop new policies and regulation to replace the Councils existing guidelines for research involving humans."<sup>26</sup> The move then was for more prescriptive and enforceable standards to replace current "guidelines".

## 2. History of the Working Group: the Four Seasons

In reflecting on the history of the TCWG, the metaphor of the four seasons seems à propos. I was there for summer, fall and winter. My account of spring is drawn from documentation, interviews and discussions with those who were there.

### Spring

In the "spring" phase which lasted about a year, there were, so to speak, spring showers and even late winter blasts. Fred Lowy, head of the University of Toronto

Centre for Bioethics, was the first chair. The TCWG held multiple one-day meetings, but little in the way of text was produced. When Fred Lowy became Principal of Concordia University, the Council Presidents appointed Jean Joly (then head of Epidemiology at Laval) as the new chair. Some members felt that the committee should be chaired by Lynch, an eminent Canadian bioethicist and President of NCBHR. After a very difficult meeting two NCBHR members – Lynch and Klassen – resigned over the choice of Joly. I was one of the replacements. The other was Peter Walker (then Dean of Medicine at the University of Ottawa).

### Summer

I call this season "summer" because it was a very productive time with only passing storms. This "summer" ran from June 1995 through July 1996. The initial three-day meeting in June 1995 was the turning point from spring to summer. While there was a strongly argued disagreement about one aspect of REB procedures (viz., whether decisions had to be unanimous or only with majority support), there was a genuine climate of mutual respect. By the end of the meeting, consensus was achieved on the disputed procedures and even more importantly on a comprehensive plan for developing other sections of the document. This was the Working Group's first of many multi-day meetings. There was a high energy level and commitment to developing "new policies and regulations".

The challenge of designing a policy for diverse disciplines and methodologies was formidable. Subject matter, methods, language, tone, and intellectual cultures differ across, and even within, disciplines. There are diverse modes and contexts for engaging human subjects – interviews in qualitative research and oral histories, recruitment to clinical trials, the use of tissue samples, engagement of participants in a psychology experiment or a marketing study, etc. The challenge was to identify elements shared by multiple areas of research (e.g., harm/benefit, informed choice, scholarly soundness) while respecting legitimate disciplinary differences. Two examples stand out here. The first was the use of deception in research. This was a standard technique especially in psychology where the rationale was that sound experimental design requires naive subjects. Given the reaction post-Beecher to deceptive medical research, deception was anathema to the MRC community. The second example concerns scholarly review. In health



research, the dictum is that good science is a necessary condition for ethical research. In the social sciences, ethical review of the scholarly merits of research smacks of prior censorship. In both cases, TCWG used minimal risk as an important benchmark for requiring increased oversight of social science research while maintaining more rigorous standards (good science and non-deception) for biomedical research.

Discussions were lively – at times there was more the atmosphere of an advanced seminar than of policy making. What I remember well was the openness to new ideas. This was exemplified in the discussion of tissue banking. The meeting began with a discussion of tissue samples as discarded and hence abandoned materials and moved to a totally different paradigm of tissues in terms of their meaningfulness to subjects; thus, for some, tissue is simply tissue while for others it is personal and even sacred. The substance of that discussion is reflected in the wording of the second paragraph of Section 10 “Human Tissue” of *TCPS*.<sup>27</sup>

By March 1996, TCWG produced a document for public distribution. It was entitled the *Code of Ethical Conduct for Research Involving Humans*.<sup>28</sup> It had eighteen sections covering the full gamut of research involving humans. Considering the fact that, with the exception of the section on Ethics Review (now Section 1 of the *TCPS*), work substantively began at the June 1995 meeting, this was remarkable progress. Three factors were important here. The first was the remarkable leadership and organizational skills of the Chair, Jean Joly. The second was the formation of a three-person Editorial Committee (Joly, Kinsella, and McDonald) to coordinate, edit and, for a few sections, serve as primary authors. Third, there was extraordinary effort put in by members of the Working Group. There were face to face meetings of the Working Group nearly every month interspersed with meetings of the Editorial Committee. Individual members were assigned to prepare and revise various sections.

The choice of a name for the document was a matter of considerable discussion. TCWG wanted a stronger term with more prescriptive force than “guidelines”. “Code” seemed a good choice even though the word has significantly different resonances in French than it has in English. In a draft 1997 article for NCEHR’s publication *Communiqué*, I underlined the basic thrust of the Code as

a type of professional self-regulation on the part of the research community:

We saw the *Code* as a *via media* between current guidelines and legislation. Hence, we chose to call our finished product a “code” as a reference to a “professional code” or “*déontologie*.” Our model was that of a profession regulating itself in the interests of its clients and the general public. In this case, the research community would be regulating itself through the three Research Councils in the best interests of research participants and the general public.

Ergo, the model of a profession that assures its members’ **trustworthiness** and **accountability** (emphasis in the original).<sup>29</sup>

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The cover of the *Code* included an apt quote from Rabelais: “Science without conscience spells but the ruin of the soul.” “Science” here was meant as an inclusive term for all scholarly modes of knowledge acquisition. This was part of the substantial effort made to write a document that would be relevant for the diverse communities of researchers potentially covered by Tri-Council. Prescriptively the document was meant to apply to all research involving humans conducted at institutions receiving Tri-Council funding and not just research directly sponsored by Tri-Council.

In the face of resistance to its distribution on the part of the Councils, the TCWG made a determined effort to ensure wide distribution of the draft *Code* to get adequate feedback from a full spectrum of affected researchers. It did not want to repeat the experience of the working



group (led by Bernard Dickens) that had drafted the 1988 *MRC Guidelines* only to find its work buried and replaced by a text drafted by two federal bureaucrats. Approximately 14,000 copies of the *Code* were distributed to every institution funded by the Councils and to all the academic groups that could be identified.

## Fall

If the previous phase of the TCWG was summer with sunny skies, the third was fall with lowering temperatures and gathering storms. The fall season ran from August 1996 to July 1997 when the final version of the *Code* was submitted.<sup>30</sup>

The results of the aforementioned consultation were substantial – over 3000 pages of comment in over 250 interventions, some as long as 50 pages.<sup>31</sup> Many interveners wanted specific changes made in particular

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sections for their areas of research while other comments were general – raising questions of language, tone and scope. Many comments were favourable, but others were negative, even inflammatory. All comments were carefully catalogued according the relevant section of the *Code* and then analysed by TCWG members.

In early fall 1996 the chair of TCWG sent a communiqué to the scholarly community indicating that the TCWG would be responsive to concerns about substance, tone and language.<sup>32</sup> One major concern was to provide more examples of how specific *Code* provisions would apply to diverse areas of research. For example, changing the section on genetic research would have implications for the section on tissues and on data banks as well as the section on collectivities. These in turn had to be linked to a clear and coherent ethical framework.

Because of strong concerns from the social sciences and humanities communities, new members (some of whom

were quite sceptical about the *Code* endeavour) from that group were appointed to the Working Group. As well, new members were needed to replace members, who for work related reasons, left the committee. While there still was an exceptional degree of solidarity on the TCWG, the work load and pressures from Councils and critics took their toll. In December 1996 at a meeting in Toronto, the chair, Joly, suffered a serious medical mishap and had to be taken by ambulance to hospital. As deputy chair I took over for a period of time. While Joly fortunately recovered, pressures were significant – members of the Editorial Committee worked virtually full time on the *Code*.<sup>33</sup> Relations between TCWG and Council staff became testy. At one point both Joly and I offered our resignations due to the perceived lack of support from the Councils who seemed to want to rush the process to a hasty completion.

In response to some criticisms TCWG trimmed its sails to the prevailing winds. For example, many social scientists and humanists were fearful about REB consideration of the scholarly merits of research proposals. Given these concerns, TCWG differentiated scholarly review requirements for biomedical from non-biomedical research (exempting minimal risk social sciences and humanities research from scholarly review). The compromise was noted in the text, and the hope was expressed that the assurance of scholarly merit would eventually be the norm for all risk levels. In other cases TCWG held to its earlier position, for example, retaining a section on collectivities – despite the threat from Canadian Association of University Teachers (CAUT) that it would “go to the wall” to block that section.<sup>34</sup>

During this fall phase, there were two important external developments in research oversight. The first was the negotiation by the U.S., Europe, and Japan of new provisions for clinical trials in the form of the Good Clinical Practice guidelines under the International Convention on Harmonization.<sup>35</sup> Only after this was a *fait accompli* was the TCWG notified. It should be noted that we still took a different position on placebo than prevailed there by maintaining with Freedman and others that placebo was not acceptable where there was a standard efficacious therapy.<sup>36</sup> Second, there was the report of the US presidential Advisory Commission on the Human Radiation Experiments (ACHRE) which revealed a pattern of both wilful and inadvertent disregard of subjects’ interests. This served as a sobering reminder of the importance of the task at hand.<sup>37</sup>



In terms of its philosophical stance on human research protection, TCWG adopted a participant-centred perspective. Researchers were encouraged to understand and deal sensitively with research subjects' actual hopes and fears whether well-grounded or not. Moreover in line with the ACHRE report, it was noted that "...in many cases prospective participants are more strongly motivated by their trust in the researchers than by the cool and careful assessment of the pros and cons of research participation."<sup>38</sup>

The *Code's* ethical framework centred on a context sensitive interpretation of the Kantian maxim which requires one to treat persons as ends and not merely as a means. This was phrased as follows:

It must be emphasized that **respect for persons** is respect for real life individuals, socially and historically situated, and not the idealized, abstracted, and decontextualized rational beings posited in various theories (e.g., the ideally rational agent, the egoistic consumer or the compliant patient). This means that respect must be shown for people as they identify themselves both as individuals and as members of groups. Factors such as race and gender, membership in a collectivity, and personal and social relationships can all have implications for the ethics of research involving humans.<sup>39</sup>

Accordingly, the TCWG was highly attentive to the situation of vulnerable communities in research and so refused on principle to design a code on collectivities that applied exclusively to research involving Aboriginal people. TCWG had neither Aboriginal members nor a mandate to speak for the many Aboriginal peoples of Canada.<sup>40</sup>

As the TCWG moved toward completion of the second draft of the *Code*, it gave attention to questions of implementation and suggested to the Councils that they provide help to institutions during the transition to the new rules. The suggestions were ignored.<sup>41</sup>

Completing revisions to the *Code* was a challenge. As noted there was the Chair's illness and tension with Council representatives (undoubtedly due to pressures they were feeling from unhappy members of their research communities). The revisions to the first

version were extensive to take into account suggestions emerging from the summer 2006 consultation process. As well, drafting a section on the participation of women in research turned out to be more difficult than anticipated when the then lead author for that section failed to provide a draft text in a timely manner – thus leaving it to other members of the TCWG to fill the gap.<sup>42</sup> TCWG also held a face to face consultation with selected members of the social sciences and humanities research community. The meeting was quite tense particularly in regard to the section on collectivities. In July 1997 the final version of the *Code* was submitted to the Councils' presidents.

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## Winter

The Winter period includes the time from submission of the *Code* to the presidents in July 1997 to the Councils' adoption of a substantially altered document – the 1998 *TCPS*. There was a consultation process which included face to face meetings across Canada. As the one member of TCWG who participated in all these meeting, I saw a rather uncivil side of the academic community with verbally abusive behaviour and, in one case, out right manipulation of fair process by a meeting chair. One well placed informant said, "He (McDonald) was savaged by members of his community." But I was not alone in this. At the meeting of the MRC standing committee on ethics where the emergent *TCPS* was being discussed, an informant reports that attempts were made to silence members, who served on the TCWG, from participating in discussions of the *Code*. That informant said in an interview:

...the MRC Standing Committee, when it was considering the various drafts of the *Tri-Council*

*Policy Statement*, had NO community input at ALL. And, it very much struck me, the debate was a very self-interested debate. I mean, there were clearly individuals on the committee, including the bureaucrats, who it was quite transparent were interested in sort of gutting any strong provisions within the document, so as to, in effect, lube the wheels of scientific progress.

Historians, psychologists and others, mainly in the social sciences, vented their spleens about alleged deficits in the *Code*. A full scale e-mail campaign was launched, often based on outright misreadings of the *Code*. Major concerns centred on *Code* provisions that allegedly imperilled academic freedom. There was a great deal of wariness about REB review with some even alleging that any review amounted to censorship. Claims were made that social sciences research was inherently non-harmful, at least as compared to medical research. A frequent charge was that there was a biomedical bias expressed in the *Code*.

In the background, *sotto voce*, we heard reports that University administrators were concerned on grounds of cost and the potential loss of competitive advantage in securing research funding. At a November 1997 meeting of Canadians for Health Research on Research Ethics Boards, the President of Concordia and the first Chair of TCWG, Fred Lowy spoke about the attitude of senior Canadian university administrators toward the draft *Code*. In summarizing the meeting, Jean Joly commented:

Fred Lowy addressed the issue of institutional conflicts of interest. I was somewhat appalled to hear Fred say some university presidents in Canada, on advice from the vice-president of research, find the *Code* unduly restrictive. I think that this is a very short-sighted view. If we go through more scandals of the sort we have seen in Canada in the last few years, public trust will decline and so will public funding; as well, we could get the sort of legislation mentioned by Justice David Marshall.<sup>43</sup>

The Councils commissioned consultants to completely rewrite parts of the *Code* – in particular the ethical framework and collectivities.<sup>44</sup> Informally members of the TCWG heard that the Department of Justice had

intervened. In the case of the new *TCPS* section on research involving Aboriginal people, the Department of Justice warned this entered the dangerous waters of Aboriginal rights and would require negotiation with Aboriginal people. As noted this had been anticipated earlier by TCWG when it refused to create a section exclusively on Aboriginal populations. The Department of Justice also insisted that language be changed – from “research participants” to “research subjects” and “informed choice” to “informed consent.” They also pressured for a blanket prohibition on research involving deception.

When members of TCWG saw the *TCPS* text, they asked to be disassociated from it. To be sure many of the words the group wrote and endorsed are in the *TCPS* (e.g., the section on REB procedures and the section on tissues). However, the excisions and additions were sufficiently far from what TCWG intended. Guy Rocher, who was involved in the revision process, remarks that the final version of the *TCPS* changed in three main ways from earlier versions:

- 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.<sup>45</sup>

### 3. Lessons Learned

I now focus on lessons that can be learned from the four seasons of the TCWG. The first lesson concerns the process of policy making. The process created for and by the TCWG was different than earlier processes used in the creation of the MRC and SSHRC documents. It was far more public and visible. Despite the complaints of many critics about the lack of consultation, the process was very consultative.<sup>46</sup> To keep matters in perspective, a well-placed informant noted that the TCWG process cost around \$800 thousand and compared this to the Royal Commission on Reproductive Technologies which conducted coast to coast hearings and cost over \$27 million.<sup>47</sup> TCWG had neither the budget nor the time for consultation on this level. TCWG did create – and this was its idea and not the Councils – the opportunity for written comments. TCWG took these very seriously in revising the 1996 *Code* into the 1997 *Code*. After



publication of the second version of the *Code* members of the TCWG participated in five site meetings with researchers across the country. For a group which had a minimal staff (a part time secretary plus for one summer an RA), the consultation process placed a major burden on members. The request to comment on post-TCWG (Winter) new versions of the “*Code*” as it was modified into the “*Policy Statement*” could have been accommodated. If it had, the resulting document might have been significantly improved in terms of intellectual coherence and practicality. All in all, I believe that a process could be devised that is more supportive and respectful of those asked to draft policy.

Second, there have been some lasting legacies and, depending on one’s perspective, these have been either good or bad. The achievement of a unified policy statement covering all areas of research was no mean feat.<sup>48</sup> Even though detractors felt the result was too

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biomedical, a *bona fide* effort had been made to embrace the full range of disciplines. Moreover as Kinsella had predicted, a unified document did reach beyond Tri-Council funded institutions to such agencies as the Department of Defence, Health Canada, the National Research Council, the Canadian Blood Services, the Alberta College of Physicians and Surgeons and most recently the newly legislated Provincial Health REB for Newfoundland.<sup>49</sup> Still, as I have argued elsewhere, in the absence of a system of quality assurance, it is difficult to say whether commitment to national standards in the *TCPS* is more than superficial.<sup>50</sup> CIHR also recently created guidelines for research involving Aboriginal People.<sup>51</sup> These were the result of an extensive consultation process with Aboriginal people

and researchers. This closed one of the policy gaps in the protection of communities involved in research.

Third, there remains a fairly deep divide between behavioural and biomedical researchers with continued lamentations from the former over various *TCPS* provisions. These continued in a seemingly interminable series of consultations of possible revisions conducted by the Panel on Research Ethics (PRE) from 2002 to 2008. SSHRC, following the 2000 Ottawa Governance Study recommendations, continued to see the primary objective as placating its constituency – researchers in the human and social sciences.<sup>52</sup> CIHR has, to a much greater degree, seen the protection of research subjects as a strategic objective. For example, CIHR’s Governing Council recognized that from a risk management as well as an ethical perspective it faces a major problem in both sponsoring research involving humans and ensuring its ethical governance.<sup>53</sup> The Governing Council recognized that the human research protection function needed to be outsourced as is done in the case of research involving animals through the Canadian Council on Animal Care or for research involving humans in the US through the Office of Human Research Protection.

This history should raise a fundamental question about whose interests should be primary for a policy on the ethical conduct of research involving humans. In the end, actual Canadian governance in this area has been far more about researcher placation than subject protection. It was striking in the many missives and comments received by the TCWG how very little was said about research participants and how much was said about researchers. The same can be said of the PRE consultations. In making this comment I want to make it clear that I am not calling into question the sincerity and ethical commitment of interveners in the TCWG, PRE or similar processes. Rather my concern is that while the interests of researchers and their institutions have been voiced loudly, those of actual and potential research participants have hardly been articulated (with the exception of those living with AIDS or breast cancer).

This raises acute systemic issues. One is how to make the voices of research participants heard. At the individual level informed consent is a necessary, but often insufficient, way of protecting subjects. At the collective level the challenge is to make research subjects an integral part of the governance system. Problems are exacerbated



here because the research councils act simultaneously as research sponsors and as subject protectors. The voices of Canadian universities and AUCC have been strikingly silent in regard to subject protection despite the visible problems at various institutions including the University of Toronto and the University of British Columbia.<sup>54</sup>

Fourth, the controversies arising during the *TCPS* process reveal some of the gaps between the creation of policy and its implementation. Academics, particularly in the social sciences, were fearful that overreaching REBs would maliciously or ignorantly impose inappropriate restrictions on their research. There is an answer to this which is the training, appointment and support for knowledgeable REB members.<sup>55</sup> But in the absence of real efforts on the part of the Councils and universities to support implementation and training, it was easier to blame the makers of the *Code* and the *TCPS* for their insensitivity. One reason for this is that ethical review

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came much later to social sciences research than to biomedical research. So it seemed to those in the social sciences that new restrictions were being imposed – hence a biomedical bias had inserted itself. My sense is that with greater familiarity with ethics review these animosities have somewhat subsided. Yet more needs to be done to address disciplinary differences in research. Ethically considered, many of these are more imaginary than real. There is high risk and low risk research on both sides of the biomedical and behavioural divide. On both sides of the divide there are researchers with fiduciary responsibilities to subjects (e.g., counselling psychologists, educators and physicians). They have role-defined responsibilities for the welfare of subjects. As well, there are both biomedical and behavioural researchers who do not have fiduciary responsibilities (e.g., oral historians and bench scientists

working with tissues). Their obligations are mainly to avoid harm and keep promises to subjects rather than protect subjects' interests.

Fifth, the history of the four seasons demonstrates that it is not enough to simply decree national policy. There has to be a smart context sensitive implementation plan. More attention needs to be paid to the cultures of our multiple research communities. Rules and regulations imposed on a resistant or oblivious constituency provoke sullen compliance by some, active resistance by others, and simple neglect by most. Yet the answer is not to capitulate on subject protection. While research communities need to be engaged in a discussion of the challenges in human research protection, research subjects and their representatives must also have an effective say and play as central a role in governance as researchers.

Finally in many publications over the years I have argued for developing an evidence-based approach to research ethics that centres on the experiences of human subjects.<sup>56</sup> In part this came out of my frustration with the anecdote-based approach that remains prevalent – in which angry researchers present anecdotes of high handed REB behaviour and REB members tell their tales of unthinking and insensitive researchers. Surely we can do better than this. Here the need for solid research on what happens to human subjects is evident. And better still if the results of that research could be fed back into the system of human research protection. I now see hopeful signs of this in the growth of empirical work in this area. Indeed, this issue of *HLR* represents the efforts of a network of researchers with an interest in such work.<sup>57</sup>

The important task of balancing the demands of research and human protection is on-going and given the dynamic nature of the relations will always be a work in progress. I believe that the TCWG did raise the bar in significant ways. In some cases, the bar was knocked down. In others it was lowered a bit. In still others, it remains in place.

Finally my hope is that this brief paper will stimulate an interest in the history of Canadian research protection. This is both a worthwhile scholarly endeavour and is essential for making ethical progress. Ahistorical policy making is not a recipe for success. I would note too that more remains to be said about the *TCPS* process. As



noted earlier, I did not in this paper go into a detailed discussion of the *Code's* content. Finally, I note that I have written from an insider's perspective with the advantages of intimate knowledge of the process but also with the disadvantages of necessarily being *parti pris* on major controversies. However, in this paper, my aim was modest – not to try to have the last word but rather to prompt discussion and reflection on an important part of our history.

### **Postscript**

Shortly after the submission of this article to the *Health Law Review*, the Interagency Advisory Panel on Research Ethics issued the long awaited *Draft 2<sup>nd</sup> Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.<sup>58</sup> Since the revisions are substantial and subject to change, it would be imprudent for me to offer more than a brief postscript here. However, it is worth noting that the draft second edition picks up some features of the *Code* that were deleted in the 1998 *TCPS*. A minor but emblematic example of this is the use of the term “research participants” rather than “research subjects.” More importantly, there seems to be a much more robust recognition of the importance of protection for communities involved in research. This includes a chapter on “Research Involving Aboriginal People,” which is modelled on and references the *CIHR Guidelines* in this area. Philosophically, there is language at various places that parallels the *Code's* context sensitive understanding that ethical respect for persons requires recognition of the social and community location of research participants. I do not know whether the authors of the draft second edition of the *TCPS* were aware of the *Code*, but I do find it interesting that in some respects they came to share at least some of the moral vision that permeated our work on the *Code*.

While the draft second edition has many worthwhile changes, it is important to put the *TCPS* revision process into context. First, *TCPS* only covers agencies that either receive Tri-Council funding or that voluntarily adhered to the *TCPS*. Private sector research involving humans is not covered. This includes research sponsored by pharmaceutical companies which is increasingly being conducted by contract research organizations.<sup>59</sup> Some of this research occurs in house while a substantial though unknown amount is conducted in private physicians' offices. Second, while the draft second edition introduces new measures for addressing institutional conflicts of interest within research institutions, it leaves unaddressed

the fundamental conflict of interest in having *TCPS* administered by agencies (CIHR, NSERC, and SSHRC) that are themselves major sponsors of research. This represents a serious systemic conflict of interest that potentially undermines confidence in Canada's major system of human research protection. Third, Canada is a long way from having a system of protection that is evidence-based, accountable and clearly effective. For example, we do not know if the current version of the *TCPS* is being followed and whether, if followed, it achieves its stated ends of ensuring the rights of subjects and advancing socially beneficial research.<sup>60</sup> In sum, I see the major issues as being around systemic effectiveness rather than policy revision.

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### **Endnotes**

- 1 This paper is based on a presentation given in honour of Professor Bernard Dickens (Law, University of Toronto) as the first paper in an annual series of lectures on research ethics at the University Club in Toronto on March 1, 2007. I also wish to acknowledge here the major contributions of all the other deeply dedicated members of the Tri-Council Working Group on Ethics (TCWG). I am grateful for comments from the reviewers for this paper and from Dr. Jean Joly who chaired the TCWG and played such an important leadership role in the creation of the *Code*.
- 2 See *Halushka v. University of Saskatchewan et al.* (1965), 53 D.L.R. (2nd) 436, 52 W.W.R. 608 (Sask. C.A.); National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Bethesda, Md.: The Commission, 1979) [*The Belmont Report*]; Jay Katz, “Ethics and Clinical Research Revisited “ (1993) 23:5 *Hastings Center Report* 31; Albert R. Jonsen, *The Birth of Bioethics* (New York: Oxford University Press, 1998); James F. Childress, Eric M. Meslin & Harold T. Shapiro, eds., *Belmont Revisited: Ethical Principles for Research with Human Subjects* (Washington, DC: Georgetown



- University Press, 2005); Office for Human Research Protections (OHRP), *Belmont Report: 25th Anniversary*, online at: OHRP <<http://www.hhs.gov/ohrp/belmontArchive.html>>).
- 3 Francoise Baylis, Jocelyn Downie & Susan Sherwin, "Reframing Research Involving Humans" in Susan Sherwin *et al.*, eds., *The Politics of Women's Health: Exploring Agency and Autonomy* (Philadelphia: Temple University Press, 1998) 234; Bernard Dickens, "Governance Relations in Biomedical Research", in Michael McDonald, ed., *The Governance of Health Research Involving Human Subjects*, (Ottawa: Law Commission of Canada, 2000) 93; Jocelyn Downie and Timothy Caulfield, eds., *Canadian Health Law and Policy* (Toronto: Butterworths, 1999); Kathleen Cranley Glass and Trudo Lemmens, "Research Involving Humans" in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy* (2<sup>nd</sup> ed.) (Toronto: Butterworths, 2002) 459; Marie Hirtle, "The Governance of Research Involving Human Participants" (2003) 11 *Health Law Journal* 137; B. Hoffmaster, "The Medical Research Council's New Guidelines on Research Involving Human Subjects: Too Much Law, Too Little Ethics" in Eike-Henner W. Kluge, ed., *Readings in Biomedical Ethics: A Canadian Focus* (Scarborough, Ontario: Prentice Hall Canada, 1993) 159; Trudo Lemmens, "Federal Regulation of REB Review: A Modest But Easy Step Towards an Accountable REB Structure in Canada" (2005) 13:2 & 3 *Health Law Review* 39.
  - 4 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* (Ottawa: Public Works and Government Services Canada, 1999 with 2000, 2002, 2005 amendments) [TCPS], online: Interagency Advisory Panel on Research Ethics (PRE) <<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>>.
  - 5 International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH), *ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice: E-6 (R1)*, online: ICH <<http://www.ich.org/LOB/media/MEDIA482.pdf>>.
  - 6 This has been promised by the Panel on Research Ethics (Sponsors' Table for Human Research Participant Protection in Canada, News Release, "Building on the Report of the Experts Committee for Human Research Participant Protection in Canada, the Sponsors' Table Identifies Four Priorities" (July 18, 2008), online: Sponsors' Table for Human Research Participant Protection in Canada <<http://www.hrppc-pphrc.ca/english/communiquedecember182008.html>>. with a planned release date of December 1, 2008.
  - 7 Sponsors Table for Human Research Participant Protection in Canada, online: Sponsors Table for Human Research Participant Protection in Canada <<http://www.hrppc-pphrc.ca/english/sponsors.html>>. The Sponsors Table initially consisted of the sponsors of the National Council on Ethics and Human Research (NCEHR) – Health Canada, the Royal College of Physicians and Surgeons and the Canadian Institutes for Health Research (CIHR) – plus the two other federal research councils, viz. the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC). They came together to consider a proposal by NCEHR for establishing a régime for accreditation of human research protection (National Council on Ethics in Human Research (NCEHR), *Promoting Ethical Research on Humans: Report of the Task Force for the Development of an Accreditation System for Human Research Protection Programs*, online: National Council on Ethics in Human Research <[http://ncehr-cnerh.org/english/Task%20Force%20Report\\_FINAL\\_18%20July%202006.pdf](http://ncehr-cnerh.org/english/Task%20Force%20Report_FINAL_18%20July%202006.pdf)>.) somewhat akin to the U.S. not-for-profit program Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). The Sponsors Table now includes a variety of other organizations with significant interest in research involving humans including the private sector in the form of Canada's Research-Based Pharmaceutical Companies.
  - 8 Michael McDonald *et al.*, *The Governance of Health Research Involving Human Subjects*, (Ottawa: Law Commission of Canada, 2000) [McDonald, *Governance*]; Michael McDonald & Eric Meslin, "Research Ethics as Social Policy: Some Lessons from Experiences in Canada and the United States" *The Tocqueville Review/La Revue Tocqueville*, Vol. XXIV (2003) 1.
  - 9 The 1988 Medical Research Council *Guidelines* superseded the 1978 *Guidelines*.
  - 10 Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects*, (Ottawa: Medical Research Council of Canada, 1987); Social Sciences



- and Humanities Research Council, *Ethics Guidelines for Research with Human Subjects*, (Ottawa: Social Sciences and Humanities Research Council of Canada, 1980).
- 11 Guy Rocher, "Origin and Development of the Tri-Council Policy Statement on the Ethics of Research Involving Humans" (1999) 9 & 10 NCEHR Communiqué, online: National Council on Ethics in Human Research <[http://www.ncehr-cnerh.org/english/communiqu4-5/comm\\_9\\_2-10\\_1e.html](http://www.ncehr-cnerh.org/english/communiqu4-5/comm_9_2-10_1e.html)>. The same point made by the late Douglas Kinsella in a personal conversation when he discussed the situation that he incidentally observed with respect to social science REBs when he led the NCBHR site visit team to Canadian medical schools REBs in 1990.
  - 12 Tom L. Beauchamp, et al., eds., *Ethical Issues in Social Science Research* (Baltimore: Johns Hopkins University Press, 1982).
  - 13 The National Council on the Bioethics of Human Research (NCBHR) was renamed the National Council on the Ethics of Human Research (NCEHR) in 1995.
  - 14 National Council on Bioethics in Human Research (NCBHR), "Facilitating Ethical Research: Promoting Informed Choice" (1996) 7 (2<sup>nd</sup> supplement) NCBHR Communiqué 1; NCBHR, "Revised recommendations of the NCBHR Report on Research Involving Children" (1993) NCBHR Communiqué 8; Douglas Kinsella, "Research Ethics Boards: A Historical Background", online: Canadians for Health Research <<http://www.chrcrm.org/main/modules/pageworks/index.php?page=015&id=11>>. The material in this paragraph is based on information gathered in interviews and in personal conversations with individuals involved in the events reported.
  - 15 Medical Research Council of Canada, *Guidelines for Research on Somatic Cell Gene Therapy in Humans*, (Ottawa: Minister of Supply and Services, 1990).
  - 16 Rocher, *supra* note 11.
  - 17 Henry K. Beecher, "Ethics and Clinical Research" (1966) 274 *New England Journal of Medicine* 1354.
  - 18 Rebecca Dresser, *When Science Offers Salvation: Patient Advocacy and Research Ethics* (Oxford: Oxford University Press, 2001) at 215.
  - 19 *Belmont Report*, *supra* note 2.
  - 20 Council for International Organization of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva: CIOMS, 1993).
  - 21 Patricia Baird, *Proceed with care: Final report of the Royal Commission on New Reproductive Technologies* (Ottawa: The Commission, 1993) at 1275.
  - 22 NCBHR Working Group on Evaluation, "Protecting and Promoting the Human Research Subject: A Review of the Function of Research Ethics Boards in Canadian Faculties of Medicine" (1995) 6 NCBHR Communiqué 3.
  - 23 Bernard M. Dickens, "The Legal Challenge of Health Research Involving Children" (1998) 6 *Health L. J.* 131.
  - 24 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Integrity in Research and Scholarship: a Tri-Council Policy Statement* (Ottawa: Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, 2007), online: Natural Sciences & Engineering Research Council of Canada <[http://www.nserc-crsng.gc.ca/doc/NSERC-CRSNG/tpsintegrity-picintegritie\\_eng.pdf](http://www.nserc-crsng.gc.ca/doc/NSERC-CRSNG/tpsintegrity-picintegritie_eng.pdf)>.
  - 25 The TCWG was chaired by Professor Fred Lowy. Members included Professors Dickens (Law, Toronto), Abby Anne Lynch (Bioethics, who was then President of NCBHR), T. Douglas Kinsella (Medicine, Calgary, who had led the site visits to medical schools), Jean Joly (Epidemiology, Laval), Michael Asch (Anthropology, Alberta), Marie-Hélène Parizeau (Philosophy, Laval), Janet Werker (Psychology, UBC), Nuala Kenny (Paediatrics and Bioethics, Dalhousie), Gerry Klassen (Medicine, Maritime Heart Association), Robert Scott (Biomedical Engineering, UNB) and Barbara McGillivray (Genetics, UBC).
  - 26 Tri-Council Working Group on Ethics [TCWG], *Code of Ethical Conduct for Research Involving Humans*, online: University of British Columbia <<http://www.ethics.ubc.ca/code/july97/j97-1b.doc>>.
  - 27 *TCPS*, *supra* note 4, section 10.
  - 28 TCWG, *supra* note 26.
  - 29 Michael McDonald, *Research Ethics Boards: What's Next? Implementing the Code*, online: Canadians for Health Research <<http://www.chrcrm.org/main/modules/pageworks/index.php?page=015&id=248>>.
  - 30 It should be noted that our work was substantively completed earlier than July. It took until July for



- Joly and our editors to carefully edit the document and complete the translation into French.
- 31 Rocher, *supra* note 11. Jean Joly, "Research Ethics Board: Summation," online: Canadians for Health Research <<http://www.chrcrm.org/main/modules/pageworks/index.php?page=015&id=250>>.
  - 32 National Council on Bioethics in Human Research "The Ethics of Human Experimentation: Reinventing the Research Ethics Board: Proceedings of a National Workshop held in Ottawa, Ontario, March 5-6, 1995" (1996) 7 NCBHR Communiqué 1.
  - 33 Joly, *supra* note 31.
  - 34 I was a participant in the meeting where this was said. The section on collectivities was essentially the work of two individuals – Michael Asch and Michael McDonald. Asch drew upon his extensive experience as an anthropologist conducting research involving aboriginal people. McDonald's point of departure was his work as a philosopher of law on collective rights in law and political theory.
  - 35 ICH, *supra* note 5. Canada was an observer in these negotiations. ICH-GCP essentially made US FDA standards effective world wide.
  - 36 Benjamin Freedman, "Equipoise and the Ethics of Clinical Research" (1987) 317 *New England Journal of Medicine* 141. Heather Sampson, *et al.*, "Examining and Understanding the Need for Canadian Research Ethics Board (REB) Member Standardized Education: Governance View from the Field" (2009) 17:2-3 *Health Law Review* 73 [Sampson *et al.*, "Examining & Understanding"]. See also Heather Sampson, Charles Weijer & Daryl Pullman, "Research Governance Lessons from the National Placebo Initiative" (2009) 17:2-3 *Health Law Review* 26.
  - 37 Advisory Committee on the Human Radiation Experiments (ACHRE), *The Human Radiation Experiments: Final Report of the President's Advisory Committee on the Human Radiation Experiments*, (New York: Oxford University Press, 1996) at 620.
  - 38 TCWG, *supra* note 26.
  - 39 *Ibid.*
  - 40 The history of this section is fairly complex and the subject of a separate as yet unpublished paper by this author.
  - 41 Michael McDonald, "What's Right, What's Missing, What's Next?" online: Canadians for Health Research: Research Ethics Boards <<http://www.chrcrm.org/main/modules/pageworks/index.php?id=248&page=015>> [McDonald, "What's Right"].
  - 42 TCPS, *supra* note 4, s. 5 "Inclusion in Research."
  - 43 Joly, *supra* note 31.
  - 44 McDonald, "What's Right" *supra*, note 41.
  - 45 Rocher, *supra* note 11.
  - 46 *Ibid.*
  - 47 The on-line *Canadian Encyclopaedia* reports that the cost of the Commission was actually \$30 million. See "Royal Commissions: Why Commissions are established" *The Canadian Encyclopaedia*, online: Canadian Encyclopaedia <<http://www.thecanadianencyclopedia.com/index.cfm?PgNm=TCE&Params=A1SEC827430>>.
  - 48 Personal Communication with Eric Meslin, who served as Executive Director of the U.S. National Bioethics Advisory Committee, who has said that from outside Canada the creation of a trans-disciplinary document covering all types of research involving humans looked like a major accomplishment.
  - 49 *Health Research Ethics Authority Act*, S.N.L. 2006, c. H-1.2.
  - 50 Michael McDonald, "Canadian Governance of Health Research Involving Human Subjects: Is Anybody Minding the Store?" (2001) 9 *Health L.J.* 1 [McDonald, "Minding the Store?"].
  - 51 Canadian Institutes for Health Research, *CIHR Guidelines for Health Research Involving Aboriginal People*, (Ottawa: Canadian Institute of Health Research, 2007), online: Canadian Institute of Health Research <<http://www.cihr-irsc.gc.ca/e/29134.html>>.)
  - 52 Centre on Governance, University of Ottawa, *Governance of the Ethical Process for Research Involving Humans* (Ottawa: Centre on Governance, University of Ottawa, 2000), at 61.
  - 53 CIHR, "Meeting Minutes – 21<sup>st</sup> Meeting of Governing Council – June 18-19, 2003", online: CIHR <<http://www.cihr-irsc.gc.ca/e/19817.html>>. See Item #14.
  - 54 Jocelyn Downie, Patricia Baird & Jon Thompson, "Industry and the Academy: Conflicts of Interest in Contemporary Health Research" (2002) 10 *Health L.J.* 103; David Healy, "Conflicting Interests in Toronto: Anatomy of a Controversy at the Interface of Academia and Industry" (2002) 45 *Perspectives in Biology and Medicine* 250; Doug Payne, "Report slams UBC ethics" online: (2004) 5:1 *The Scientist* 2 <<http://www.the-scientist.com/article/display/22495/>>.



- 55 Sampson *et al.*, "Examining & Understanding", *supra* note 36.
- 56 McDonald, *Governance*, *supra* note 8; B. Beagan, "Ethics Review for Human Subjects Research: Interviews with Members of Research Ethics Boards and National Organizations" in McDonald, *Governance*, *supra* note 8 at 173; Michael McDonald, "The Governance of Health Research Involving Human Subjects: Reflections on Ethical Policy for Scientific Research" (2000) 6:11 *Transactions Science & Ethics: Royal Society of Canada Special Issue 49*; McDonald, "Minding the Store?" *supra* note 50.
- 57 See the papers in this volume on challenges in conducting such research (Michael Owen *et al.*, "Informing Governance Through Evidence-Based Research on REBs: Challenges and Opportunities" (2009) 17:2 *Health Law Journal* (Page #) and Susan Cox *et al.*, "Ethical Challenges and Evolving Practices in Research on Research Ethics" (2009) 17:2 *Health L.R.* (Page #)
- 58 Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Draft 2<sup>nd</sup> Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, online: Interagency Advisory Panel on Research Ethics (PRE) <[http://www.pre.ethics.gc.ca/english/pdf/newsandevents/TCPS\\_Dec\\_4\\_en.pdf](http://www.pre.ethics.gc.ca/english/pdf/newsandevents/TCPS_Dec_4_en.pdf)>.
- 59 Philip Mirowski & Robert Van Horn, "The Contract Research Organization and the Commercialization of Scientific Research" (2005) 35:4 *Social Studies of Science* 503.
- 60 Michael McDonald, "Special Issue: Canadian Governance for Ethical Research Involving Humans" (2005) *Health L.R.* 13:2 & 35.

