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Unfinished Business: Ongoing Ethical Exceptionalism in the Oversight of Human Pluripotent Stem Cell Research in Canada

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In this article, we critically examine the arguments for and against the exceptional status given human pluripotent stem cell research in Canada (through the latest [December 2010] revision of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*), and conclude that this exceptionalism is unwarranted and ethically unsound. In our view, the three federal research granting agencies should honor their longstanding commitment that researchers, research sponsors, and Research Ethics Boards in Canada have access to “a single reference document for all research involving humans conducted under the auspices of institutions eligible for Agency funding.” As well, responsibility for the development, interpretation, and implementation of Canada’s research ethics guidelines should be under the authority of a single oversight body that is independent of the federal research granting Agencies.

Keywords: ethics guidelines, governance, oversight, research ethics, stem cells

In Canada, the leading research ethics oversight instrument is the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)*, first issued in 1998. The development, interpretation and implementation of this Policy Statement is the responsibility of the Interagency Advisory Panel on Research Ethics (PRE).¹ This oversight body was created in 2001 by Canada’s three federal research granting Agencies, three years after the first edition of the *TCPS* was published. The three federal research granting Agencies are the Canadian Institutes of Health Research (CIHR), the Natural Sciences and

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Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC).

The current (second) edition of the *TCPS*, *TCPS 2*, stipulates that ethics review and approval by a Research Ethics Board (REB) is required for all research “(a) involving living human participants; (b) human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells” (CIHR, et al., 2010, Article 2.1). *TCPS 2* also provides researchers, research sponsors, and REB members with detailed substantive ethics guidance. Notably, it does so for all areas of research involving humans that require REB review and approval, except for research to derive and use human pluripotent stem cells. For this (and only this) area of research, the relevant rules are set out in “the *Guidelines for Human Pluripotent Stem Cell Research*, as amended from time to time and published by the Canadian Institutes of Health Research” (CIHR, et al., 2010, Article 12.10). Not only are the rules for human pluripotent stem cell research set out in a separate research ethics document, but responsibility for the development, interpretation, and implementation of these rules rests with a separate oversight body—namely, the CIHR Stem Cell Oversight Committee (SCOC).

In this article, we critically explore the arguments for and against the exceptional status given human pluripotent stem cell research in Canada. We conclude that this exceptionalism is unwarranted and ethically unsound. We advocate that the three federal research granting agencies honor their longstanding commitment to have “a single reference document for all research involving humans conducted under the auspices of institutions eligible for Agency funding” (PRE, 2010).²

THE *TCPS*

The *TCPS* was introduced in 1998 by the three federal research granting Agencies. Research conducted by individuals or in institutions that receive funding from any of these Agencies must be in conformity with the *TCPS*. To be precise, individuals must certify compliance with the *TCPS* in their grant applications, and institutions that receive Agency funding must sign a formal “Memorandum of Understanding” with the Tri-Agencies certifying compliance (Hadskis, 2011, 263; Tri-Agencies, 2008).

In 2000, 2002, and 2005, minor amendments were made to the *TCPS*. Then, in 2008 PRE—the group responsible for the development and evolution of the *TCPS*—determined that significant revisions were needed in light of “changes in research and society at large” (PRE, 2010). In December 2010, following nearly two years of work that included two public consultations, a second edition of the *TCPS* was published. The official name for the new edition of the research guidelines remains unchanged, but the acronym now includes the edition number; viz., *TCPS 2*.

There are many important differences between the *TCPS* and *TCPS 2*; some of these differences are positive, while others are quite disturbing. Among the disturbing differences is the intentional decision to ignore the Agencies' commitment mentioned above to have "a single reference document for all research involving humans conducted under the auspices of institutions eligible for Agency funding" (PRE, 2010). Instead, there are currently two authoritative "reference documents" each under the purview of a distinct governance body—*TCPS 2* and the *Updated Guidelines for Human Pluripotent Stem Cell Research*.

CIHR RESEARCH ETHICS GUIDELINES

In the years between the *TCPS* and *TCPS 2* (1998 and 2010, respectively) CIHR developed separate research guidelines in 2002 (*Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research*, later revised and renamed *Updated Guidelines for Human Pluripotent Stem Cell Research*), and in 2007 (*CIHR Guidelines for Health Research Involving Aboriginal People*). The guidelines for stem cell research were developed because there was nothing governing this area of research in the *TCPS* at that time. The guidelines for research involving Aboriginal Peoples were developed "to promote ethical and culturally competent research involving Aboriginal people" (CIHR, 2007). As well, in the weeks following the release of *TCPS 2*, CIHR released its *Policy on Registration and Results Disclosure of Controlled and Uncontrolled Trials Funded by CIHR*. This policy was developed "to increase the transparency and accessibility of trials by improving their registration and disclosure of their results" (CIHR, 2011).

Beginning in 2003, consistent with the goal of having a "single reference document," the three federal research granting Agencies signalled that the *Updated Guidelines for Human Pluripotent Stem Cell Research* were to be incorporated into the *TCPS*.

In the Stem Cell Presidential Reference to PRE (dated August 2003), the three federal granting Agencies made the following request of PRE:

The Presidents of the CIHR, NSERC, and SSHRC, Recognizing . . .

- That the communities of the three granting Agencies would *benefit from a common set of workable research ethics guidelines on human stem cell research in the TCPS . . .*

Therefore, Request the Interagency Advisory Panel on Research Ethics to: . . . Report and Advise,

- in a timely manner to the Presidents of the three Agencies on how to incorporate the CIHR and/or like guidelines into the *TCPS* (emphasis added). (CIHR et al., 2003a)

In the *Interim Tri-Agency Measures for Human Pluripotent Stem Cell Research* (dated “June 2003; as extended in September 2005”), the federal granting Agencies jointly informed the Vice Presidents of Research and Research Grants Officers that they had asked PRE for advice on:

how to incorporate the [stem cell] Guidelines into the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) of 1998, which currently does not explicitly address human stem cell research. (CIHR et al., 2003b)

In addition, the commitment to incorporation is repeated in Section 3.0 of the 2005, 2006, 2007, and 2010 versions of the *Updated Guidelines for Human Pluripotent Stem Cell Research*:

The Guidelines were intended to be an interpretation and extension of the Tri-Council Policy Statement (TCPS) and as such will be incorporated into the TCPS, which applies to all research conducted under the auspices of the granting Agencies. Accordingly, NSERC and SSHRC joined CIHR in agreeing to an Tri-Agency approach requiring adherence to the Guidelines as a condition for Agency funding of research. *This will apply until the Guidelines are formally incorporated into the TCPS* (emphasis added). (CIHR, 2010)

Despite these statements, with *TCPS 2* the development, interpretation and implementation of ethics guidelines for, and oversight of, research involving human pluripotent stem cells remains under the purview of the CIHR CSOC. Article 12.10 of *TCPS 2* stipulates: “Researchers who intend to conduct research to derive or use pluripotent stem cells shall follow the *Guidelines for Human Pluripotent Stem Cell Research*, as amended from time to time and published by the Canadian Institutes of Health Research” (CIHR, et al., 2010). Thus, as yet, the commitment to a “single reference document for all research involving humans conducted under the auspices of institutions eligible for Agency funding” (PRE, 2010) has intentionally not been met.

We describe the decision to have two research ethics reference documents as *intentional* for three reasons. First, this outcome is consistent with the February 2008 recommendation of The Stem Cell Working Committee (a Working Committee of PRE) to “[i]ncorporate the CIHR Stem Cell Guidelines into the TCPS by reference” instead of pursuing full incorporation of the guidelines (Stem Cell Working Committee, 2008). The Stem Cell Working Committee made this recommendation having explicitly recognized that “the downside [of the approach recommended and ultimately taken] is that researchers and REB members would not be able to solely refer to the *TCPS but would rather have to refer to two different documents*” (emphasis added) (Stem Cell Working Committee, 2008). The decision made by PRE and the Agencies was therefore made with full knowledge of the fact that it meant

the retention of two reference documents (i.e., two sets of research ethics guidelines).

Second, arguments against the option of incorporating the stem cell guidelines into the *TCPS 2* by reference (thereby continuing to have two reference documents) were formally submitted to PRE on more than one occasion during the nearly two year consultation period on revisions to the *TCPS*.³ As well, similar arguments were publicly presented and discussed at the Canadian Bioethics Society annual meeting in the summer of 2009 at which both the Executive Director and then-Chair of PRE were present.⁴ None of the arguments presented about stem cell research resulted in changes to the Revised Draft 2nd edition of the *TCPS*, whereas arguments about other flawed aspects of the Draft 2nd edition of the *TCPS* did result in significant changes in the Revised Draft 2nd edition. All of the parties working on *TCPS 2* were therefore aware of the arguments and had time to take the steps necessary to fully incorporate the stem cell guidelines, so as to have a single reference document.

Third, the alternative to having two authoritative research ethics guidelines under the purview of two different organizations—i.e., “full incorporation” of the stem cell guidelines into the final draft version of *TCPS 2* (August 2010)⁵—was discussed by PRE’s Interagency Steering Committee (composed of the three Agency Presidents) on July 7, 2010. At this meeting, two options for incorporation of the stem cell guidelines were discussed—“incorporation by reference” and “full incorporation.” These options were to be reviewed by e-mail by the CIHR Governing Council, and the preferred option was to be reported to the Interagency Secretariat on Research Ethics.⁶ *TCPS 2* (released in December 2010) incorporates the stem cell guidelines by reference—*res ipsa loquitur*.

Given all of the above, it is clear that the retention of two research ethics guidelines was not an oversight. The PRE Stem Cell Working Committee, the PRE Interagency Steering Committee, and CIHR Governing Council *intentionally* chose not to fully incorporate the stem cell guidelines into *TCPS 2* and thereby failed to meet the one document commitment.

In sharp contrast, there was no similar publicly available discussion of the intent to incorporate the 2007 *CIHR Guidelines for Health Research Involving Aboriginal People* into *TCPS 2*, and yet CIHR elected to cede authority to PRE for the development, interpretation, and implementation of guidelines for health research involving First Nations, Inuit, and Metis people in Canada. The *CIHR Guidelines for Health Research Involving Aboriginal People* are no longer CIHR funding policy. Instead, such research is now governed exclusively by Chapter 9 of *TCPS 2*.

Thus, the intentional decision regarding the stem cell research guidelines turns its back on the prior commitment to a single reference document,

while the decision regarding the guidelines for research involving Aboriginal Peoples appears to embrace this commitment. These concurrent yet conflicting decisions are perplexing and, we argue below, indefensible.

Of course, the decision to proceed with “incorporation by reference” does not preclude future revisions to *TCPS 2* in pursuit of the option of “full incorporation.” Indeed, according to the Executive Director of the Interagency Secretariat on Research Ethics, fully incorporating the stem cell research ethics guidelines into the *TCPS 2* is “the first priority for revisions to *TCPS 2*.”⁷ The proposed plan for revisions with respect to the ethics guidelines for stem cell research includes the following steps:

1. “transfer responsibility for the evolution of the guidelines from CIHR to the Panel [PRE]” (scheduled for consideration at the June 22–23, 2011, Governing Council Meeting; minutes for this meeting not available at the time of writing).
2. “re-craft the Stem Cell Guidelines so that they match the language of *TCPS 2*” (completed as at June 10, 2011)
3. “publicly disseminate the integrated articles of Chapter 12 over the summer [of 2011] and into the early fall so that the research community can familiarize themselves [sic] with the new section of *TCPS 2* and provide comments to the panel.”
4. “present . . . revised provisions to the three Agency Presidents in the fall and, once approved, incorporate them into the electronic version of *TCPS 2*”.⁸

Despite recent assurances that revisions to *TCPS 2* are forthcoming, those who have been advocating full incorporation of the stem cell research ethics guidelines into the *TCPS* and the *TCPS 2* for many years may well be cynical about the prospects for full incorporation. After all, it has been close to eight years from the time the Agencies recognized the need to capture the stem cell research ethics guidelines in the *TCPS* and close to three years from the time the public consultations on revisions to the *TCPS* were initiated. Cynicism, however, will not increase the chances of the original Tri-Agency commitment to a single reference document being met. Rather, engagement with those who have the authority to effect change, articulation of the arguments for change, and calls for institutions to meet their prior commitments, compel us to reengage, to give the federal research granting Agencies the benefit of the doubt, and continue to provide arguments in support of what the Agencies say they want to do. There’s many a slip ‘twixt the cup and the lip. Persistence and publicity may help to prevent any slips with respect to the planned revisions. In the next sections, therefore, we

critically examine reasons given for the exceptional status granted human pluripotent stem cell research, and develop a number of arguments against such exceptionalism.

REASONS GIVEN FOR EXCEPTIONAL STATUS AND REBUTTALS

There are three reasons commonly given for excluding human pluripotent stem cell research from *TCPS 2* and not having PRE be responsible for the development, interpretation, and implementation of the stem cell research ethics guidelines. They are that such research is: (i) especially unique, (ii) especially fast-paced, and (iii) its oversight requires special expertise not otherwise available to PRE.

In response to the first two claims, we note that there are many areas of science that are “unique” and “fast-paced.” These two features of an area of research are insufficient justification for separate research ethics oversight. Consider, for example, research on Aboriginal Peoples—this area of research is unique in a number of ways including, for example, the unique status of the Aboriginal peoples of Canada, the requirement of community engagement prior to recruitment and during the course of research, and the obligation to promote the welfare of the collective. Yet, the oversight of such research was brought under the umbrella of *TCPS 2*. Or, consider research on cerebral implants. This is undeniably fast-paced research with numerous neuroscientific, neurosurgical, psychological, technological, and ethical challenges, yet no one is seriously proposing that we develop separate research ethics guidelines and separate oversight for the surgical implantation of brain devices. As regards the pace of this research, in 1995 Canada approved DBS for the treatment of patients with essential tremor and Parkinsonian tremor. In 2003, the U.S. Food and Drug Administration granted a Humanitarian Device Exemption for the treatment of major chronic drug-refractory dystonia. In 2009, a similar exemption was granted for chronic, severe treatment-refractory obsessive compulsive disorder. Research is ongoing in these areas and has recently been extended to major depression, Tourette’s syndrome, addiction, schizophrenia, Alzheimer’s disease, and morbid obesity. This is all as fast as (or faster than) human pluripotent stem cell research for which the world’s first-in-human clinical trial involving hESC-derived cells was initiated in October 2010 (Geron, 2010) and suspended in November 2011 (Baylis, 2011; Geron, 2010).

In response to the third claim, that special oversight expertise in human pluripotent stem cell research rests with CIHR, one need only point out the fact that PRE’s mandate explicitly provides for the establishment or commissioning of *ad hoc* expert groups to address specific issues (PRE, 2011). As such, if and

when special expertise is required for the development, interpretation, and implementation of research ethics guidelines governing human pluripotent stem cell research, PRE has access on an as-needed basis to the same expertise that is available to the CIHR SCOC.

REASONS AGAINST EXCEPTIONAL STATUS

There are at least three reasons why PRE and the three federal research granting Agencies should not treat human pluripotent stem cell research differently from all other research involving human participants and human biological material. The decision to keep research to derive and use human pluripotent stem cells out of *TCPS 2*: (i) violates several important precedents; (ii) fails to reduce conflicts of interest; and (iii) risks confusion and inconsistency that ultimately could result in harm to clinical trial participants.

Violates Important Precedents

In 1998, when the *TCPS* was first introduced, a precedent was set to disallow carrying forward co-existing external independent research ethics guidelines. The original *TCPS* replaced:

- (i) General research ethics guidelines published by SSHRC (*Ethics Guidelines for Research with Human Subjects*);
- (ii) General research ethics guidelines published by MRC (*Guidelines on Research Involving Humans*); and
- (iii) “Topic specific” research ethics guidelines published by MRC (*Guidelines for Research on Somatic Cell Gene Therapy in Humans*).

In 2010, when *TCPS 2* was endorsed by the three federal research granting Agencies, CIHR announced that the *CIHR Guidelines for Health Research Involving Aboriginal People* were superseded by *TCPS 2* (CIHR, 2007).

In 2011, CIHR rescinded its “Policy on registration and results disclosure of controlled and uncontrolled trials funded by CIHR” in favor of *TCPS 2*. The CIHR policy originally published on the CIHR website December 20, 2010 (a few weeks after *TCPS 2* was made public) was erased⁹ mid-March 2011. At the time, the reason given for the decision was that overlap with *TCPS 2* would “cause confusion and inconsistent application of the requirements” (Silversides, 2011). More recently, the President of CIHR explained the decision as:

an effort to harmonize all of its ethics policies on research involving humans and to integrate operational requirements in relevant programs where appropriate and feasible. In so doing, CIHR recognized that the second edition of the

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2) was now the single reference document dealing with these issues. (CIHR, 2011)

We can find no principled ethical reason why these three discrete precedents should not be followed with human pluripotent stem cell research. Indeed, it seems to us particularly egregious that CIHR should eliminate its guidelines on research involving Aboriginal People and its policy on registration and results disclosure of CIHR-funded trials, while retaining exclusive authority over human pluripotent stem cell research (Baylis and Downie, 2011).

Fails to Reduce Conflicts of Interest

The mandate of PRE is to develop, interpret, and implement research ethics guidelines for all research involving humans (PRE 2011). The mandate of the SCOC includes doing the same for research involving the derivation and use of human pluripotent stem cells.¹⁰ This includes basic research and clinical trials.

Both PRE and SCOC are in a structural conflict of interest within the governance structure of *TCPS 2*. Each has an overarching mandate to regulate the ethical conduct of research. Yet, each reports to an agency/agencies with an overarching mandate to promote research. PRE reports to the Interagency Steering Committee which is the Presidents of the three federal research granting Agencies. SCOC reports to the Governing Council of CIHR. This places the granting Agencies in the dual role of both promoting research and regulating its ethical conduct.

Although the structural conflict of interest is real for both PRE and SCOC, in our estimation the risk of actual conflict of interest compromising the protection of research participants is greater with SCOC than it is with PRE. The stem cell research community is a small community with an understandably strong interest in expanding the scope of research eligible for funding. On more than one occasion, concerns have been raised about conflicts of interest stemming from the relationships between SCOC and researchers whose work is subject to SCOC ethics oversight (e.g., Baylis and McInnes, 2007; Baylis and Herder, 2009; Downie, 2003). For this reason, as a first step, we advocate including the substance of the stem cell research ethics guidelines into *TCPS 2*, in which case developing, implementing, and interpreting the stem cell research ethics guidelines would no longer be the responsibility of the SCOC, but would become the responsibility of PRE.¹¹

Beyond this, we maintain that oversight of the ethical conduct and review of research involving humans should be the responsibility of an organization that does not have a competing mandate to promote research, and does not report to an organization with such a mandate (Downie, 2003; Downie, 2006;

Experts Committee, 2008). This would be consistent with the recommendations of the Experts Committee on Human Research Participant Protection in Canada mandated by the three national research granting agencies, as well as the other major organizations in research in Canada: Alberta Ministry of Health and Wellness; The Association of Canadian Academic Healthcare Organizations; The Association of Faculties of Medicine of Canada; The Association of Universities and Colleges of Canada; Canada's Research-Based Pharmaceutical Companies; The Canadian Federation for the Humanities and Social Sciences; Fond de la recherche en santé du Québec; Health Canada; Health Charities Coalition of Canada; Research Canada; and The Royal College of Physicians and Surgeons of Canada (Experts Committee, 2008). This would also be consistent with practice in a number of jurisdictions. For example, in the United States, regulatory oversight is the responsibility of the Office for Human Research Protections (OHRP), a federal organization that "provides leadership in the protection of the rights, welfare, and well-being of subjects involved in research" (OHRP, 2011). OHRP does not report to the National Institutes of Health research, or any other federal granting agency, but rather reports to the U.S. Department of Health and Human Services.

Risks Confusion and Inconsistency

In explaining the decision to remove the *CIHR Policy on registration and results disclosure of controlled and uncontrolled trials funded by CIHR* (released weeks after the *TCPS 2* was released) CIHR's vice president Knowledge Translation and Public Outreach, Ian Graham, indicated that the policy was rescinded "as the overlap [with *TCPS 2*] will cause confusion and inconsistent application of the requirements" (Silversides, 2011).

And yet, CIHR currently willingly courts the risk of confusion and inconsistent application of the research ethics requirements for clinical trials involving the transplantation of human pluripotent stem cells into patients. Notwithstanding any statement to the contrary in *TCPS 2*, such research clearly would be governed by both the *Updated Guidelines for Human Pluripotent Stem Cell Research* (under the purview of CIHR through its SCOC) and Chapter 11 of *TCPS 2* on clinical trials (under the purview of PRE). There can be little doubt about the potential for confusion among researchers, research sponsors, and REBs who believe themselves bound to follow the *Updated Guidelines for Human Pluripotent Stem Cell Research* and *TCPS 2*. Of equal concern is the risk of inconsistent application, especially if the two official bodies with the authority to develop, interpret, and implement the applicable research ethics guidelines disagree about the scope of their authority.

CONCLUSION

Based on the preceding arguments, we make the following recommendations. First, we recommend that PRE immediately amend *TCPS 2* to include the substance of the *Updated Guidelines for Human Pluripotent Stem Cell Research* (“full incorporation”), and that the three federal research granting Agencies responsible for PRE approve such an amendment on an expedited basis. Second, we recommend that, contemporaneously, CIHR rescind the *Updated Guidelines for Human Pluripotent Stem Cell Research*. Such actions on the part of PRE and the federal granting Agencies would most effectively address the specific concerns raised above and, more generally, promote the public interest and protect the interests of those affected by stem cell research, especially clinical trial participants.

Beyond this, we call on the three federal research granting Agencies to step away from the governance of research ethics; this is the only way to address the structural conflict of interests that they have long been aware exists.¹²

It is long past time for the Agencies to conclude all of this unfinished business.

CONFLICT OF INTEREST

Françoise Baylis was a member of the Canadian Institutes of Health Research (CIHR) Ad Hoc Working Group on Stem Cell Research (responsible for the 2002 version of the stem cell research guidelines), and a member of the CIHR Governing Council. She is a current member (ethics designate) of the CIHR Institute of Gender and Health.

NOTES

1. The organizational structure of the Interagency Panel on Research Ethics is available at: <http://www.pre.ethics.gc.ca/eng/panel-group/about-apropos/structure/>. Accessed September 2, 2011.

2. The most recent Agency statement concerning the commitment to a single reference document can be found on the CIHR website in relation to the CIHR decision to eliminate its policy document *Registration and Results Disclosure of Controlled and Uncontrolled Trials* Available at: <http://www.cihr-irsc.gc.ca/e/43756.html>. Accessed September 2, 2011.

3. See, for example, correspondence dated March 6, 2009 (http://noveltechethics.ca/files/files/Policy/Research_Ethics/TCPS_Archive/TCPS%20Proposed%20Revisions.pdf at page 22, item 9); correspondence dated March 31, 2009 (http://noveltechethics.ca/files/files/Policy/Research_Ethics/TCPS_Archive/Incorporation_of_Stem_Cell_Guidelines.pdf); and correspondence dated February 25, 2010 (http://www.pre.ethics.gc.ca/pdf/eng/Comments2009/45_Baylis,%20Francoise.pdf OR http://noveltechethics.ca/files/files/Policy/Research_Ethics/stemcells_Baylis.pdf). Accessed September 2, 2011.

4. Canadian Bioethics Society Annual Meeting. June 12, 2009 (http://noveltechethics.ca/files/files/Policy/Research_Ethics/TCPS_Archive/TCPS_CBS.pdf). Accessed September 2, 2011.

5. This second Revised Draft 2nd edition of the TCPS is not (and never was) publicly available. Publicly available versions—Draft 2nd edition of the TCPS and Revised Draft 2nd edition of the TCPS—can be accessed at: <http://www.pre.ethics.gc.ca/eng/archives/Default/>. Accessed September 2, 2011.

6. Excerpt from the Minutes of the Interagency Steering Committee meeting (Presidents of the three Agencies) July 7, 2010 (Provided by Susan Zimmerman, personal communication to Jocelyn Downie, June 10, 2011).

5b. Incorporation of Stem Cell Guidelines

Dr Beaudet [President of CIHR] noted that approval of the recommendation to fully incorporate the CIHR Stem Cell Guidelines into the TCPS would require approval by CIHR’s Governing Council. The Steering Committee agreed in principle to incorporate the CIHR Stem Cell Guidelines into the TCPS, subject to approval by CIHR’s Governing Council. The Secretariat will present both options (incorporation by reference and full incorporation) in the August 2010 version of the TCPS. Dr Beaudet undertook to consult Governing Council by email on its preferred option and inform the Secretariat of the result. If the option of full incorporation is adopted, the Panel will have the mandate to recommend future revisions to the Stem Cell Guidelines to the Steering Committee as part of annual revisions to the TCPS. CIHR’s Stem Cell Oversight Committee will continue to review stem cell research applications and report on those directly to CIHR’s Governing Council.

7. Personal communication from Christine Fitzgerald (Executive Vice-President of CIHR) to Françoise Baylis, May 2010. Personal communication from Christine Fitzgerald (Executive Vice-President of CIHR) to Françoise Baylis and Jocelyn Downie, May 7, 2011. Personal communication from Susan Zimmerman (Executive Director, Interagency Secretariat on Research Ethics) to Jocelyn Downie, June 11, 2011.

8. Personal communication from Susan Zimmerman (Executive Director, Interagency Secretariat on Research Ethics) to Jocelyn Downie, June 11, 2011.

9. We use the term “erased” because the Policy is no longer available on the CIHR website. A cached copy is available at <http://sjlibrarian.wordpress.com/2011/04/06/cached-copy-policy-on-registration-and-results-disclosure-of-controlled-and-uncontrolled-trials-funded-by-cihr/>. Accessed September 2, 2011.

10. The mandate of the SCOC is not limited to review of the stem cell research guidelines, but also includes ethics review of “human stem cell research funding applications submitted to CIHR and approved by CIHR’s peer review committees . . . [and] stem cell research proposals submitted by other public or private granting agencies, by mutual agreement.” Available at: <http://www.cihr-irsc.gc.ca/e/20410.html>. Accessed September 2, 2011. Our discussion of conflicts of interest, however, is limited to the SCOC’s mandate with respect to review of the guidelines, as only this aspect of the mandate is relevant to our conclusion about incorporation of the stem cell research guidelines into *TCPS 2*.

11. We do not here take a position on whether other aspects of the SCOC’s mandate should also be amended. For example, research ethics review of specific protocols is an important governance issue. However, it is a distinct governance issue from that concerning responsibility for the development, implementation and interpretation of the guidelines. To remove the SCOC’s mandate with respect to review of the stem cell research guidelines has no necessary implications for the SCOC’s mandate with respect to ethics review of specific protocols.

12. See, for example, various CIHR meeting minutes: Standing Committee on Ethics, Meeting Minutes (May 6–7, 2002). Available at: <http://www.cihr-irsc.gc.ca/e/1169.html>; Standing Committee on Ethics, Meeting Minutes (September 19–20, 2002). Available at: <http://www.cihr-irsc.gc.ca/e/16771.html>; Standing Committee on Ethics, Meeting Minutes (December 3, 2002). Available at: <http://www.cihr-irsc.gc.ca/e/18180.html>; Standing Committee on Ethics, Meeting Minutes (February 27–28, 2003). Available at: <http://www.cihr-irsc.gc.ca/e/18182.html>; Standing Committee on Ethics, Meeting Minutes (May 8–9, 2003). Available at: <http://www.cihr-irsc.gc.ca/e/19036.html>; CIHR Governing Council, Meeting Minutes (November 20–21, 2002). Available at: <http://www.cihr-irsc.gc.ca/e/13135.html>; CIHR Governing Council, Meeting Minutes (March 19–20, 2003). Available at: <http://www.cihr-irsc.gc.ca/e/18016.html>; CIHR Governing Council, Meeting Minutes (June 18–19, 2003). Available at: <http://www.cihr-irsc.gc.ca/e/19817.html>. Accessed September 2, 2011.

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