

Interagency Secretariat on Research Ethics  
350 Albert Street  
Ottawa, ON Canada  
K1A 1H5

February 25, 2010

To Whom It May Concern:

During the previous consultation period, I underlined the importance of acting on the June 2003 commitment to formally incorporate the *Updated Guidelines for Pluripotent Stem Cell Research* into the revised *TCPS* -- a commitment spelled out in the Interim Tri-Agency Measures for Human Pluripotent Stem Cell Research (See, [http://www.nserc-crsng.gc.ca/NSERC-CRSNG/Politiques-Politiques/stemcell-cellulesouche\\_eng.asp](http://www.nserc-crsng.gc.ca/NSERC-CRSNG/Politiques-Politiques/stemcell-cellulesouche_eng.asp)) and referenced in section 3.0 of the 2005, 2006 and 2007 versions of the *Updated Guidelines*.

I further argued that formal incorporation of the *Updated Guidelines for Pluripotent Stem Cell Research* into the revised *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* should not be by reference, or as an appendix, but by including the substance of the *Updated Guidelines* into the *TCPS* (correspondence dated March 6 and March 31, 2009). I also presented this argument at the annual meeting of the Canadian Bioethics Society (June 12, 2009).

March 6, 2009:

[http://www.noveltechethics.ca/pictures/File/Health\\_Policy\\_Private/TCPS%20Documents/TCPS%20Proposed%20Revisions.pdf](http://www.noveltechethics.ca/pictures/File/Health_Policy_Private/TCPS%20Documents/TCPS%20Proposed%20Revisions.pdf) (see page 22, item 9)

March 31, 2009:

[http://www.noveltechethics.ca/pictures/File/Health\\_Policy\\_Private/TCPS%20Documents/Incorporation\\_of\\_Stem\\_Cell\\_Guidelines.pdf](http://www.noveltechethics.ca/pictures/File/Health_Policy_Private/TCPS%20Documents/Incorporation_of_Stem_Cell_Guidelines.pdf)

June 12, 2009:

[http://www.noveltechethics.ca/site\\_beyond.php?page=487](http://www.noveltechethics.ca/site_beyond.php?page=487)

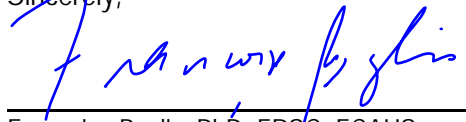
I had hoped that my arguments would be persuasive and that the suggested change would be made. Instead, in defense of the *status quo*, it has been suggested that stem cell research is a unique, fast paced area of research and for this reason the relevant research guidelines should be developed, interpreted and implemented by the Stem Cell Oversight Committee (SCOC) of CIHR (subject to approval from CIHR Governing Council) and not the Panel on Research Ethics (PRE). The underlying assumption is that the SCOC has more expertise than PRE, and is more easily able to amend research ethics guidelines in a timely fashion. On this basis, the Revised Draft 2nd Edition of the *TCPS* still leaves the *Updated*

*Guidelines for Pluripotent Stem Cell Research* outside the purview of the *TCPS* and PRE.

I am writing at this time to explain that the reasoning provided to date in defense of the Revised Draft 2<sup>nd</sup> Edition of the *TCPS* is deeply flawed and, again, to encourage PRE to carefully consider the arguments for including the substance of the stem cell guidelines in the *TCPS*, as outlined in the attached document

Permission is granted to post these comments on the PRE website.

Sincerely,



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Françoise Baylis, PhD, FRSC, FCAHS

*Professor and Canada Research Chair in Bioethics and Philosophy*

## ARGUMENTS FOR THE FORMAL INCORPORATION OF THE *UPDATED GUIDELINES FOR PLURIPOTENT STEM CELL RESEARCH* INTO THE REVISED *TCPS*

1. When the *TCPS* was first introduced in 1998, a precedent was set not to allow 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*).

At this time, with the first comprehensive effort to update the 1998 *TCPS*, this precedent should be followed.

2. The description 'a unique fast paced area of research' does not apply only to stem cell research. For example, the same could be said for research on brain-machine interfaces – yet there are not separate research guidelines for this area of research. While research involving Aboriginal Peoples may not be fast paced research, it is a unique area of research, and yet a decision has been made to incorporate the substance of the CIHR guidelines on Aboriginal Peoples into the *TCPS* and not to include these guidelines by reference. In this context, the decision to leave the stem cell guidelines outside the *TCPS* (and incorporated by reference) is clearly anomalous. There seems to be no principled argument for giving "unique fast paced research" its own guidelines and there is no consistency in application of the purported justification.
3. The need for special expertise does not in itself justify the retention of topic-specific research guidelines external to the *TCPS*. Arguably, special expertise is needed for many areas of research and when this is the case presumably the need has been met by having PRE access the requisite expertise. More generally, just as PRE, through the *TCPS*, enjoins REBs to access additional expertise on an as-needed basis, so too PRE can access additional expertise on an as-needed basis.
4. With a committee external to PRE responsible for the development, interpretation, and implementation of the stem cell guidelines there is an increased risk of conflict of interest. The stem cell research community is a small community and concerns have been raised, on more than one occasion, about close ties between the SCOC and researchers whose work is subject to SCOC review. These concerns could be minimized by including the substance of the stem cell guidelines in the *TCPS* and ensuring that these guidelines under the purview of PRE,
5. If the *Updated Guidelines* are only incorporated by reference, then there are two official bodies with the authority to develop, interpret and implement research ethics guidelines (i.e., CIHR (through SCOC) for stem cell research and PRE for all other research involving humans). This introduces at least four potential problems: (i) policy disagreement between the different authoritative bodies, (ii) potential

confusion for researchers; (iii) potential failure to capture all research; and (iv) overlapping jurisdiction.

(i) *Policy disagreement (e.g., the scope of the reach-through provision)*

According to the *TCPS*, "As a condition of funding, the Agencies require that *researchers and their institutions* apply the ethical principles and the articles of this Policy and be guided by the applications to the articles." [emphasis added] According to an SCOC interpretation of the stem cell guidelines (Article 6.0 "All human embryonic stem cell lines generated using CIHR funds will be listed with the registry and made available by the researcher to other researchers, subject to reasonable cost-recovery charges.") the reach-through provision does not apply to all aspects of the *Updated Guidelines for Pluripotent Stem Cell Research*. Specifically, the SCOC maintains that not all hESC lines created in an Agency-funded institution (with or without Agency funding) need be included in the stem cell registry. Only hESC lines created with CIHR funds must be in the registry (email correspondence dated December 24, 2009 from stemcell.cihr-irsc.gc.ca). Four stem cell lines have been created in Canada in Agency funded institutions and none of these are in the stem cell registry because of the SCOC interpretation.<sup>1</sup>

(ii) *Potential confusion (e.g., the oversight of research involving the creation of chimeras)*

The Revised Draft 2<sup>nd</sup> Edition of the *TCPS* provides definitions of hybrids and chimeras that are consistent with the *Assisted Human Reproduction Act* and refers researchers to the *AHR Act* for guidance as regards the prohibitions related to these areas of research. But elsewhere, in 12.E, stem cell researchers are also directed to follow the *Updated Guidelines for Human Pluripotent Stem Cell Research, June 29, 2007*. These guidelines are more restrictive than the legislation as regards chimera research in that they prohibit both: (i) "research in which human or non-human ES cells, EG cells or other cells that are likely to be pluripotent are combined with a human embryo"; and (ii) "research in which human ES cells, EG cells or other cells that are likely to be pluripotent are combined with a non-human embryo." Meanwhile, the *AHR Act* only concerns the manipulation of human embryos and is silent as regards research that involves non-human embryos. As the law is silent on this point, the stem cell guidelines are authoritative. Will researchers understand this? Will researchers be able to navigate through the *TCPS*, the *AHR Act*, and the stem

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<sup>1</sup> I am here leaving aside the question of whether the SCOC interpretation is correct. I have argued elsewhere that this exclusion is in direct conflict with the reach-through provision in: (i) the *TCPS*, (ii) agency-institution MOUs, (iii) the *Updated Guidelines for Pluripotent Stem Cell Research*, (iv) FAQs for stem cell research prepared by SCOC, and (v) SCOC Policy Highlights. I have further argued that the sentence in question from Article 6.0 of the stem cell guidelines is an artefact of the guidelines update process. See, Baylis, F. & Herder, M. (forthcoming 2010) Policy Design for human embryo research in Canada. However, the point here is that the *TCPS* and the stem cell guidelines (as interpreted by the SCOC) are in disagreement.

cell guidelines?

(iii) *Potential failure to capture all research (e.g., research to derive iPS cells)*

The Revised Draft 2<sup>nd</sup> Edition of the *TCPS* stipulates that “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.” But nowhere is the expression “pluripotent stem cells” defined. A researcher might genuinely believe that induced pluripotent stem cells (iPS cells) count as pluripotent stem cells and thus believe that her research on iPS cells is governed by the stem cell guidelines. But depending upon the nature of her research she could be wrong.

The May 8, 2008 SCOC minutes make clear that research to create iPS cells does not fall within the scope of the stem cell guidelines.

“SCOC recommended that the application to create human induced pluripotent stem cell lines does not fall within the scope of the Guidelines and therefore the application in question does not require SCOC review. This recommendation was presented and endorsed by the Governing Council Executive Committee on May 1.” <http://www.cihr-irsc.gc.ca/e/36722.html>

The FAQs on stem cell research further indicate that “research using iPS cells requires SCOC review only if grafting experiments are proposed” <http://www.cihr-irsc.gc.ca/e/15349.html>.

On this basis, it might reasonably be concluded that research to use iPS cells involving grafting experiments is governed by the stem cell guidelines, but that any other research involving iPS cells (e.g., derivation) is not covered by either the stem cell guidelines or the *TCPS*.

(iv) *Overlapping jurisdiction*

The SCOC believes that research involving grafting experiments using iPS cells is within its purview. But arguably, this is also within the purview of PRE under Chapter 11 of the *TCPS* on clinical trials.

6. If it is permissible to have two official bodies with the authority to develop, interpret and implement research ethics guidelines, what is to stop the proliferation of separate research ethics guidelines for other specific areas of research under the authority of one or more of the federal granting Agencies? If there can be separate research ethics guidelines for stem cell research (ultimately under the authority of CIHR Governing Council), then why not separate research ethics guidelines for other ethically challenging areas of research also under the authority of CIHR, or under the authority of one of the other federal granting Agencies? Allowing the *Updated Guidelines* to be incorporated into the revised *TCPS* by reference is an invitation to all three federal granting Agencies to proliferate research ethics guidelines that are, and will remain, under their sole control (as contrasted with the shared control through PRE over the *TCPS*).<sup>2</sup>
7. Article 12.10 directs those who do research to derive or use pluripotent stem cells to follow the stem cell guidelines. However, this Article is included in the section on “research involving materials related to human reproduction”. As much research to derive and use stem cells does not use materials related to human reproduction, it is possible that some stem cell researchers (e.g., those who work with adult stem cells) will never refer to this Article and will assume (logically) that their research is governed by Chapter 12 sections A-D of the *TCPS* concerning research “involving human biological materials” or Chapter 11 on clinical trials.

### **Recommendations**

The *Updated Guidelines for Pluripotent Stem Cell Research, 2007* should be incorporated into the revised *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* not by reference, or as an appendix, but by including the substance of the guidelines in the *TCPS*. There should be one independent organization with the authority to develop, interpret and implement ethics guidelines for all research involving humans.

The mandate of the SCOC should be revised so as to exclude responsibility for developing, interpreting, and implementing research guidelines. The SCOC should remain a national oversight body to review research protocols involving the derivation and use of stem cells.

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<sup>2</sup> Shared control of the research guidelines through PRE is problematic because PRE is not at arms-length from the funding Agencies. This is a significant problem of structural conflict of interest. Unfortunately, this matter is beyond the scope of the present consultation.