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**Memorandum to the  
Interagency Advisory Panel on Research Ethics:  
Incorporating the CIHR Stem Cell Guidelines  
into the TCPS**

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*Prepared by the*  
**Stem Cell Working Committee:  
A Working Committee of the  
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February 2008



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*The content and views expressed in this document are those of members of this committee, and do not necessarily reflect those of the Interagency Advisory Panel or Secretariat on Research Ethics.*

*The Panel and Secretariat welcome your comments:*  
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## 1. Purpose

To update the Interagency Advisory Panel on Research Ethics (PRE) on the Stem Cell Presidential Reference.

## 2. Issue

The Presidential Reference, signed in 2003, asked PRE to:

- *Build further* on the work and the guidelines of the Canadian Institutes of Health Research (CIHR): namely in reviewing relevant federal and international developments and consulting with appropriate experts, interests, and stakeholders, as necessary; and
- *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.

## 3. Background

The CIHR *Guidelines for Human Pluripotent Stem Cell Research* were released in 2002, ahead of the then pending legislation on assisted human reproduction. PRE struck a working committee who started monitoring international developments, consulting with experts and in particular monitored the progress of the Canadian legislation, knowing that it would have an impact on their deliberations.

The Working Committee was working towards a complete revision of Section 9 *Research Involving Human Gametes, Embryos or Foetuses* (and parts of Section 10 *Human Tissue*) of the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* (TCPS) but some factors emerged that caused delays in the process of moving forward the recommendations and caused the Working Committee to reconsider whether integrating the actual CIHR Guidelines into the TCPS was the best course of action.

### *The CIHR Stem Cell Oversight Committee*

In 2003 the same year the Reference was signed, CIHR set up a Stem Cell Oversight Committee (SCOC) to review applications for stem cell research conducted under the auspices of institutions eligible to receive agency funding. SCOC was also given a mandate in part to “[p]rovide ongoing review and revision of the guidelines in light of changing scientific data and social climate.” Thus the Working Committee was placed in a position where its authority in relation to SCOC was unclear.

### *The Assisted Human Reproduction Act*

On 29 March 2004, the *Assisted Human Reproduction Act* received Royal Assent. However, many aspects of the legislation were not finalized. For example, regulations regarding consent (Section 8) surrounding the use of gametes and embryos were published only this past June 2007 and came into force on 1 December 2007. Therefore, the Working Committee felt compelled to wait for the legislation and regulations to develop in order to ensure that its recommendations would not contravene the Act. The Act, moreover, is due to be reviewed as of January 2009.

Given the above developments, the Working Committee felt themselves to be in a difficult and unworkable position with respect to the first part of the Presidential Reference, with no real power to contribute to matters of substance or ongoing international developments.

With respect to the second part of the Presidential Reference, the Working Committee reconsidered its decision to integrate the CIHR Guidelines into the TCPS given that SCOC revised the Guidelines numerous times (in 2005, 2006 and 2007). However, the legislation specifically incorporated the 2002 Guidelines by reference, thus the Working Committee was unclear if it should be bound by the Act and incorporate only the 2002 Guidelines or if it should work with the Guidelines as updated by SCOC over the years. Confusion surrounded the legality of the updates until November 2007 when CIHR pronounced that as it is only the consent provisions of the 2002 Guidelines that are incorporated into the Act, CIHR is at liberty to amend all other provisions of the Guidelines. The Working Committee will abide by this position.

## **4. Considerations**

In relation to the first bullet of the Presidents' Reference, given all the different players that exist, the Working Committee will not be making its own recommendations regarding stem cell research but has extended its willingness to participate in such discussions to those involved and will continue to monitor the evolving landscape to ensure that regulatory developments do not depart from the core principles of the TCPS.

In regard to the second bullet of the Presidents' Reference, given CIHR's position that they are at liberty to revise the Guidelines bar the consent sections, the Working Committee has debated whether to append the existing version of the Guidelines or simply incorporate by reference.

### Appending

Appending the Guidelines could cause problems in that when SCOC does update the Guidelines, the TCPS would become out of date, in particular in print versions. This could cause confusion in the community. In addition, it could set a precedent to develop other extra-TCPS guidelines which could make the TCPS unwieldy in the future. However, having the Guidelines appended would make the TCPS a "one shop stop" for researchers and REB members who would not have to follow a link or work with two separate documents.

### Referencing

Including a sentence into the text of Section 9 would be a simple matter and require virtually no upkeep. In addition, should SCOC update the Guidelines the TCPS would be updated automatically. The downside 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.

Given the above arguments, the Working Committee is of the opinion that the CIHR Guidelines should be incorporated by reference in order to keep the TCPS a living document.

## **5. Recommendations**

1. The Stem Cell Working Committee recommends that PRE accept its decision to not build further independently on the CIHR Guidelines for their incorporation into the TCPS but rather to participate in discussions when invited to; and
2. Incorporate the CIHR Stem Cell Guidelines into the TCPS by reference.

## APPENDIX

August 6, 2003

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Chair, Interagency Advisory Panel on Research Ethics  
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**Subject: Reference to the Interagency Panel on Research Ethics: Human Pluripotent Stem Cell Research Guidelines for the TCPS**

*The Presidents of the CIHR, NSERC, and SSHRC,*

### **Recognizing**

- That an increasing number of nations have begun to address the therapeutic potential and ethical issues of human pluripotent stem cell research;
- That such nations have tended to do so by developing ethical and legal guidelines to regulate the procurement and use of human stem cells in research;
- That the *Tri-Council Policy Statement Ethical Conduct for Research Involving Humans* (TCPS) of 1998 – having preceded the era of human stem cell research – has yet to address directly the issues presented by this rapidly evolving research, even while some of its standards bear on the relevant issues;
- That the TCPS needs to stay current with modern research ethics needs;
- That the research ethics community which uses the TCPS is increasingly likely to need meaningful guidance on the ethical review of human stem cell research;
- That the CIHR has recently announced ethical guidelines to govern its funding of pluripotent stem cell research: *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* (2002);
- That the recent CIHR guidelines should serve as a model for the three granting Agencies;
- 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;

- That the particular issues raised by human embryonic stem cells research are likely to be addressed in part by federal legislation and implementing regulations;

**Therefore, Request the Interagency Advisory Panel on Research Ethics to:**

- *Build further* on the work and the guidelines of the CIHR: namely in reviewing relevant federal and international developments and consulting with appropriate experts, interests, and stakeholders, as necessary; and
- *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.

Ottawa \_\_\_\_\_ 2003.

Dr Alan Bernstein  
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Dr Tom Brzustowski  
President, Natural Sciences and Engineering Research Council of Canada

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