WOMEN AT RISK: EMBRYONIC AND FETAL STEM CELL RESEARCH IN CANADA

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In March of 2002, in the absence of explicit Canadian law or policy regulating the burgeoning and ethically controversial field of human embryonic stem cell research, the Canadian Institutes of Health Research (CIHR) published its Guidelines for Human Pluripotent Stem Cell Research. These Guidelines—largely based on the recommendations of CIHR's ad hoc Working Group on Stem Cell Research—aimed to enable the advancement of the stem cell science whilst protecting and promoting the interests of research participants, most particularly women. Unfortunately, as detailed in this paper, some of the ad hoc Working Group's recommendations specifically aimed at shielding women from potential coercion and exploitation were either omitted or amended, absent stated authority, in the 2002 Guidelines as later amended in 2005 and 2006. This paper traces the omissions and amendments to key recommendations on: (i) free and informed consent to research participation; (ii) decision-making regarding the future disposition of unwanted embryos; (iii) potential conflicts of interest; and (iv) the research use of frozen embryos. Concerns are raised about the consequences of the changes made to the protection and promotion of women's interests and the lack of legitimate authority for some of the changes.

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Competing Interests: Françoise Baylis was a member of the CIHR *ad hoc* Working Group on Stem Cell Research from November of 2000 to December of 2001 and a member of the CIHR Governing Council from January of 2002 to December of 2004. She was a Principal Investigator with the Stem Cell Network from January of 2002 to December of 2005.

INTRODUCTION

In November of 1998, James Thomson[1] and John Gearhart[2] announced their respective successes in deriving human embryonic stem cells (hESCs) and human germ stem cells. Many in the scientific community greeted this news with considerable enthusiasm.[3] Others, however, including some members of the scientific community, were much less optimistic;[4] some expressed concern about the moral status of embryos and fetuses,[5] and others expressed concern about the risks to women and couples who would provide the embryos and fetal tissue for research use.[6] These and other ethical concerns have since been the subject of intense international debate not only in the media and academia, but also in numerous governmental and quasi-governmental reports.[7]

Of particular interest in this paper are concerns about the health and safety of women and more specifically the twin risks of coercion and exploitation. According to some, these concerns are overstated. According to others, they are sufficiently serious as to preclude stem cell research involving embryos or fetal tissues.[8] Between these extremes are those who believe that these concerns are legitimate but that they can be managed effectively with the introduction and implementation of a sound regulatory framework.[9] On this view, rules and regulations can be introduced to protect and promote the interests of women.

Canada, as is frequently the case in matters of public policy and public opinion, occupies this middle ground: the concerns of and for women are recognized as legitimate and are addressed in relevant policy and legislative documents. In our estimation, however, the current protections offered to women are inadequate. In this paper we trace the evolution of the Canadian Institutes of Health Research (CIHR) stem cell research guidelines from 2001 to 2006, with particular attention to those parts of the guidelines

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1 James A. Thomson *et al.*, "Embryonic Stem Cell Lines Derived from Human Blastocysts" (1998) 282 Science 1145.

2 Michael J. Shamblott *et al.*, "Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells" (1998) 95 Proceedings of the National Academy of Sciences 13726.

3 See e.g. Elliott Marshall, "A Versatile Cell Line Raises Scientific Hopes, Legal Questions" (1998) 282 Science 1014; and Davor Solter & John Gearhart, "Putting Stem Cells to Work" (1999) 283 Science 1468.

4 Gretchen Vogel, "Stem Cells: New Excitement, Persistent Questions" (2000) 290 Science 1672.

5 See e.g. Brent Waters & Ronald Cole-Turner, eds., *God and the Embryo: Religious Voices on Stem Cells and Cloning* (Washington: Georgetown University Press, 2003); Richard Doerflinger, "Destructive Stem-cell Research on Human Embryos." (1999) 28 Origins 769.

6 See e.g. Suzanne Holland "Beyond the Embryo: A Feminist Appraisal of the Embryonic Stem Cell Debate" in Suzanne Holland, Karen Lebacqz & Laurie Zoloth, eds., *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy* (Cambridge: MIT Press, 2001) 73; Ingrid Schneider & Claudia Schumann, "Stem Cells, Therapeutic Cloning, Embryo Research: Women as Raw Material Suppliers for Science and Industry" *Proceedings of ReproKult: Women's Forum for Reproductive Medicine; Reproductive Medicine and Genetic Engineering; Women Between Self-Determination and Societal Standardisation, Berlin, 15 - 17 November 2001* 79, online: ReproKult <http://www.reprokult.de/e_forum_3.pdf>.

7 See e.g. American Association for the Advancement of Science & Institute for Civil Society, *Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research* by Audrey R. Chapman, Mark S. Frankel & Michele S. Garfinkle (Washington, D.C., 1999), online: <http://www.aaas.org/spp/sfrl/projects/stem/report.pdf>; U.K., Department of Health, *Government Response to the Recommendations Made in the Chief Medical Officer's Expert Group Report "Stem Cell Research: Medical Progress with Responsibility"* by Secretary of State for Health (2000), online: <http://www.dh.gov.uk/assetRoot/04/05/77/34/04057734.pdf>; Australian Academy of Science, *On Human Cloning: A Position Statement* (Cranberra: Australian Academy of Science, 1999), online: <http://www.science.org.au/reports/clone.pdf>; U.S., National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research: Report and Recommendations of the National Bioethics Advisory Commission*, (Rockville, MD: National Bioethics Advisory Commission, 1999), online: <http://www.bioethics.gov/reports/past_commissions/nbac_stemcell1.pdf> [USNBAC, *Report*]; Gretchen Vogel, "Stem Cell Scorecard" (2000) 290 Science 1673.

8 See e.g. Kelly Hollowell, "Federal Stem Cell Research: What Taxpayers Should Know" (Heritage Lecture #888 for the Heritage Foundation: Policy Research and Analysis, 24 June 2005) [unpublished], online: The Heritage Foundation <http://www.heritage.org/Research/HealthCare/hl888.cfm>; Center for Genetics and Society, *Egg Extraction for Stem Cell Research: Protecting Women's Health Fact Sheet* (2005), online: Center for Genetics and Society <http://www.genetics-and-society.org/resources/background/eefactsheet.html>.

9 See e.g. Meredith Wadman, "NIH Stem-Cell Guidelines Face Stormy Ride" (1999) 398 Nature 551; Rick Weiss, "Panel Drafts Ethics Plan for Embryo Cell Studies: Rules Would Guide Federally Funded Research" *The Washington Post* (9 April 1999) A2; Debra Greenfield, "The Impatient Polis: What's Wrong with the California Stem Cell Research and Cures Act?" (Paper presented at the Gender and Justice in the Gene Age conference, New York, NY, 6–7 May 2004) [unpublished], online: <http://www.gjga.org/conference.asp?action=item&source=documents&id=82>; American Society for Reproductive Medicine (Ethics Committee), "Donating Spare Embryos For Embryonic Stem-Cell Research" (2002) 78 Fertility and Sterility 957 (Reviewed June 2006), online: ASRM <http://www.asrm.org/Media/Ethics/donatingspare.pdf> [ASRMEC, "Donating"].

that have been formally incorporated into the *Assisted Human Reproduction (AHR) Act*.[10] This *Act*, in addition to defining and prohibiting assisted reproduction procedures deemed ethically unacceptable, regulates the research use of embryos. Our comparative analysis of relevant documents reveals both substantive and procedural problems with the ways in which key elements related to the protection and promotion of women's interests were eliminated or amended.

I
A BRIEF CHRONOLOGY OF THE CIHR GUIDELINES FOR STEM CELL RESEARCH IN CANADA

In the absence of Canadian laws or explicit research guidelines regulating the rapidly evolving and ethically controversial field of human embryonic stem cell research, CIHR established an *ad hoc* Working Group on Stem Cell Research in late 2000. This was a nine-member committee composed of scientists, clinicians, philosophers, and a lawyer that together possessed national and international proficiency in stem cell research and human reproductive technologies.[11] The mandate of the *ad hoc* Working Group was to determine whether and, if so, under what conditions, individuals and institutions funded by CIHR could undertake stem cell research consistent with the existing ethical framework set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Human* (TCPS).[12] On March 29, 2001, CIHR released a Discussion Paper prepared by the *ad hoc* Working Group, initiating a three-month public consultation.[13]

The Discussion Paper was sent to all CIHR-funded organizations and institutions, posted on CIHR's website, and publicized through the media. A total of 116 responses were received: 89 from individuals and 27 from "special interest groups, professional groups, health charities, [and] governmental agencies".[14] Importantly, a number of the ethical issues identified during the public consultation process were also of concern to members of the *ad hoc* Working Group. Chief among the shared concerns was the worry that "an increasing demand for human embryos or fetal material could result in coercion of women involved in fertility treatment or considering therapeutic abortion."[15] The *ad hoc* Working Group's response to this and other ethical concerns was multi-faceted, as explained in Appendix iii of their final report *Human Pluripotent Stem Cell Research: Recommendations for CIHR-Funded Research*.[16]

On January 16, 2002, the CIHR Governing Council unanimously adopted Motion GC-13-5:

> To accept the report of the ad hoc Working Group on Stem Cell Research outlining clear guidelines and prohibitions on stem cell research eligible for CIHR funding, as well as the following recommendations:
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> - establishment of a National Stem Cell Oversight Committee;
> - establishment of an electronically accessible national registry of human embryonic stem cell lines generated in Canada;
> - collaboration with other Federal funding agencies to ensure the Tri-Council Policy Statement is revised to clarify the ethical guidelines for human stem cell research;
> - the establishment of a new working group to examine the scientific and ethical issues of inter-specific chimeras [organisms with cell populations derived from two different organisms from different species]; and
> - the review of the field of human stem cell research on an ongoing basis with respect to the research guidelines and to review the need for, and process of national research ethics review.[17]

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10 *Assisted Human Reproduction Act*, S.C. 2004, c.2.

11 Canadian Institutes of Health Research *ad hoc* Working Group on Stem Cell Research, *Human Pluripotent Stem Cell Research: Recommendations for CIHR-Funded Research*, (January 2002), online: CIHR <http://www.cihr-irsc.gc.ca/e/1489.html> at App. ii. One of the authors (Françoise Baylis) was a member of the CIHR *ad hoc* Working Group on Stem Cell Research.

12 Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. 1998. *Tri-Council Policy Statement Ethical Conduct for Research Involving Humans*. Ottawa: Medical Research Council of Canada, online: PRE <http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf>.

13 Canadian Institutes of Health Research *ad hoc* Working Group on Stem Cell Research, *Human Stem Cell Research: Opportunities for Health and Ethical Perspectives*, (29 March 2001), online: CIHR <http://www.cihr-irsc.gc.ca/e/pdf_14370.htm>.

14 *Supra* note 11 at App. iii.

15 *Ibid*. [emphasis omitted].

16 *Ibid*. App. iii usefully summarizes the details of the policy response to the public consultation initiative.

17 Canadian Institutes of Health Research 13th Meeting of the Governing Council, *Minutes*, (Ottawa, ON, 16 January 2002), online: CIHR <http://www.cihr-irsc.gc.ca/e/1386.html> at s. 8. One of the authors (Françoise Baylis) was a member of Governing Council.

Of course, a Governing Council can accept the final report of an *ad hoc* Working Group without embracing all of the content of the report. This did not happen in this instance, however. First, the final report of the *ad hoc* Working Group was adopted unanimously and verbatim by the Governing Council. Second, there were no changes initiated by, or proposed to, the Governing Council between the unanimous adoption of the report in January of 2002 and the public release of the CIHR document *Human Pluripotent Stem Cell Research: Guidelines for CIHR Funded Research*[18] in March of 2002. Third, at no time was there any indication in public announcements or documents that the *2002 Guidelines* were different from the *Governing Council Report*. It follows that "accepting the report" did not mean "accepting the report for consideration", but rather meant accepting the guidelines and prohibitions, as well as other recommendations as stated in the final report. In this paper, we therefore refer hereafter to the final report of the *ad hoc* Working Group[19] as the *Governing Council Report*.

On March 4, 2002—with enthusiasm, confidence,[20] and direct reference to the *Governing Council Report*—Dr. Alan Bernstein, President of CIHR, announced "[t]oday, the Canadian Institutes of Health Research is taking a major step in setting guidelines that will enable Canadian researchers to conduct research using human pluripotent stem cells. The guidelines, effective today, will apply to researchers and institutions that receive funding from CIHR."[21]

A few years later, on June 7, 2005, the *Human Pluripotent Stem Cell Research: Guidelines for CIHR Funded Research* (hereafter the *2002 Guidelines*)[22] were officially updated pursuant to a Governing Council decision on March 24, 2005.[23] Consistent with the Governing Council directive to develop a "comprehensive communications plan to inform the research community"[24] of the policy changes, the *2005 Guidelines for Human Pluripotent Stem Cell Research*[25] (hereafter *2005 Guidelines*) were posted on the CIHR website[26] and an email notice was sent to "all CIHR staff, including Institutes, CAURA [Canadian Association of University Research Administrators], Business Officers, University Delegates, Communication Departments within universities, among others".[27] Unfortunately, this notice to the research community did not include a summary of the changes to the *2002 Guidelines* or a summary of the underlying rationale for any of the changes. On June 28, 2006, just over a year later, the *2005 Guidelines* were updated again.*[28]*

A comparative analysis of the *Governing Council Report* and the *2002*, *2005*, and *2006 Guidelines* reveals that several of the articles in the *Governing Council Report* directly relevant to the protection and promotion of women's interests, as well as the presumption in favour of the research use of frozen (not fresh) embryos, were either omitted or significantly amended in one or more versions of the *Guidelines*. In our view, these changes, not only thwart the intent and direction of the CIHR Governing Council, the recommendations of the *ad hoc* Working Group, and the legitimate concerns of Canadians (as identified through the public consultation process), but they also represent a serious threat to the interests of women and a serious threat to the integrity of the CIHR policy-making process. Each of these threats is carefully examined below.

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18 Canadian Institutes of Health Research, *Human Pluripotent Stem Cell Research: Guidelines for CIHR-funded Research,* (March 2002), online: CIHR <http://www.cihr-irsc.gc.ca/e/1487.html>.

19 *Supra* note 11.

20 The characterization of Dr. Bernstein's tone is based on direct observation of the event.

21 Alan Bernstein, "CIHR Guidelines on Human Pluripotent Stem Cell Research" (President's Address at the National Press Theatre 4 March 2002), online: CIHR <http://www.cihr-irsc.gc.ca/e/1203.html>. As CIHR is not a legislative body, its Guidelines only apply to individuals and institutions that receive CIHR funding. The regulation of privately funded stem cell research conducted in privately funded institutions would not occur until the *Assisted Human Reproduction Act* received Royal Assent in March of 2004.

22 *Supra* note 18.

23 Canadian Institutes of Health Research 33rd Meeting of the Governing Council, *Minutes*, (Ottawa, ON, 23-24 March 2005), online: CIHR <http://www.cihr-irsc.gc.ca/e/28683.html>.

24 *Ibid.* at s. 13.

25 Canadian Institutes of Health Research, *Guidelines for Human Pluripotent Stem Cell Research*, (7 June 2005), online: CIHR <http://www.cihr-irsc.gc.ca/e/28216.html>.

26 Canadian Institutes of Health Research, *Funding News and Developments: Application and Funding Policy News*, online: CIHR <http://www.cihr-irsc.gc.ca/e/26626.html>. The direct link to the notice is <http://www.cihr-irsc.gc.ca/e/28267.html>.

27 Personal phone communication between Karen Wallace (CIHR Ethics Office) and Caroline McInnes (5 August 2005), documented in email correspondence to Françoise Baylis.

28 Canadian Institutes of Health Research, *Updated Guidelines for Human Pluripotent Stem Cell Research*, (28 June 2006), online: CIHR <http://www.cihr-irsc.gc.ca/e/31488.html>.

II
THREATS TO THE INTERESTS OF WOMEN

As summarized in Appendix iii of the *Governing Council Report*, there were five articles specifically aimed at promoting the health, safety, and rights of women. First, in an effort to minimize the potentially ever-increasing demand for embryos for research use, the *Governing Council Report* required that successfully derived hESC lines be made available to all Canadian researchers on a cost-recovery basis. Second, in an effort to promote free and informed consent to embryonic and fetal stem cell research, the *Governing Council Report* required full disclosure and a two-part consent process for embryo research. There was to be an initial consent from the gamete providers at the time gametes were collected to make embryos for therapeutic purposes and a second consent from the embryo providers at the time of anticipated research use. Third, to ensure voluntariness and minimize the risk of coercion, the *Governing Council Report* made clear that consent to the research use of embryos or fetal tissue must *never* be a condition of access to treatment. Fourth, it was stipulated that physicians responsible for fertility treatment, persons responsible for securing the initial consent for the future disposition of unwanted embryos, and physicians responsible for therapeutic abortions must *not* be part of the stem cell research team. Last, the *Governing Council Report* called for the creation of a national Stem Cell Oversight Committee to provide national research ethics review of stem cell research (in addition to local Research Ethics Board review) and, as needed, to update the CIHR *Guidelines*. It was assumed that this Committee would continue to attend to the risks of coercion and exploitation of women.[29]

The first and last of these issues are dealt with in the *2002*, *2005* and *2006 Guidelines* in a manner entirely consistent with the *Governing Council Report*—successfully derived hESC lines are to be made available to Canadian researchers on a cost-recovery basis and hESC and germ stem cell research conducted by individuals or institutions that receive CIHR funding must be reviewed by the Stem Cell Oversight Committee.[30] As detailed below, however, the other issues more explicitly linked to the twin risks of coercion and exploitation are not dealt with in a similar manner. They are either omitted or significantly amended in the *2002*, *2005* and/or *2006 Guidelines*.

A. Free and Informed Consent

In an effort to promote free and informed consent, the *Governing Council Report* insisted on the need for "full disclosure of information by the researchers and free and informed consent from the research participants ... at the time that gametes are provided and again when the research use of the discarded embryos is anticipated".[31] Two articles in the *Governing Council Report* are relevant to this aspect of consent—articles 5.1 and 5.4. The first of these two articles stipulated that gamete providers and embryo providers must be informed of all options for the disposition of unwanted embryos, not merely the option of research use, and a decision regarding the future disposition of unwanted embryos must be made prior to the collection of gametes and the creation of embryos for reproductive purposes. The second article detailed the information that must be disclosed.[32]

As regards the requirement for full disclosure, the *Governing Council Report* carefully identified all of the information to be disclosed to prospective research participants in an effort to reduce the possibility of confusion, ambiguity, or misinterpretation, and to promote clarity and consistency.

> 5.4 For the purpose of obtaining free and informed consent to human stem cell research, at a minimum, researchers shall provide prospective research participants or authorized third parties with the following information.
>
> 1) A description of the purpose of the research;
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> 2) A description of the research procedures;
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> 3) A description of reasonably foreseeable harms and benefits that may arise from research participation;
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> 4) An explanation that consent to, or refusal of, research participation will not affect access to treatment;
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> 5) An explanation of the potential uses of the stem cells including any commercial uses, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors;

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29 *Supra* note 11 at App. iii.

30 *Supra* note 18 at art. 5.0; *supra* note 25 at art. 6.

31 *Supra* note 11 at App. iii.

32 *Ibid*. at arts. 5.1, 5.4.

> 6) An explanation that the research participants will not benefit directly financially from any future commercialization of cell lines; nor will there be any personal benefit in terms of dispositional authority over any cell lines created (i.e., there will be no directed donation of the cells or cell lines to particular individuals), except if the research involves autologous donation;
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> 7) An explanation that the cell line(s) will be anonymized, except if the research involves autologous donation ...
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> 8) An explanation that the research could result in the production of a cell line that could be maintained for many years and used for different research purposes;
>
> 9) An assurance that prospective research participants are free not to participate and have the right to withdraw at any time before an anonymized cell line is created.
>
> In the case of stem cell research involving human embryos where "donor" gametes have been used to create the embryos, only a subset of the disclosure requirements will apply because consent will be sought for unrestricted research use.[33]

An amended version of this article in the *Governing Council Report* appeared in article 7.2.3 of the *2002 Guidelines* and article 8.3.3 of the *2005* and *2006 Guidelines*. Of note, the requirements detailed in subsections 1) to 5) were eliminated and replaced with the general description "the usual information". Subsections 6) to 9) appeared with small wording changes and in a different order from that in the *Governing Council Report*.[34]

Though Canadian common law,[35] provincial legislation, legal literature,[36] and the TCPS[37] provided the backdrop against which the requirements for disclosure and consent to stem cell research were elaborated, the novelty of such research presented a unique challenge in defining these requirements, making their details particularly important to the goal of promoting clarity and consistency. Unfortunately, over half of the disclosure requirements in the *Governing Council Report* (articles 5.4.1–5) were replaced in the *2002, 2005* and *2006 Guidelines* with the instructions "in addition to the usual information given", when nowhere in these *Guidelines* is the "usual information" divulged, nor is there a reference to the appropriate authoritative source for the "usual information". This leaves the disclosure requirements for stem cell research seriously under-specific, which increases the risk of uninformed consent.

As the *2002, 2005* and *2006 Guidelines* are to be read in conjunction with the TCPS,[38] which outlines information that researchers must disclose to prospective research participants, the TCPS is at least one potential source of the "usual information". But will stem cell researchers know to consult the TCPS? Will they see these guidelines as authoritative?[39] Might they be confused by the reference to the "usual information" and look to the common law or provincial legislation? To say the least, it would seem unwise to invite guesswork on the part of stem cell researchers who are not legal scholars. In our view, in replacing the specific disclosure requirements with the ambiguous phrase "the usual information" without including a directive to the authoritative source, the *2002, 2005* and *2006 Guidelines* failed to effectively promote clarity and consistency and thereby failed to effectively insulate women from potential coercion associated with uninformed consent.

The second relevant consent issue concerns the requirement for advance planning regarding the future disposition of unwanted embryos prior to the creation of embryos. The *Governing Council Report* stipulated that:

> 5.1 Embryos no longer wanted for reproductive purposes may be donated to another couple, used for research (including research to derive and study human ES cells), or discarded. These options should be discussed with the gamete providers (and the embryo providers if these are different individuals), and *a decision regarding the eventual disposition of unwanted embryos should be made prior to the collection of gametes and the creation of embryos for reproductive purposes.*[40]

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33 *Ibid*. at art. 5.4.

34 *Supra* note 18 at art. 7.2.3; *supra* note 25 at art. 8.3.3.

35 See e.g. *Halushka v. University of Saskatchewan*, [1965] 52 W.W.R. 608 (Sask. C.A.); *Weiss v. Solomon*, [1989] 48 C.C.L.T. 280 (Qc. Sup. Ct.).

36 See generally Kathleen Cranley Glass & Trudo Lemmens, "Research Involving Humans" in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Markham: Butterworths, 2002) at 479-487. See also Ellen Picard & Gerald Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3d ed. (Scarborough: Carswell, 1997) at c. 3.

37 *Supra* note 12.

38 *Ibid*.

39 The TCPS applies to individuals and institutions that receive funding from CIHR, SSHRC and NSERC.

40 *Supra* note 11 at art. 5.1 [emphasis added].

The highlighted clause was included, verbatim, in article 7.2.1 of the *2002 Guidelines*.[41] However, it was later amended in article 8.3.1 of the *2005 Guidelines* so that disclosure, but not decision-making, regarding the future disposition of unwanted embryos was required at the time of gamete collection and prior to the creation of embryos:

> 8.3.1 Those who no longer require fresh or frozen embryos for their reproductive purposes may: 1) donate the embryos to others to use for reproductive purposes; 2) donate the embryos for research (including research to derive and study human ES cells); or 3) provide authorization for the embryos to be destroyed. The embryo provider(s) (and the third party gamete provider(s), if applicable) *must be informed of these options prior to the collection of gametes and the creation of embryos for reproductive purposes.*[42]

A few months after the *2005 Guidelines* were published, the proposed regulatory text for the Consent Regulations (section 8), pursuant to the *AHR Act*, was published in the Canada Gazette. [43] As required by law, the draft Consent Regulations were consistent with the *2002 Guidelines* and as such they included a clear requirement for both disclosure and decision-making. The resulting predictable (and predicted) inconsistency between the *2005 Guidelines* and the draft Consent Regulations was brought to the attention of CIHR. The CIHR Ethics Office was provided with a confidential copy of an earlier version of this paper explaining that: (i) the original *2002 Guidelines* were consistent with national and international practice; (ii) the *2005 Guidelines* did not adequately protect and promote women's interests; and (iii) the *2005 Guidelines* would appear to be inconsistent with the law insofar as the consent regulations would have to be consistent with the *2002 Guidelines*. The following year, with the *2006 Guidelines*, the text from article 8.3.1 reverted to the text of article 7.2.1 of the *2002 Guidelines*.

One principled reason for eliciting an initial consent to the future disposition of excess embryos is to ensure that patients not only understand and agree to the purposes of creating IVF embryos, but are also willing to accept responsibility for the associated consequences. A second principled reason for early decision-making is to explicitly recognize and value the dispositional rights of individuals over their reproductive material. In part, patients' understanding and control is evidenced by decision-making regarding the future disposition of embryos no longer wanted for infertility treatment.

An additional pragmatic reason for eliciting an initial consent to the future disposition of excess embryos is to avoid the possibility of no decision being made about the future of embryos created for infertility treatment but no longer wanted for this purpose, and the IVF clinic having in its possession embryos for which there is no advance planning and over which they have no dispositional authority. IVF clinics have no interest in the permanent storage of frozen embryos, hence their interest in making sure that there are disposition plans in place prior to the creation and freezing of embryos. As the time between the creation and possible freezing of embryos is short, there is reason to elicit a choice prior to the creation of embryos. Further, decision-making about the creation and possible freezing of embryos for infertility treatment can be psychologically stressful for women. One way of addressing some of this stress involves assuring women that the future disposition of their embryos is at their discretion (i.e., under their control).

Current practice in Canada (consistent with the Canadian Fertility and Andrology Society and the Society of Obstetricians and Gynecologists of Canada Guidelines,[44] as well as international practice[45]) is to require advance planning for the future disposition of unwanted frozen embryos, recognizing all the while that any advance plans can always be amended (by definition, consent is always revocable). This common practice was reflected in the original consent requirements of the *Governing Council Report* and the *2002 Guidelines*.[46] With the *2005 Guidelines*, however, these consent requirements were amended such that although information about disposition options had to be disclosed, no decision about the future disposition of embryos had to be made.[47]

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41 *Supra* note 18 at art. 7.2.1.

42 *Supra* note 25 at art. 8.3.1 [emphasis added].

43 Department of Health, "*Erratum*: Assisted Human Reproduction (Section 8) Regulations" in *Canada Gazette*, vol. 139 (24 September 2005) at 3181, online: Canada Gazette <http://canadagazette.gc.ca/partI/2005/20050924/pdf/g1-13939.pdf>.

44 Canadian Fertility and Andrology Society and Society of Obstetrics and Gynaecology Canada, "Disposition of Frozen Embryos" (1999) 21:1 Journal of the Society of Obstetricians and Gynaecologists of Canada 19 at 22.

45 See e.g. American Society for Reproductive Medicine (Ethics Committee), "Disposition of Abandoned Embryos" (2004) 82: Suppl 1 Fertility and Sterility S253 (Reviewed July 2006), online: <http://www.asrm.org/Media/Ethics/abandonedembryos.pdf>; ASRMEC, "Donating", *supra* note 9 at 959.

46 *Supra* note 11 at art. 5.1; *supra* note 18 at art. 7.2.1.

47 *Supra* note 25 at art. 8.3.1.

Another pragmatic benefit of decision-making prior to the creation of embryos is that potential problems with clinic practice regarding the disposition of frozen embryos could be rectified before embryos were created and frozen. For example, a 2005 Canadian study of consent documents for embryo freezing revealed that in some circumstances (such as loss of contact), IVF clinics conferred upon themselves decision-making authority for the disposition of frozen embryos.[48] If women were aware of this practice prior to the creation and freezing of their embryos, then they would be in a position to take appropriate measures to preclude this practice.

A third discrete consent issue concerns the explicit requirement that consent to the research use of embryos be renewed at the time of anticipated research use. The *Governing Council Report* stipulated:

> 5.2 At the time when the embryos are to be used for research to derive and study ES cells and other human cells or cell lines of a pluripotent nature, consent of the embryo providers should be confirmed. A renewal of the consent given by the gamete providers (if the gamete providers are not the same individuals as the embryo providers), is not required provided that appropriate consent for the unrestricted research use of the embryos was given at the time of gamete "donation".
>
> 5.6 To help ensure voluntariness, at the time the embryo(s) are to be used for research, a reconfirmation of the original consent to the research use of embryos must be obtained from the embryo providers. This requirement affirms the right to withdraw and is necessary because of the possible lengthy delay between the time at which the original consent is given and the time at which the embryos are utilized for research purposes.[49]

These two articles were collapsed as article 7.2.2 in the *2002 Guidelines*[50] and reprinted (with minor modification) as article 8.3.2 in the *2005* and *2006 Guidelines*.

> 8.3.2 At the time when the embryos are to be used for research to derive and study ES cells (and other human cells or cell lines of a pluripotent nature), consent of the embryo providers must be reiterated. This requirement affirms the right to withdraw and is necessary because of the possible lengthy delay between the time at which the original consent is given and the time at which the embryos are utilized for research purposes....[51]

The principled and pragmatic reason for requiring a reiteration of the initial consent to the research use of embryos is to allow women to change their mind. Evidence suggests that decision-making regarding the future disposition of embryos is complicated and influenced by one's experiences during fertility treatment.[52] Indeed, in 2001, Klock et al. reported that only 29% of couples stuck with their initial disposition decision, and more specifically, that 88% of couples who initially decided to donate their frozen embryos to research changed their mind.[53] More recently, in a 2006 survey of one Canadian IVF clinic, Nisker et al. reported that only 55% of couples who had specifically designated their frozen embryos for donation to research consented to embryonic stem cell research when contacted to reiterate their consent to this research use of their frozen embryos.[54] Thus, it appears that many IVF patients who initially consent to the future donation of excess frozen embryos to research (consent provided prior to the creation of *in vitro* embryos) change their mind once they are no longer in active treatment and no longer potentially influenced by what their physicians want.[55]

The fourth consent issue concerns the right to withdraw. The *Governing Council Report* explicitly addressed the right to withdraw consent for both the embryo providers and the gamete providers.

> 5.7 Consent to the research use of embryos is always revocable by the embryo providers who may change their mind regarding the future research use of embryos no longer wanted for reproductive purposes. Gamete providers who consent to the possible future research use of embryos created using their gametes cannot later withdraw their consent. They should be so advised during the informed choice process.[56]

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48 Françoise Baylis and Natalie Ram, "Eligibility of Cryopreserved Human Embryos for Stem Cell Research in Canada" (2005) 27:10 Journal of Obstetrics and Gynaecology Canada 949.

49 *Supra* note 11 at arts. 5.2, 5.6.

50 *Supra* note 18 at art. 7.2.2.

51 *Supra* note 25 at art. 8.3.2.

52 Robert D. Nachtigall *et al.*, "Parents' Conceptualization of Their Frozen Embryos Complicates the Disposition Decision" (2005) 84:2 Fertility and Sterility 431. See also, C.A. McMahon *et al.*, "Mothers Conceiving through in Vitro Fertilization: Siblings, Setbacks, and Embryo Dilemmas after Five Years" (2000) 10:3 Reproductive Technologies 131.

53 S.C. Klock, S. Sheinin & R.R. Kazer, "The Disposition of Unused Frozen Embryos" Letter (2001) 345 New Eng. J. Med. 69.

54 Jeffrey Nisker *et al.*, "Development and Investigation of a Free and Informed Choice Process for Embryo Donation to Stem Cell Research in Canada," (2006) 28:10 Journal of Obstetrics and Gynaecology Canada 903.

55 Carolyn McLeod & Françoise Baylis "Women Donating Fresh Embryos to Stem Cell Research: In Whose Interests?" (in review); and Carolyn McLeod & Françoise Baylis "The Ethics of Asking IVF Patients to Donate Fresh Embryos to Stem Cell Research" (Poster presented to the Canadian Fertility and Andrology Meeting, Ottawa, November 2006) [unpublished].

56 *Supra* note 11 at art. 5.7.

There is no comparable article in either the *2002, 2005* or *2006 Guidelines* that both affirms the embryo providers' right to withdraw and limits the gamete providers' right to do so. There is an indirect reference to the embryo providers' right to withdraw in article 7.2.2 of the *2002 Guidelines* and article 8.3.2 of the *2005 and 2006 Guidelines* with the statement about how the "requirement [for a reiterated consent] affirms the right to withdraw".[57] There is no statement in either the *2002, 2005* and *2006 Guidelines*, however, limiting the gamete providers' right to withdraw, as per the *Governing Council Report*. Indeed, article 7.2.3 of the *2002 Guidelines* and article 8.3.3 of the *2005* and *2006 Guidelines* stipulate that "prospective research participants are free not to participate and have the right to withdraw at any time before an anonymized cell line is created."[58] As gamete providers are clearly prospective research participants, then contrary to the *Governing Council Report*, it would appear that they have the right to withdraw "at any time before an anonymized cell line is created".[59]

In sum, for those committed to free and informed consent, it is distressing that many of the ethically sound consent requirements carefully outlined in the *Governing Council Report* were amended in the *2002 Guidelines* (and that many of these amendments were retained in subsequent updates to the *Guidelines*). This is of particular concern because the *2002 Guidelines* (not the more comprehensive and ethically sound *Governing Council Report*) have been formally incorporated into the *AHR Act*.[60] This *Act* defines consent as follows:

> "consent" means fully informed and freely given consent that is given in accordance with the applicable law governing consent and that conforms to the provisions of the *Human Pluripotent Stem Cell Research Guidelines* released by the Canadian Institutes of Health Research in March, 2002, as detailed in the Regulations.[61]

Furthermore, in its administrative section, the *AHR Act* requires that

> (3.1) The Agency shall not issue a licence under subsection (1) for embryonic stem cell research unless it has received the written consent of the original gamete providers and the embryo provider in accordance with the *Human Pluripotent Stem Cell Research Guidelines* released by the Canadian Institutes of Health Research in March, 2002, as specified in the regulations.[62]

One can only dream of how much better consent law on embryo research could have been if the original *Governing Council Report* had not been amended with the release of the *2002 Guidelines*. Imagine, for example, if the original disclosure requirements had been included in the *2002 Guidelines* instead of the general statement about the "usual information" with no clear instruction as to the authoritative source for the content of the "usual information". Unfortunately, even if CIHR were persuaded to revise its *Guidelines* (yet again) to better correspond with the *Governing Council Report*, it cannot amend this aspect of the law. The legislation is clear; given the specificity of the reference to the guidelines in the *AHR Act*, that the consent requirements of the *2002 Guidelines*, not any subsequent revisions, have legal force.[63]

B. Consent to embryo research not a condition of access to treatment

The *Governing Council Report* required "that consent to the use of unwanted embryos or aborted fetal tissue never be a condition of access to treatment."[64] Several articles in the *Report* specifically addressed this issue.

> 4.1 Research to derive and study human embryonic stem cell lines or other cell lines of a pluripotent nature from human embryos is eligible for funding provided that:

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57 *Supra* note 18 at art 7.2.2 and *supra* note 25 at art 8.3.2.

58 *Supra* note 18 at art 7.2.3 and *supra* note 25 at art 8.3.3.

59 *Ibid*.

60 *Supra* note 10.

61 *Supra* note 10 at s. 3.

62 *Supra* note 10 at s. 40(3.1).

63 Applying principles of statutory interpretation, the definition of "consent" in section 3 of the Act is exhaustive: see Pierre-André Côté, The Interpretation of Legislation in Canada, 3d ed. (Scarborough: Thomson Canada Limited, 2000) 62: "A first reading is usually sufficient to indicate whether a definition is exhaustive or not: if introduced by the word 'means' it is deemed to be exhaustive." In this case, the definition of consent in section 3 starts with the deeming word "means". At 61, Côté says, "An exhaustive definition purports to encompass all possible meanings of a term." In this case, only the March *2002 Guidelines* are encompassed in the definition as a possible meaning in relation to consent.

64 *Supra* note 11 at App. iii.

> ...
>
> 3. Neither the ova nor the sperm from which the embryos were created, nor the embryos themselves, were obtained through commercial transactions, including exchange for service.
>
> 4.2 Research to derive and study human embryonic germ cell lines, or other cell lines of a pluripotent nature from human fetal tissue or amniotic fluid is eligible for funding provided that:
>
> The proposed research does not compromise the pregnant woman's decision on whether to continue her pregnancy....
>
> 5.3 For research to derive and study EG cells and other human cells or cell lines of a pluripotent nature from human fetal tissue, the option of using fetal tissue for research must only be discussed with the pregnant woman after a free and informed choice has been made to have a therapeutic abortion. A woman's decision about whether to continue her pregnancy must not in any way be influenced by the possible research use of the fetal material.
>
> 5.4 For the purpose of obtaining free and informed consent to human stem cell research, at a minimum, researchers shall provide prospective research participants or authorized third parties with the following information.
>
> ...
>
> An explanation that consent to, or refusal of, research participation will not affect access to treatment....
>
> 5.10 Consent to the research use of unwanted embryos, aborted fetal tissue, umbilical cord or adult tissues should never be a condition, explicit or implicit, of access to treatment.[65]

In the *2002 Guidelines*, article 4.1(3) appeared verbatim as article 7.1.1(3). In the *2005* and *2006 Guidelines*, this article appeared as 8.1.1(3) with the text amended to redefine commercial transactions as "payment of money in excess of costs actually incurred or in exchange for healthcare services."[66] In the *2002 Guidelines*, article 4.2(1) became article 7.1.2(1) and in the *2005* and *2006 Guidelines* this was included as part of article 8.1.2(1) with the following additional text: "To ensure that such compromise does not occur, the stem cell researcher shall provide SCOC with satisfactory evidence that the pregnant woman's decision to discontinue the pregnancy was made prior to any request made to her to participate in the research." In this way a version of article 5.3 was reintroduced as part of article 8.1.2 in the *2005* and *2006 Guidelines*. The other two articles (5.4.4 and 5.10) were eliminated from the *Guidelines*, though there is a statement to the effect that embryos (no mention of fetal or other tissues) cannot be used for research if they were obtained through commercial transactions (defined differently in the *2002* and the *2005* and *2006 Guidelines*).[67]

The importance of the original articles in the *Governing Council Report* in shielding women from potential forms of coercion must not be overlooked. Coercion is often unintentional and is not always obvious; this makes it imperative that the rules governing stem cell research remove all foreseeable potential sources of coercion. Article 5.3 of the *Governing Council Report*,[68] for example, circumvented several possible sources of coercion by insisting that the research use of fetal tissue "must only be discussed with the pregnant woman after a free and informed choice has been made to have a therapeutic abortion".[69] This constraint recognized that the decision to have a therapeutic abortion might be influenced by discussion about the potential use of fetal material for stem cell research.[70] For example, a woman might feel obliged to donate her fetal material for research, fearing that her physician will be angry or upset with her if she did not want to donate, or worse, would not assist her with access to treatment. From another perspective, knowledge of the option of fetal tissue donation for research use might persuade an ambivalent person to forge ahead whereas under other circumstances she might have reconsidered her decision.

The importance of article 5.3[71] in the original *Governing Council Report* protecting pregnant women against possible forms of coercion is affirmed by its reintroduction in the *2005* and *2006 Guidelines* in article 8.1.2.[72] It is of concern, however, that only this missing article was reintroduced.

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65 *Supra* note 11 at arts. 4.1, 4.2, 5.3, 5.4.4, 5.10.

66 *Supra* note 25 at art 8.1.1.

67 *Supra* note 18 at art. 7.1.1; *supra* note 25 at art. 8.1.1.

68 *Supra* note 11 at art. 5.3.

69 *Supra* note 11 at art. 5.3

70 National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research: Volume 1 Report and Recommendations of the National Bioethics Advisory Commission* (Rockville: National Bioethics Advisory Commission, 1999) at 69, online: National Bioethics Advisory Commission <http://www.georgetown.edu/research/nrcbl/nbac/stemcell.pdf>.

71 *Supra* note 11 at art. 5.3.

72 *Supra* note 25 at art. 8.1.2.

C. No research team role for members of the health care team

In an effort to minimize the potential problem of conflict of interest, the *Governing Council Report* specified that persons in a clinical relationship with the women considered prospective research participants should not be members of the research team. The *Governing Council Report* required that "the physician responsible for the fertility treatment, the person seeking a consent to the disposition of embryos or the physician responsible for the therapeutic abortion, not be part of the stem cell research team."[73]

Several articles in the *Governing Council Report* addressed this concern:

> 5.5 To help ensure voluntariness and to minimize the risk that women and couples will be pressured to create more embryos than needed for reproductive purposes, the physician responsible for the fertility treatment and the person seeking a consent to the disposition of embryos no longer wanted for reproductive purposes (including the option of embryo research) may not be part of the stem cell research team.
>
> 5.9 To help ensure voluntariness and to minimize the risk that pregnant women will be pressured to terminate their pregnancy to provide fetal tissue for research purposes, the physician responsible for the therapeutic abortion may not be part of the stem cell research team.[74]

These two articles were collapsed into one in the *2002 Guidelines* as article 7.2.7 and in the *2005* and *2006 Guidelines* as article 8.3.7: "Physicians responsible for fertility treatment and physicians responsible for termination of pregnancy will not be part of a stem cell research team."[75] Significantly, persons "seeking consent to the disposition of embryos" were not listed among those excluded from membership on the hESC research team. If the persons "seeking consent to the disposition of embryos" are not also the "physicians responsible for fertility treatment", then the problem of conflict of interest arises. To explain, there are several legitimate options for the disposition of embryos no longer wanted for infertility treatment including destruction, donation to another couple, use for instructional purposes, and research use. If the persons seeking consent to the disposition of these embryos are members of an hESC research team, they have a particular interest in promoting the research option in preference to other options.

Equally problematic for the *2005 Guidelines*, but not the *2006 Guidelines*, is article 8.3.2. This article is identical to article 7.2.2 of the *2002 Guidelines* but for the addition of the following statement: "Members of the health team treating and/or counseling the client should not be the persons to obtain consent from the embryo provider at *the time of re-consent*."[76] A first problem with this article is the requirement for a re-consent when there is no longer a requirement for an initial consent in the *2005 Guidelines* (article 8.3.1 eliminated the requirement for decision-making and only required the disclosure of disposition options). A second problem with this article for the *2005 Guidelines* is that it potentially introduces ambiguity regarding who is responsible for any possible, but not required, "initial consent". With the original *Governing Council Report*[77] and the *2002 Guidelines*,[78] members of the fertility treating team were responsible for the initial consent to IVF, embryo freezing, and the future disposition of unwanted embryos, and if the woman chose to donate unwanted embryos to research, then, at the time of anticipated research use, members of the research team were responsible for the re-consent. The *Governing Council Report*[79] and the *2002 Guidelines*,[80] further stipulated that members of the treating team were precluded from being members of the research team. With the *2005 Guidelines*, there is an explicit statement to the effect that members of the treating team should not be involved in the re-consent, but it is not clear what role they do or do not have with any possible initial consent and whether this consent process does or does not include a general consent to research use, that is then to be followed up by others seeking a re-consent to specific research use. These problems are eliminated with the *2006 Guidelines* because the text for article 8.3.1 has reverted to the text in article 7.2.1 of the *2002 Guidelines*.

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73 *Supra* note 11 at App. iii.

74 *Supra* note 11 at arts. 5.5, 5.9.

75 *Supra* note 18 at art. 7.2.7; *supra* note 25 at art. 8.3.7.

76 *Supra* note 25 at art. 8.3.2. [emphasis added].

77 *Supra* note 11.

78 *Supra* note 18.

79 *Supra* note 11.

80 *Supra* note 18.

D. Fresh embryos for hESC research

In the *Governing Council Report* and the *2002 Guidelines*, it was understood that, for ethical reasons, embryos used for stem cell research usually would be frozen embryos. Generally, it is not in the medical or other-regarding interests of infertile women using assisted reproductive technologies to donate their fresh embryos for research when these could be frozen for later infertility treatment.[81] In a subsequent treatment cycle, frozen embryos not transferred in the initial treatment cycle may be thawed and transferred, thereby: (i) increasing the chance of pregnancy and childbearing; (ii) decreasing the number of risky or painful procedures; (iii) decreasing the psychological stress experienced as a result of IVF; (iv) decreasing the social disruption that IVF causes; and (v) decreasing the financial burden of infertility treatment. Indeed, studies have shown that there is an "emphatic benefit" associated with the use of frozen embryos in subsequent cycles, as such transfers are not only low risk, "avoid[ing] the hazards of oocyte retrieval and ovarian hyperstimulation syndrome",[82] but they are also highly cost-effective.[83] Neither infertility patients nor their physicians can know whether non-transferred embryos will be wanted for future reproductive use unless these embryos are being discarded for morphological, biological, or genetic reasons.[84] It follows that if embryos are truly being created for therapeutic purposes, as required by the *Governing Council Report*, the *2002*, *2005* and *2006 Guidelines*, and the *AHR Act*, then usually they would be frozen for such future use.[85]

The *Governing Council Report* and the *2002 Guidelines* were silent on the issue of frozen versus fresh embryos. In both of these documents, however, there was a clear requirement for a dual consent because of possible lengthy delays between the time at which the initial consent was given (prior to the creation of embryos) and the time at which the embryos might be used for research (when the consent was to be reiterated). This original consent requirement clearly presumed that frozen (not fresh) embryos were to be used for research, as with fresh embryos the maximum delay between the time of fertilization and the research use of these embryos to derive stem cells would only be three to five days—hardly a lengthy delay. On this point—as to when consent should be obtained—the Ethics Committee of the American Society for Reproductive Medicine holds that:

> Using only frozen embryos for research ensures that time passes between the creation of embryos for conception and their donation for research. Still, it is reasonable to expect questions eventually to arise about the donation of fresh but supernumerary embryos. Donation of fresh embryos raises the possibility that a physician might induce a patient to allow insemination of extra eggs so that they may be donated for research. Moreover, this increases the chance that decisions will be made quickly and later regretted by couples. Without evidence that fresh embryos are significantly preferable to frozen embryos for ES cell use, it is appropriate to use only spare embryos that have been frozen. The number of embryos created and frozen should be determined by the clinical needs of the infertile couple.[86]

The *2005 Guidelines* changed the presumption that non-transferred healthy embryos typically would be frozen for later therapeutic use and explicitly endorsed the research use of fresh embryos. Unfortunately this change remains in the *2006 Guidelines* despite the lack of evidence to support the claim that there is any scientific benefit to the research use of fresh versus frozen embryos, and the abundance of evidence showing that this is potentially harmful to women. Significantly, the little evidence that is available comparing the efficacy of fresh versus frozen embryos suggests that it is easier to derive human embryonic stem cells from frozen-thawed embryos than fresh embryos.[87] Further, the *2005* and *2006 Guidelines* do not limit the research use of fresh embryos to embryos that could not otherwise be frozen for future therapeutic use (e.g., embryos with a morphological, biological, or genetic disorder). This policy change potentially undermines the commitment to prohibit the purposeful creation of embryos for research use any time more embryos are created than are intended for transfer (usually between three and

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81 *Supra* note 55.

82 Ian S. Tummon, Mark A. Wentworth & Alan R. Thornhill, "Frozen-thawed embryo transfer and live birth: Long-term follow-up after one oocyte retrieval" (2006) 86:1 Fertility and Sterility 239.

83 Bradley J. Van Voorhis *et al.*, "The efficacy and cost effectiveness of embryo cryopreservation compared with other assisted reproductive techniques" (1995) 64:3 Fertility and Sterility 647.

84 Jeffrey Nisker & Angela White, "The CMA Code of Ethics and the Donation of Fresh Embryos from Stem Cell Research" (2005) 173:6 Canadian Medical Association Journal 621.

85 *Supra* note 11 at art. 4.1; *supra* note 18 at art. 7.1.1; *supra* note 25 at art. 8.1.1.

86 ASRMEC "Donating", *supra* note 9 at 959.

87 A. Sjogren *et al.*, 'Human blastocysts for the development of embryonic stem cells', online: (2004) 9:3 Reproductive Biomedecine Online 326 <http://www.rbmonline.com>.

five embryos, depending upon clinic practice). Article 8.1.1 identifies the types of research that conform to the *2005* and *2006 Guidelines*:

> 8.1.1 Research to derive and study human embryonic stem (ES) cell lines or other cell lines of a pluripotent nature from human embryos, provided that:
>
> 1. The embryos used, *whether fresh or frozen*, were originally created for reproductive purposes and are no longer required for such purposes....[88]

This amendment to explicitly authorize the research use of fresh embryos for hESC research (under review in the *2005 Guidelines* and fully endorsed in the *2006 Guidelines*) marks an important and troubling shift in CIHR stem cell research policy.

III
THREATS TO THE INTEGRITY OF THE CIHR POLICY-MAKING PROCESS

As explained in detail above, the *2002*, *2005* and *2006 Guidelines* substantially amended the *Governing Council Report* in relation to (i) several aspects of free and informed consent, (ii) the prohibition on consent to stem cell research as a condition of access to treatment, (iii) the prohibition on members of the health care team also being members of the stem cell research team, and (iv) the presumption that frozen (not fresh) embryos generally would be used for hESC research. And, while there is a public record of the changes made to the *2002 Guidelines* as well as the *2005 Guidelines*, there is no public accounting of the substantive changes made to the *Governing Council Report*. How did these changes occur? Who made them and on what authority?

Governing Council authorized very specific content for its stem cell research guidelines through its unanimous and verbatim adoption of the *ad hoc* Working Group final report, but this content is not completely and accurately reflected in the *2002 Guidelines*. Given (i) the explicit reference to the *Governing Council Report* in the release of the *2002 Guidelines*, (ii) the failure to publicly identify and explain any changes made to the *Governing Council Report*, (iii) the fact that Governing Council was unaware of any changes,[89] and (iv) the fact that such changes were made without the authority of Governing Council, this raises the uncomfortable possibility that those who drafted and/or released the *2002 Guidelines* did not wish the readers of the guidelines (including members of Governing Council) to realize that changes had been made—changes that removed certain constraints on stem cell research and in so doing introduced certain risks of harm to women. This possibility raises profound questions about CIHR's valuation of the public consultation process and the deliberations of the *ad hoc* Working Group. As well, it raises important questions regarding the perceptions within CIHR about the authority of the Governing Council. These questions, in turn, potentially undermine public trust and confidence in the integrity of CIHR's policy-making process.

With the *2005* and *2006 Guidelines*, unlike the *2002 Guidelines*, the public record indicates that some of these changes were proposed by the Governing Council while others were proposed by the Stem Cell Oversight Committee. All of the proposed changes were approved by the Governing Council. As such, there are no unanswered questions about who made what changes and on what authority. Questions remain, however, as regards why some of the changes, especially with the *2005 Guidelines*, were made. The official rationale for the *2005 Guidelines* is summarized in the Governing Council March 2005 minutes as follows:

- minor editorial changes for better clarity and interpretation;
- changes to clarify alignment with the Tri-Council Policy Statement;
- changes to inform researchers that stem cell research applications falling within the scope of the Guidelines must be reviewed by both a local Research ethics Board and SCOC; and ...
- deletion of a section which references a suggestion by the Ad Hoc Working Group on Stem Cell Research for a national research ethics board, which is not relevant to the current Guidelines;
- *changes to recognize that fresh embryos (and not just frozen embryos) and stem cells derived from embryos created by parthenogenesis are also being used for stem cell research* [;]

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88 *Supra* note 25 at art. 8.1.1 [emphasis added].

89 One of the authors (Françoise Baylis) was a member of Governing Council and can report that the Governing Council was never informed of the changes. Françoise Baylis first became aware of some of the changes to the *2002 Guidelines* on the eve of the press release, March 3, 2002. A few corrections were made at that time, reducing (but clearly not eliminating) the number of inconsistencies between the *Governing Council Report* and the *2002 Guidelines*.

- *to recognize that fresh embryos (and not just frozen embryos) are also being used for stem cell research; and …*
- updates to clarify how human stem cells that are created outside Canada will be evaluated for compliance with CIHR's guidelines.[90]

While this list raises many questions, the most important one concerns the Governing Council decision to amend the *2002 Guidelines* to explicitly allow the research use of fresh embryos in order to align the guidelines with current research practice (see text in emphasis). This change was recommended to the Governing Council by the Stem Cell Oversight Committee as recorded in the minutes of the January–February 2005 meeting—the same meeting at which the Committee approved Canada's first two hESC lines (CA1 and CA2), both of which were derived from fresh embryos. With surprising frankness the Stem Cell Oversight Committee recommended the change in policy "to recognize that stem cells derived from fresh embryos (and not just frozen embryos) are also being used for stem cell research".[91] The Governing Council accepted this recommendation at its March 2005 meeting and determined that changes were needed "to recognize that fresh embryos (and not just frozen embryos) are also being used for stem cell research".[92]

The stated rationale for the change is perplexing, to say the least. The fact that a specific research practice is potentially inconsistent with the *2002 Guidelines* hardly counts as an ethically sound or sufficient reason to amend the *2002 Guidelines*. Indeed, a more reasonable response would be to investigate any apparent inconsistency between the stem cell guidelines and current research practice in terms of possible non-compliance and to determine whether, (i) contrary to appearances, the practice is indeed consistent with the existing *Guidelines*, highlighting the need for "editorial changes for better clarity and interpretation"; (ii) the practice is inconsistent with the *Guidelines*, thus requiring sanctions as per the rules governing non-compliance; or (iii) the practice is inconsistent with the *Guidelines*, but that upon careful reflection the original *Guidelines* are ethically unsound and in need of revision, in which case a sound ethical reason could be articulated for proposed revisions to the *Guidelines*.

It is also troubling to note that the practice with which the Stem Cell Oversight Committee and the Governing Council sought to align the guidelines—namely the ongoing research use of fresh embryos to derive stem cells—was only publicized after the *2005 Guidelines* were released. To explain, the *2005 Guidelines* were approved by Governing Council in March of 2005. They then had to be reviewed and accepted by Natural Sciences and Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC) which delayed the public release of the *2005 Guidelines* until June 7, 2005. Two days later, on June 9, 2005, the successful derivation of Canada's first two hESC lines was announced and the research use of fresh embryos was disclosed.[93] As these hESC lines appear to have been approved by the Stem Cell Oversight Committee at its January–February 2005 meeting, questions arise about the delay in reporting this scientific accomplishment to the public. For example, could it be that the announcement of the successful derivation of these hESC lines—based on research involving the use of fresh embryos and dating back to 2003[94]—was delayed until the *2005 Guidelines* (explicitly allowing the research use of fresh embryos) were in the public domain? *Res ipsa loquitur*?

CONCLUSION

The federal government, the Canadian public, and the CIHR have each independently expressed explicit concern about the potential threats to the well-being of women with the rise of assisted human reproductive technologies and hESC research. For example, subsection (c) in the Principles section of Canada's *AHR Act* states that "while all persons are affected by these technologies, women more than men are directly and significantly affected by their application and the health and well-being of women must be protected in the application of these technologies."[95] Similarly, during the CIHR *ad hoc* Working Group's

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90 *Supra* note 23 [emphasis added].

91 Canadian Institutes of Health Research. 4th Meeting of the Stem Cell Oversight Committee, January 31–February 2, 2005, online: Canadian Institutes of Health Research <http://www.cihr-irsc.gc.ca/e/28853.html>.

92 *Supra* note 23.

93 Katie Rook, "Canadian Stem-Cell Research Wins Approval" *The Globe and Mail* (9 June 2005) A13.

94 Helen Branswell, "Toronto Institute Develops Canada's First Two Embryonic Stem Cell Lines" *Canadian Press* (8 June 2005).

95 *Supra* note 10 at s. 2(c).

consultation process, members of the public expressed concern for the well-being of women involved in stem cell research, collectively stating their worry that "an increasing demand for human embryos or fetal material could result in coercion of couples involved in fertility treatment or women considering therapeutic abortion."[96] Further, CIHR's *ad hoc* Working Group shared this concern and developed its recommendations with this concern as a principal guide. What is more, CIHR's Governing Council unanimously voted to adopt the recommendations set out by the *ad hoc* Working Group, with its focus on the protection of women from potential sources of coercion and exploitation in stem cell research at the forefront. It follows that the *Governing Council Report*, unlike the *2002*, *2005* and *2006 Guidelines*, sought to effectively insulate women from various potential sources of coercion and exploitation as actual or prospective participants in stem cell research.

It should be the grave worry of those concerned with the welfare of Canadian women, then, that articles directly related to the protection and promotion of women's interests, as outlined in the *Governing Council Report*, were not accurately reflected in the CIHR stem cell guidelines. This is a problem for both the women whose interests are not adequately protected and for the integrity of CIHR's policy-making process.

We hope this comparative analysis of the *Governing Council Report* and the *2002*, *2005* and *2006 Guidelines* will spur action on the part of CIHR Governing Council to direct the reinstatement of those articles in the *Governing Council Report* that were either omitted or significantly amended. Such a move would not only foster trust in the legitimacy and accountability of CIHR's policy-making process, but would also give women a fair chance of escaping the many potential sources of coercion and exploitation surrounding stem cell research involving the use of eggs, embryos, or fetal tissue. Properly revised stem cell research guidelines might also usefully inform future parliamentary deliberations on the regulations pursuant to the *AHR Act* as well as future possible revisions to the *Act*.

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96 *Supra* note 11 at App. iii [emphasis omitted].