

Consent to Embryo Donation for Human Embryonic Stem Cell Research

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Introduction

Since the first report of the derivation of human embryonic stem cells (hESCs) in 1998,¹ ethical debate has raged around hESC research. The primary, if not exclusive, concern raised in relation to hESC research is the inescapable reality that this research results in the destruction of human embryos. Stem cell research is not the only type of research performed using human embryos, and it is not the only focus of those who object to the use of human embryos in research.² But because stem cell research holds enormous promise in terms of its potential clinical applications, and because it is often linked in the public consciousness with somatic-cell nuclear transfer (roughly synonymous in the lay understanding with “cloning”), it has become a flash-point at the intersection of science, medicine and ethics.

Human embryos are inevitably destroyed in hESC research. Those who oppose embryo research because they ascribe full moral status to the embryo therefore take the view that such research is ethically impermissible. Those who hold that human embryos do not share the same moral status as persons, but do have heightened moral status compared to other human tissues or biologic matter, are prepared to permit stem cell research, but insist that as few embryos as possible be destroyed in the process.³ Many who hold this view also oppose the creation of human embryos solely for research purposes, meaning that such research is acceptable only insofar as it uses embryos that are supernumerary to the reproductive needs of those for whom they were created.⁴

But even among those who do not agree that embryos deserve special treatment, morally speaking, ethical unease has been expressed around the use of human embryos in stem cell research. Concerns around the commodification of gametes and embryos, and the related worry that women’s reproductive capacity and reproductive material will be exploited have been articulated.⁵ Questions have also been raised about who decides what research is worth pursuing and about the use of public funds to support research into what are likely to become very expensive therapies, possibly available only to the “privileged few.”⁶

In spite of these concerns, many nations, including Canada, have decided to pursue a research agenda that includes hESC research. In light of the fact that such research is permissible, we must consider the process by which those who will donate embryos to the pursuit of hESC research will provide consent.

In this paper, I consider the unique ethical issues that arise in hESC research. I then discuss consent policy in relation to human subjects research generally, and look to existing Canadian policy regarding consent to hESC research (the *Guidelines for Human Pluripotent Stem Cell Research*⁷ and the *Assisted Human Reproduction Act*),⁸ with a view to critiquing consent policy. I also reflect on the subject of consent to the donation of fresh embryos to research, given the national attention this matter has received. Finally, I conclude by suggesting points for discussion at the workshop for which this background paper has been written.



1. Stem Cell Research and Human Subjects Research

Regulation of research involving human subjects is of relatively recent vintage, having originated as an outcome of the Nuremberg trials that followed the Second World War.⁹ The aim of regulation of research using human subjects is to attempt to find the elusive balance between permitting the conduct of scientifically sound, potentially beneficial research and ensuring that human subjects are treated in an ethically appropriate manner during their participation in research. Two important mechanisms employed to safeguard the interests of research subjects are the requirement of consent to research and mandated research ethics board (REB) review. In this paper, the focus will be on the former.

Research using human tissue is considered “human subjects research.”¹⁰ As such, research on gametes and embryos – specific human tissues – clearly constitutes human subjects research. Although hESC research falls within the broad category of human subjects research and shares much in common in terms of ethical issues raised by such research,¹¹ specific ethics policy and legal rules have begun to evolve in response to the burgeoning field of stem cell research. These rules are in many ways similar to rules governing research using human tissues, but they also have some unique aspects. Are the differences between hESC research and other human subjects research sufficient to warrant unique legal and policy responses? In particular, should consent rules be substantively different for hESC research? A number of arguments have been made that seem to favour the “unique rules” approach. Canadian research ethics policy, for example, treats gametes and embryos as distinct from other types of human cells and tissues, noting that “the topic of human reproduction invokes a discussion of fundamental values,” and that such research “engenders acute ethical concerns for both the research community and the public at large.”¹² Most prominent among the reasons given for treating embryo research as unique relates to the moral status of the embryo. While I have no interest in replaying the moral status debate here, it is important to consider what is unique about embryonic stem cell research, with a view to raising some concrete ques-

tions about whether consent rules in this research context should be different from the rules in other research involving human tissue and, if so, how they should be different.

As noted in the introduction, a significant ethical issue (and arguably the main impetus for the debate) in the context of human embryonic stem cell research is the preliminary question of whether such research is acceptable at all – what Hank Greely calls the “what’s in the dish” question.¹³ This question has played (and continues to play) an important role in the development of many national policies on embryo research, including that of Canada.¹⁴ Moral objections to the use of embryos in research have existed ever since the very possibility of such research has been on the scientific horizon,¹⁵ and such objections show no sign of abating as embryonic stem cell research continues to

move forward. In essence, the “moral status” question can be boiled down as follows: is the embryo a human being from the moment of fertilization, or is it “too rudimentary in ... development to yet have interests and be the subject of moral duties”?¹⁶ If the former, then research that will result in embryonic destruction is impermissible; if the latter, such research is permissible, at least in some circumstances.

In spite of the unsettled nature of the moral status question, Canada (like many other nations)¹⁷ has decided that, in some circumstances at least, it is ethically appropriate to conduct research on human embryos. The compromise position adopted in the *Assisted Human Reproduction Act (AHR Act)* and the Canadian Institutes of Health Research (CIHR) Guidelines prohibits the creation of embryos for research purposes, but permits the use of embryos that are no longer required for reproductive purposes.

This policy stance is the background against which we must assess legal and ethical issues related to consent, and to an extent, at least, further debate about the moral status of the embryo is irrelevant. This is an important point insofar as the primary motivation behind creating ethical and legal rules unique to stem cell research has been this argument about the special moral status of embryos. In a sense, adopting a position that embryonic stem cell research is permitted

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but is nevertheless distinct from other research using human tissue may be viewed as a compromise between adopting the “embryo as human being” argument and the position that an embryo is nothing special, no more than a collection of cells. In other words, although the embryo is not the same thing as a person and can therefore be used in research, it deserves special respect and should not be discarded or destroyed cavalierly. While embryo research is a subset of the broader category of “human tissue research,” it is a special subset that requires unique and specific rules. Arguably, however, the resulting policy stance is unprincipled and logically inconsistent.¹⁸ To a degree, it appears that the compromises that have been made are founded on a desire to appease both the scientists who want to push ahead with stem cell research and those who ardently oppose the conduct of such research on the basis of the moral status of the embryo.

In addition to the moral status of the embryo, concerns have been raised about commodifying human cells and tissues, commodifying women’s reproductive capacity and exploiting women.¹⁹ Of course, concerns also exist relating to the commodification of human cells and tissues in the health research context, as do concerns about the potential exploitation of research subjects (the source of the cells and tissues).²⁰ Just as worries have been raised that selling gametes or embryos is tantamount to selling babies, similar arguments have been made in the human tissue research context, that selling cells or tissues amounts to selling persons.

Aside from the question of the moral status of the embryo, a major distinction between stem cell research and other research involving the use of human cells or tissue is the role that women play in research using human gametes and embryos. Human tissue generally can be donated for research purposes by both sexes and such donation is equally invasive, regardless of the sex of the donor. While both an egg and a sperm cell are required in order to create an embryo, obtaining ova from women is quite a different matter than obtaining sperm cells from men. Sperm donation is relatively uninvasive and involves no drug therapy or medical procedures.

Ovum donation, by contrast, is extremely invasive. It involves several steps, each requiring medical intervention. In some circumstances, women will be prescribed medication to interrupt their normal menstrual cycle. They then undergo ovarian stimulation, which entails the use of medication to stimulate the ovaries to produce more than the usual one egg per menstrual cycle. Additional medications are required to prevent premature ovulation. During the period of ovarian stimulation, frequent blood tests and ultrasound examinations will take place in order to determine the woman’s response to fertility drugs and to track the progress of maturing ovarian follicles. Ova are then retrieved using ultrasound-guided aspiration, a minor surgical procedure that involves the use of anaesthesia. There are risks involved in all of the medical interventions that take place in the context of an egg donation cycle, including side

effects related to the medications used to interrupt the donor’s menstrual cycle and the drugs used in ovarian stimulation.²¹ In addition, there is a risk of ovarian hyperstimulation syndrome (OHSS), which can cause severe complications in about 0.05 - 5% of IVF cycles²² and in very rare cases, can be fatal. Finally, there are potential long-term risks of ovarian stimulation, which are currently unknown.²³ Some studies suggest a link between ovarian stimulation and the risk of developing ovarian and other cancers later in life,²⁴ but more research is needed in order to substantiate or rule out this concern.

As a result of the risks involved in procuring ova, stem cell research is unique in the human subjects research context. It may also be unique from the perspective of infertility patients / potential research subjects. Studies show that in general, individuals and couples with supernumerary cryopreserved embryos do not choose to donate these embryos to research.²⁵ Further, as Klock has noted, even those who initially consent to donate embryos to stem cell research frequently change their minds after some time away and emotional distance from the clinical experience.²⁶ Researchers have begun to explore the reasons for the ambivalence potential embryo donors feel about the disposition of supernumerary embryos,²⁷ and have found that donors conceptualize their cryopreserved embryos in a multitude of ways

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ranging from “biologic material,” to “virtual children” or siblings of their living children.²⁸

Not only are there unique considerations around what is being donated to research in the stem cell context, there are distinctive issues related to who is donating human reproductive material for use in stem cell research. Hank Greely has identified a number of different groups of potential tissue donors for human embryonic stem cell research. These are: couples donating supernumerary cryopreserved or fresh embryos that were created for reproductive purposes; women donating fresh ova for reproductive purposes; women donating fresh ova for research purposes; men or women donating somatic cells for use as nuclear donor cells; and men donating sperm.²⁹ As Greely has pointed out, distinct consent issues may be raised by some of these groups.³⁰ In particular, concerns arise around consent in the “fresh” embryo context, given the time pressure involved, and around the donation of ova solely for research purposes. As David Magnus and Mildred Cho have noted, women donating ova solely for purposes of research are undergoing the significant risks entailed by egg donation with no corresponding benefit to themselves.³¹ As such, Magnus and Cho suggest that these donors are more like living organ donors, whose donations are not always accepted. Indeed, in the case of organ donation there is at least a significant and real benefit to be gained by the recipient, whereas in the case of stem cell research, it is uncertain whether any clinical benefit will result.³²

Clearly, there are other ethical issues to consider in relation to hESC research, including those related to resource allocation and the possibility that the availability of treatments using stem cell lines may pose a threat to public health care systems.³³ But these are questions about the much larger debate as to the legitimacy of pursuing a research agenda that involves stem cell research, and as such do not raise issues specifically related to consent to participation in hESC research. It appears, based on the foregoing, that there may indeed be reasons to depart from traditional consent rules in the hESC research context. The next section of the paper considers to what extent this has been done in Canadian law and policy and explores whether and, if so, how we should deviate from existing consent principles.

2. Consent

a. Consent and Human Subjects Research

The key reason for the importance of consent to participation in research in law and ethics is to demonstrate respect for the dignity and autonomy of research participants. To be sure, the concept of human dignity is slippery and difficult to define. As a result, dignity has recently come to be used to reject the possibility of stem cell research or to justify a policy of restraining science and technology through government regulation.³⁴ There is general agreement, though, that the concept of human dignity is closely linked to human rights. As Caulfield and Brownsword put it, “[i]n this reading, human dignity is an engine of individual empowerment, reinforcing individual autonomy and the right to self-determination.”³⁵

The significance of autonomy and self-determination in the health research context can be traced through various research ethics policies as well as legal interpretations of the rights of research subjects.³⁶ The requirement of consent has, in many ways, come to signify respect for the autonomy of participants in health research.

Consent, or more particularly, informed consent, is a cornerstone of legal and ethical governance of health research.³⁷ In the human subjects research context, as in the clinical treatment context, consent is understood as a process.³⁸ A signed consent form does not constitute a contract for participation in research. All major research ethics policies make this very plain, in specifying that consent must be “free and informed” and that subjects are entitled to withdraw from participation at any time, for any reason and without consequence.³⁹

In order to satisfy legal and ethical requirements, researchers must obtain the “free and informed consent”⁴⁰ of each participant. Legally and ethically valid consent to participation in research must be voluntary (given without undue influence, manipulation or coercion),⁴¹ it must be given by a person competent to provide it,⁴² and it must be “informed.”

From an ethical perspective, determination as to the voluntariness of consent involves consideration of the existence of inducements to participation, exercises of authority over the subject by another, and the context in which consent is given, with a view to whether a relationship of trust and / or dependency is at play.⁴³ Similarly, in the legal context, consent is voluntary where not obtained by undue influence,



coercion or fraudulent misrepresentation as to the nature of the procedures involved in the research.⁴⁴ Obviously, many factors play a role in shaping decisions about participation in medical research, including the impact of the decision on one's family, fear about the risks involved, the level of trust placed by the potential subject in the researcher (this is especially important of course where the investigator is also the subject's physician), the importance of the research to others, and the ability to alleviate suffering of others. But the existence and influence of these varied considerations do not necessarily render the decision to participate involuntary. The difficulty lies in articulating the boundary between such considerations being influential and being coercive. In the clinical context, it is rare for the courts to find that consent to treatment has not been provided voluntarily.⁴⁵

In the clinical practice context, the law holds that an informed patient is one who has been apprised of all "material, special or unusual risks" related to the proposed therapeutic intervention.⁴⁶ In the health research context, particularly where the research is not of intended benefit to the participants, the courts have held researchers to a higher standard of disclosure, that of "full disclosure" of all risks: rare, remote or potential.⁴⁷ Canadian courts have held that the duty of disclosure to research subjects is "at least as great, if not greater than, the duty owed by the ordinary physician or surgeon to his patient"⁴⁸ and that the duty to disclose information to subjects participating in research from which they do not derive any benefit is more demanding than that required in the treatment context.⁴⁹ As Glass and Lemmens note, Canadian courts have not yet articulated a specific standard of disclosure vis-a-vis research with intended benefit for participants, or indicated whether it would be different from that outlined in *Weiss v. Solomon*.⁵⁰

b. Consent and Stem Cell Research

Given the consent-related principles articulated above, in this section, several key aspects of consent to hESC research will be explored in detail: Who must provide consent to research participation? When is consent to be obtained? Who should inform the potential subject about the research and obtain consent? Can subjects who have agreed to par-

ticipate in health research withdraw their consent and, if so, when in the process may they do so? After briefly explaining how consent in the hESC research context is governed, each of these questions will be considered in turn. There is some overlap among the questions, meaning that some concepts are relevant to more than one of the questions, but in each case I have attempted to highlight the predominant issues that demand consideration.

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i. Background CIHR Guidelines

In March 2002, the Canadian Institutes of Health Research issued guidelines for human pluripotent stem cell research. Compliance with the Guidelines is required in order for any such research to receive federal grant funding. At the same time, the CIHR also established the Stem Cell Oversight Committee (SCOC). The SCOC reviews all

human pluripotent stem cell research that is funded by any of the three federal granting agencies, or that is conducted "under the auspices" of institutions that receive such funding.⁵¹ The SCOC is essentially a specialized REB charged with review of all research proposals involving human pluripotent stem cells that fall within the above-noted criteria (agency-funded or conducted with involvement of an agency-funded institution). Such research proposals must also be reviewed by the local REB and, if appropriate, the relevant animal care committee, meaning that the SCOC adds an additional level of scrutiny to human pluripotent stem cell research. The SCOC also has a mandate to advise investigators and local REBs as to the application of the Guidelines.

The CIHR Guidelines are intended as "an interpretation and extension" of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS); as such, they are based on the guiding principles adopted in the TCPS, which include respect for human dignity, respect for free and informed consent and non-commercialization.⁵² The Guidelines explicitly require that any embryos used in human pluripotent stem cell research were originally created for reproductive purposes and are no longer needed for such purposes,⁵³ and that free and informed consent is obtained from relevant parties.



The Assisted Human Reproduction Act

In 2004, the *AHR Act* was passed by Parliament. The *AHR Act* provides a comprehensive governance structure for clinical and research uses of human reproductive material, including embryos. The scope of the *Act* is limited to uses of human reproductive material. It therefore governs the derivation of stem cells only insofar as this is achieved using human embryos. It does not govern research involving stem cells from any other source, nor does it cover research using stem cell lines that have already been derived from human embryos. In addition, once stem cell lines have been derived from human embryos, the *Act* no longer has any application to those cell lines, nor does it apply to any material derived from such cell lines. The *AHR Act* explicitly incorporates the CIHR Guidelines into its definition of consent, and the argument has been made that since the *AHR Act* refers to the 2002 version of the CIHR Guidelines, any revisions to the Guidelines are inapplicable in the context of the legislation. This issue is explored in more detail below.

The enactment of this legislation follows a long and tortured path commencing in 1989 with the creation of the Royal Commission on New Reproductive Technologies.⁵⁴ The Canadian legislation is most similar in approach to that adopted in the U.K. with the *Human Fertilisation and Embryology Act*,⁵⁵ in that it adopts the model of a single national regulator for research and clinical applications of ARTs. The legislation holds some promise of comprehensive governance specifically in relation to embryo research, including stem cell research, but currently, the *AHR Act* itself is only partly in force. The regulatory process began in the Fall of 2004, and will continue for a three year period, after which the entire *Act* will be proclaimed in force.⁵⁶

The Act contains a “sunset” clause, meaning that it will be reviewed by a Parliamentary committee with a view to reporting on that review as well as recommending modifications to the legislation.⁵⁷ The review is to take place three years after the coming into force of s. 21, which speaks to the establishment of the Assisted Human Reproduction Agency of Canada (AHRA). Although the members of the AHRA’s Board of Directors have just been appointed, the Agency itself was established in January 2006;⁵⁸ the review will thus have to take place beginning no later than January 2009. It will be interesting to see what, if anything, is accomplished by that time, given the lack of progress on regulation-making to date.

The AHR Act and the CIHR Guidelines

The *AHR Act* defines consent as

... 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.⁵⁹

Since the enactment of the *AHR Act*, the Canadian Institutes of Health Research (CIHR) has issued three sets of revised guidelines, in 2005, 2006 and 2007.⁶⁰ It has been argued that the updated CIHR Guidelines are inapplicable to the *AHR Act*, given that the *Act* expressly adopts the 2002 version of the Guidelines. According to Françoise Baylis and Natalie Ram, “[i]n the absence of any act of parliament, changes to the 2002 CIHR guidelines with respect to the issue of consent do not constitute changes to the legislation.”⁶¹ The specific concern articulated by Baylis and Ram is aimed at the change of language relating to decision making at the time of gamete donation. The 2002 Guidelines called for a decision to be made at the time of gamete collection as to the eventual disposition of embryos. In the 2005 version of the Guidelines, the language was softened somewhat to require that gamete donors be “informed of [the] options” for embryo disposition. While this concern was alleviated with the 2006 amendment to the CIHR Guidelines (this iteration of the Guidelines reestablishes the requirement for an advance directive as to the eventual disposition of embryos at the time of gamete donation), the question remains whether Baylis and Ram’s interpretation of the *AHR Act* is accurate.

The argument made by Baylis and Ram is puzzling in the context of the *AHR Act*. Given that the *AHR Act* defines consent in relation to the regulations governing consent, there is at least implicit acknowledgment that the specific rules around consent will be outlined in the regulations, and the regulations are clearly not intended to be static. Indeed, the very point of granting a regulation-making power within legislation is to permit more timely modification of the rules than would be entailed in amending the legislation.⁶² It is clear that regulations must conform to the ambit provided by the parent legislation and, as regulations are normally made by the Governor-in-Council (not by Parliament), this is sensible. But the *AHR Act* builds an extraordinary feature into the regulation-making process.⁶³ Proposed regulations must



be laid before both Houses of Parliament for review and reporting by the appropriate committee(s) of each House.⁶⁴ The only situations in which this extraordinary process does not have to be followed are (i) where the Minister considers the changes to an existing regulation so “immaterial or insubstantial” that the requirement should not apply, or (ii) where the regulation must be made immediately to protect health or safety.⁶⁵ Parliament will therefore have the opportunity to review every proposed regulatory measure prior to its adoption pursuant to the *AHR Act*. This reality weakens Baylis and Ram’s assertion that the 2002 CIHR Guidelines are somehow immortalized in the *AHR Act* until the statute is amended.

ii. Who Gives Consent? CIHR Guidelines

In outlining requirements for consent to participation in stem cell research, the CIHR Guidelines are clear that the only embryos eligible for use in stem cell research are those that are “no longer wanted for reproductive purposes.”⁶⁶ Potential embryo donors, as well as gamete donors who are providing gametes for reproductive use by third parties, must be informed that such surplus embryos may be donated to another couple for reproductive use, used in research or discarded. The Guidelines call for potential donors to make a decision about eventual disposition in advance of the collection of gametes.

Consent to the use of embryos in research therefore must be obtained from embryo donors and gamete donors, if donated gametes were involved in the creation of embryos. The Guidelines also call for consent to be reiterated by *embryo donors* at the time when the embryos are sought to be used in research, meaning that valid consent exists only when consent has been provided by embryo donors on these two separate occasions. With respect to *gamete donors* where the donors are not seeking to create embryos for their own reproductive use, gamete donors “must have given at the time of donation free and informed consent to the unrestricted research use of any embryos created, when these embryos are no longer required for reproductive purposes.”⁶⁷

AHR Act Consent Regulations

In September 2005, Health Canada introduced draft proposed Regulations under section 8 of the *AHR Act*. One year later, in September 2006, new draft Regulations were circulated.⁶⁸ The Regulations were vetted by both the House of Commons Standing Committee on Health⁶⁹ and the Senate Standing Committee on Social Affairs, Science and Technology.⁷⁰ The 2006 version of the Regulations have now been adopted (with minor changes) and came into force on December 1, 2007.⁷¹

Section 8 of the *Act* prohibits the use of human reproductive material to create an embryo without the written consent of the gamete donors, and it prohibits the use of *in vitro* embryos for any purpose without the consent of the donor.⁷² Part I of the Regulations deals with consent under s.8(1) of the *AHR Act* – the use of human reproductive material (defined in the *AHR Act* as a sperm, ovum or other

human cell or a human gene), to create an embryo. Because the creation of embryos solely for research purposes is prohibited by s. 5(1)(b) of the *AHR Act*, the part of the Regulations directed at s.8(1) does not mention research.

Part 3 of the Regulations addresses consent in relation to s. 8(3) of the *AHR Act*. Section 8(3) simply states that prior to making any use of an *in vitro* embryo, the written consent of the donor must be obtained. Part 3 of the Regulations delineates the specific requirements for a valid consent to the use of an *in vitro* embryo. The first task of this section of the Regulations is to define “donor” such that researchers proposing to use an embryo know from whom they must obtain consent. Section 10 of the Regulations provides as follows:

10.(1) Subject to section 15, in this Part, “donor” means the following individual or individuals for whose reproductive use an *in vitro* embryo was created:

(a) the individual who has no spouse or common-law partner at the time the *in vitro* embryo is created, regardless of the

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source of the human reproductive material used to create the *in vitro* embryo, or

(b) subject to subsection (3), the couple who are spouses or common-law partners at the time the *in vitro* embryo is created, regardless of the source of the human reproductive material used to create the *in vitro* embryo.

(2) If the donor is a couple, the consent of each spouse or common-law partner must be compatible in order for the consent of the donor to comply with the requirements of this Part.

(3) In the case of an *in vitro* embryo created using human reproductive material from only one of the individuals in the couple that was the donor of the embryo at the time it was created, that individual becomes the donor of the embryo under paragraph 1(a) if, before the use of the embryo, in respect of the couple, the individual is no longer a spouse or common law partner.

Embryo donors include the individual or couple for whose reproductive use the embryo was created, regardless of the source of the gametes. This means that when consent is sought for the purpose of using an embryo in research, only the party or parties for whom the embryo was created need to be asked to consent. In the case of an individual woman seeking IVF services, embryos could be created using the woman's ovum and donor sperm. Once the embryo has been created, the consent of the sperm donor is no longer needed should the woman wish to have surplus embryos used in research. Even if the embryos were created using donor ova and sperm, the woman for whose reproductive use they were created is now considered the embryo donor. Neither gamete donor has any decision making authority in respect of the disposition of the embryos at this point, whether that is for reproductive use by the woman, reproductive use by a third party, or research use.

Sections 4(2) and 13(2) of the Regulations make it clear that the consent of gamete donors is not irrelevant. Before making use of any human reproductive material to create an embryo, the consent of the donor of the human reproductive material must be obtained. Where a donor has consented to posthumous reproductive use of their human reproductive material by their spouse or common law partner, or

to reproductive use by a third party, the consent must also indicate whether the *in vitro* embryos created from the donor's human reproductive material that are not needed for the purpose for which they were donated may be used for research purposes.

Where a couple (either married or in a common law relationship) seeks IVF services, there are a number of possibilities in terms of how embryos may be created, as indicated below:

- using gametes donated by both members of the couple;
- using ova donated by the female member of the couple and sperm donated by an anonymous donor;
- using sperm donated by the male member of the couple and ova donated by an anonymous donor; or
- using sperm and ova donated by anonymous donors.

According to s.10 of the Regulations, both members of the couple for whose reproductive use the embryos were created are the embryo donors, meaning that they are the individuals to look to in order to obtain consent. Moreover, both members of the couple must agree as to the proposed use of the embryos in order for the consent to be valid (s.10(2)). The requirement of mutual consent exists regardless of the manner in which the embryos were created (with a very limited exception – see s.10(3)). As such, even where the female partner's gametes and the sperm of a donor were used to create the embryos, both members of the couple must consent to *any* proposed use of the embryos. The sperm donor plays no role in the consent process beyond the consent obtained at the time of gamete donation.

There are potential problems with this regulatory framework for consent, which can be grouped into two categories: (i) the elimination of the gamete donor from the picture where gametes are being donated for reproductive use by third parties and (ii) the mutual consent requirements.

(a) Gamete donation

The Regulations as adopted represent a significant improvement over the original proposed Regulations from the perspective of the gamete donor's consent to research using embryos created from the donor's gametes. The original proposed consent Regulations indicate that donors consenting to third party reproductive use of their gametes, or an embryo created using their gametes, were, in effect, consent-



ing to all possible future uses authorized by the legislation. The Regulations, by contrast, provide that gamete donors shall indicate whether any supernumerary embryos created from their gametes may be used in research when they initially consent to the reproductive use of their gametes by third parties. It is now clear that in donating gametes for reproductive use by third parties, donors are not also required to forfeit their right to withhold consent to the use of their human reproductive material in research.

This is a welcome change in the regulatory text (and arguably alleviates the concern expressed by Baylis and Ram about the original proposed Regulations),⁷³ but it does not resolve all of the concerns around gamete donation and withdrawal of consent to research. Suppose that X donates ova for reproductive use by her cousin and cousin's husband. Embryos are created using X's ova and donor sperm from Y. The cousin and her husband acknowledge in writing that the gametes have been donated for their reproductive use. The couple then undertake two unsuccessful attempts at conception through IVF. Five embryos remain cryopreserved. Two years later, the cousin's husband dies and the cousin subsequently remarries. X has met her cousin's new husband and has seen signs that he is emotionally abusing her cousin. X no longer wishes to permit the use of the five remaining embryos by her cousin, as she is gravely concerned about the prospect for abuse of a child born to the couple. It is unclear from the Regulations whether X may withdraw her consent to the reproductive use of her embryos. Based on s.10 of the Regulations, the cousin, having acknowledged in writing that the embryos were designated for her reproductive use, now seems to be the embryo donor and thus has dispositional authority with respect to the embryos. Likewise, if the cousin and her original husband remain married but decide to give up on IVF and to donate the remaining embryos to stem cell research, X may not withdraw her earlier consent to research, even if she has changed her mind and does not want her gametes used in research, because the cousin and her husband are now the embryo donors. Alternatively, the cousin and husband may decide to donate the embryos to another couple for reproductive use; here again, X has no ability to withdraw her initial consent.

The reason for the broad discretion to withdraw from research participation rests on recognition of the importance of self-determination in health care decision making.

In the clinical health care context, consent is viewed as an ongoing process. Consent may be varied or withdrawn by the patient, even after a procedure has begun, unless respecting the withdrawal of consent would lead to harm to the patient.⁷⁴ In the health research context, a research subject is free to withdraw their consent to continued participation at any time. While there are important differences between consent in medical law, and even in the usual health

research context, and consent to stem cell research, it is questionable whether this pronounced difference in the rules about the treatment of gamete donors as research subjects is justified. The reason for the broad discretion to withdraw from research participation rests on recognition of the importance of self-determination in health care decision making. It is not clear that stem cell research is so distinct from other health research that such considerations can be disregarded.

In the context of human subjects research, as noted earlier, subjects may withdraw their consent at any time, even after they have commenced participation in a research project. If the project involves stored tissue and the tissue sample is identifiable (*i.e.*, it can be linked to the research subject), subjects may ask for their tissue sample to be destroyed.⁷⁵ Researchers do not gain the right to use stored tissue indefinitely should subjects change their mind about participation in research. Yet the Regulations stipulate that once a gamete donor has consented to the possibility of research use (even though the donor likely was not informed of the specific type of research project for which the embryos could potentially be used), there is no possibility of varying or withdrawing consent.

The Regulations should contain more robust provisions for an ongoing role for gamete donors. Obviously, the donor's ability to change his or her mind after having consented will depend on the situation as regards third parties to whom the gametes or embryos have been donated.⁷⁶ But in the example given above, there are decision points in the various scenarios that would allow the gamete donor to be contacted and asked to renew (or withdraw) her consent. If the gametes or embryos have not been used by a third party, there appears to be no good reason why a donor should not



be able to vary his or her consent, or withdraw it altogether. The position taken in the Regulations is certainly more expedient in that the person or persons with immediate control over the embryo are the only ones from whom consent must be sought.⁷⁷ And, in the case of intended reproductive use by third parties, requiring the gamete donor to withdraw consent before the recipients have acknowledged the designation of the gametes for their reproductive use avoids potential emotional trauma for the individual or couple seeking to conceive through IVF. But expedience is not a legitimate reason for the abrogation of an individual's right to decide whether or not to participate in research, and the potential for heartbreak or emotional trauma seems to apply equally to the disappointed couple and the gamete donor who has had a change of heart. Why is preference being given to the couple on this front?

(b) Mutual consent

The question of uses that can be made of embryos where the couple for whose use the embryos were created disagree raises complex and difficult issues, as can be seen by the litigation on these issues in the United States and in England.⁷⁸ There are problems here in the definition of an embryo donor, and the implications of that definition on the mutual consent requirement. In addition, the lack of clarity around what happens if the embryo donors simply cannot come to an agreement respecting use of the embryos is cause for concern.

In its consent consultation document, Health Canada uses a fictionalized scenario as an example to illustrate the effect of the mutual consent provisions.⁷⁹ Two gamete donors (whom we shall call X and Y) donate gametes from which embryos are created for reproductive use by Mr. and Mrs. P. The effect of the definition of "donor" provided in s.10 of the Regulations is that Mr. and Mrs. P. are embryo donors (for the purposes of reproductive use by another individual or couple, or for use in research). X and Y are not embryo donors, meaning that they have no decision-making power with respect to the embryos. As embryo donors, both Mr. and Mrs. P. must consent to any use of the embryos.

There is an improvement in the Regulations as adopted compared with the 2005 regulatory proposal. The Regulations provide that where only one member of a couple seeking ART services has donated human reproductive material, and where the couple is no longer married or in a common law relationship, the embryo donor is the individual whose human reproductive material was used to create the embryo.

The 2005 proposal made no allowance for this possibility. But, even with this improvement, it remains unclear what happens to an embryo if both members of a couple cannot come to an agreement as to its disposition.

iii. When Should Consent Be Obtained? CIHR Guidelines

According to Art. 8.3.1, gamete donors and individuals or couples involved in fertility treatment should be informed of their options for disposition of unwanted embryos and should make a decision about the eventual disposition of these embryos, prior to the collection of gametes and the creation of embryos. Article 8.3.2 specifies that, in addition to the decision contemplated in Art. 8.3.1, consent of the embryo providers must be "reiterated" at the time when the embryos are sought to be used in stem cell research. The rationale for this requirement is that a significant period of time may have elapsed between the creation of embryos for reproductive use and the commencement of the research project. After either completing their families through IVF or abandoning infertility treatment, donors may have come to very different opinions about the propriety of embryonic stem cell research than they had at the outset of their clinical journey. Indeed, studies have shown that such changes of heart are common in this population.⁸⁰ Where the embryos were created using donated gametes, there is no need for re-consent by gamete donors, provided that, at the time of gamete donation, the donor(s) consented to the unrestricted research use of any embryos no longer required for reproductive purposes.⁸¹

Another issue, one which is intimately connected to that of the timing of consent, is the question of whether consent may be general or whether it must be referable to a specific research project. The more removed the timing of consent from the actual research project, the less specific consent will be. Canadian stem cell research policy makes it clear that consent to research on future supernumerary embryos must be provided by gamete and / or embryo donors at the time of gamete donation, and must be reiterated by embryo donors at the time of the research use of the embryos.⁸² Canadian policy on this point corresponds with the draft guidelines issued by the International Society for Stem Cell Research (ISSCR).⁸³ Given the requirement for contemporaneous consent, it is clear that the consent to stem cell research must be specific. If donors are to consent at the time of research use of the embryos, there is no reason why the consent should be non-specific.



AHR Act Consent Regulations

The Regulations provide that consent must be obtained from embryo donors before any use is made of *in vitro* embryos.⁸⁴ There is no mention in the Regulations as to the two-stage consent process outlined in the CIHR Guidelines. It is unclear whether the definition of consent within the *AHR Act*, which explicitly incorporates the CIHR Guidelines, has been overlooked, or whether the drafters of the Regulations assumed that the two-step consent process outlined in the CIHR Guidelines is implicitly included in the Regulations.

iv. Who Should Obtain Consent?

In the health research context generally, physicians who are also research investigators obtain consent to participation from their patients. This practice is both legally and ethically sound. In the clinical context, the treating physician is responsible for obtaining consent.⁸⁵ Likewise, where the physician is also the investigator under a research protocol, it is the investigator's responsibility to obtain consent from the patient. Part of this responsibility relates to the provision of information to potential subjects in an effort to ensure that consent is informed.

Caulfield, Ogbogu and Isasi note that the CIHR Guidelines were initially silent on the matter of whether the infertility clinician could be involved in or responsible for the informed consent process vis-a-vis stem cell research.⁸⁶ The revised CIHR Guidelines state that "[m]embers of the health team treating and/or counselling the client should not be the persons to obtain consent from the embryo provider at the time of re-consent."⁸⁷ The Guidelines do not specify who is best placed to obtain consent, but seem to contemplate that the researcher who intends to use the embryos to derive stem cells will be the person obtaining consent.⁸⁸

The concern that drives this new rule in the CIHR Guidelines is that physicians might coerce or unduly influence their patients in order to procure donations of embryos for stem cell research. This concern is not without foundation; many commentators have noted that patients might feel pressured

into agreeing to donate embryos to research because their physician is raising the possibility with them.⁸⁹ As *Lo et al.* explain, "[t]he concern is that patients are so dependent upon their ART physician that they might consent to anything that the doctor requests or even presents."⁹⁰

As in the stem cell research context, worries about conflicts of interest pervade the ethical and legal rules around physician disclosure in both the clinical and research settings. Physicians are in fiduciary relationships with their patients. As such, they owe duties of loyalty and utmost good faith.⁹¹ As fiduciaries, physicians are required to disclose conflicts of interest to their patients. Whether clinical researchers who are not the subjects' physician also owe fiduciary duties to their subjects is unclear (and, in my view, unlikely). Regardless of the legal position of researchers, however, ethics policy makes it clear that researchers are under an obligation to identify and address conflicts of interest and to disclose their existence to subjects.⁹²

Clearly, there is cause for concern around conflicts of interest in the health research context. But are the concerns around conflict of interest more serious or less manageable in the stem cell research arena than in other human subjects research? If not, then why create unique rules for stem cell research? As Caulfield, Ogbogu and Isasi point out, it may well be the case that the potential for conflicts of interest is more profound in health research generally than in the stem cell context.⁹³ Physicians receive remuneration for research-related tests and procedures; indeed, this is quite possibly the very reason why some community physicians do research at all. Remuneration gives rise to a potential conflict of interest in that the physician has an incentive to enroll patients as research subjects.⁹⁴ While such conflicts must be disclosed to potential subjects, calls for bans on such research have not been made. Even more importantly, we allow patients to consent to research on cancer treatments, although we recognize that where patients have exhausted all "traditional" treatments for their disease, the promise of benefit from a new treatment may exert considerable influence on patient decision-making. Finally, we permit healthy volunteers to decide for themselves whether

There is cause for concern around conflicts of interest in the health research context. But are the concerns around conflict of interest more serious or less manageable in the stem cell research arena than in other human subjects research?



they wish to participate in Phase I clinical trials in exchange for payment.⁹⁵ Such research subjects do not stand to benefit in any way from the drug being tested, and may even suffer significant harm. It is at least arguable that there is nothing especially worrying about stem cell research, when we consider it in the context of health research in general. At the very least, it does not seem as if the potential conflicts of interest are unmanageable.

It bears mention as well that there are significant potential benefits to having infertility specialists involved in the process of obtaining informed consent to research. First, given that the CIHR Guidelines preclude physicians from involvement in the research team, the potential for conflict of interest is minimized.⁹⁶ The physician will simply be telling her patients about research in which they might be interested, but in which she has no stake – financial or otherwise. Second, the physician knows her patients and will therefore be more likely than either a researcher or an independent advocate to approach the consent process in a manner that is sensitive to the patient's needs and interests.⁹⁷ Third, the relationship between patient and physician may mean that it is more likely that patients will feel comfortable asking questions about the research of their physician.⁹⁸

I am not suggesting that we need not be concerned about the potential for conflicts of interest in the stem cell research context. Ideally, an independent third party who knows the patient and knows all about the research could obtain consent.⁹⁹ But it is not clear how practical this solution is, nor does it resolve the legal question of where responsibility for the consent process ultimately lies. In my view, the concerns around conflicts of interest raised in the stem cell research context are not substantially weightier than they are in health research generally. Provided that the informed consent process is appropriately robust, there seems to be nothing especially objectionable about physicians discussing consent to embryo donation with their patients. Certainly the process can be structured in such a way as to minimize any concerns around conflict of interest. One very obvious example would be to have the physician discuss the research with the patient, answer any questions the patient has, and then leave the decision to the patient. The consent form need not ever be returned to the physician, and the physician need not ever know what the patient decided.¹⁰⁰

v. Withdrawing Consent CIHR Guidelines

The CIHR Guidelines contemplate withdrawal of consent to stem cell research. The CIHR Guidelines require re-consent from donors when the embryos are going to be used in stem cell research. Article 8.3.2 states that the requirement for reiteration of consent affirms the subjects' right to withdraw from participation in research. Article 8.3.3 provides more detail, and stipulates that as part of the informed consent process, subjects must be informed that they "have the right to withdraw at any time before an anonymized cell line is created."

AHR Act Consent Regulations

The Regulations also contemplate the possibility that some embryo donors might wish to withdraw their consent to a proposed use of their embryo(s). Where the donor is a couple, only one member of the couple need withdraw consent (*i.e.*, it is not necessary for both members of the couple to withdraw in order for the withdrawal of consent to be valid; Regulations, s.14(3)). Embryo donors are free to withdraw their consent to research (or to reproductive use by a third party) provided that they do so in writing (Regulations s.12(b)), and that the person who intends to make use of the embryo is notified in writing (Regulations, s.12.(c)). In the research context, the notification must take place *before* the latest of the following three events:

- the person who intends to make use of the embryo has acknowledged in writing that the embryo has been designated for research;
- the process of thawing the *in vitro* embryo for use in research has begun;¹⁰¹ or
- a stem cell line has been created using the *in vitro* embryo.¹⁰²

As Caulfield, Ogbogu and Isasi articulate, the subject's right to withdraw consent to participation in research is "rarely qualified."¹⁰³ Indeed, the right to withdraw is fundamental in both law and ethics policy, and captures linkable (or identifiable) tissues and other biologic samples and health information. Canadian policy respecting human embryonic stem cell research, like many such policies,¹⁰⁴ clearly departs from the practice of respecting the subject's right to withdraw consent.

There may well be good reasons to have a cut off point beyond which consent cannot be withdrawn. In the case of an-



onymized stem cell lines, the point of anonymization seems to be a clear cut off point. However, the possibility of true anonymization of stem cell lines in Canada seems remote. First, the community of stem cell researchers is very small, as is the number of cell lines. As long as that remains the case, anonymization is going to prove difficult. Second, if it is ever going to become possible to use a particular stem cell line for therapeutic purposes, the stem cell line will not be anonymized. The ability to follow-up with embryo donors is essential, in order to ensure that the donor has not developed health problems since the time of embryo donation. In the context of the *AHR Act*, which applies only to uses of human reproductive material, and not to stem cell lines themselves, the creation of a stem cell line seems to be a natural end point for the donor's ability to withdraw consent. While it is clear that the *Act* is not intended to govern stem cell lines or their derivative products, it is not necessary for the Regulations to restrict the right to withdraw in this manner. Instead, the Regulations could simply say that withdrawal of consent after the embryo has been destroyed is to be governed by consent law and policy relevant to participation in research, not by the *Act* itself. This would safeguard the integrity of the *Act* itself while also safeguarding donor autonomy.

From the perspective of the researcher, once resources – grant funds, investigator time, laboratory resources – have been dedicated to the production of a stem cell line, it would be profoundly problematic to have subjects notify the researcher that they no longer wish to participate. But, as Caulfield, Ogbogu and Isasi point out, the same is true in cases of biobank research and other research that involves the use of human tissue or other biologic samples.¹⁰⁵ Yet consent policies in these contexts nevertheless contemplate an ongoing right to withdraw.¹⁰⁶

Arguably, stem cell research is unique and should be treated differently. There are two main distinctions that could be drawn on. First, one could argue that embryos are unique (as compared to, for example, blood samples) because they are a new entity as opposed to a part of the research subject. As Caulfield *et al.* note, however, the danger in adopting this approach is that it creates a paradox “whereby the

proponents of the view reject vesting a special status on the embryo for the purpose of performing research on the embryo, but allow such status for the purpose of avoiding established research ethics principles.”¹⁰⁷ It is also problematic in that, although the embryo is genetically unique from the embryo donors, a stem cell line will contain genetic information derived from the donors and will be potentially capable of imparting health information about the donors. So while stem cell lines are different in kind from embryos, the donor continues to have an interest in what happens to the cell line.

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Second, it is clear that there is a marked difference between the investment required to bank genetic information or store biologic samples and that entailed in the creation of a stem cell line. Withdrawal of consent by participants after biobanking might therefore pose much less of a problem than withdrawal of consent after the development of a stem cell line. In addition, one might contend that stem cell research has more promise

for future therapeutic intervention than does biobanking or storage of tissue samples and that stem cell research therefore demands a *sui generis* approach. The problem here is that research ethics policy tends to give short shrift to the argument from societal benefits of research when such benefits are weighed against the interests of the participant.¹⁰⁸ Indeed, given the attitudes of infertility patients toward cryopreserved embryos,¹⁰⁹ it can be argued that provision for withdrawal of consent should be even more robust than in the context of health research in general. It is unlikely that participants in health research experience this profound level of ambivalence and uncertainty about whether to permit investigators to extract information from, or even develop treatments or products with, other biologic samples.

Practical concerns exist in permitting withdrawal of consent after the creation of a stem cell line from an embryo. Where a stem cell line is particularly useful and in widespread use internationally, it may be all but impossible to effect meaningful withdrawal of consent, as it would be very difficult to police all the labs using the cell line to ensure they have stopped doing so. Questions also remain around products derived from stem cell lines, and whether such products would also be covered by a donor's withdrawal of consent.



There may well be reasons, then, to have distinct rules in place in terms of donor withdrawal of consent to participation in stem cell research. But in my view such reasons need to be carefully considered and any such departures from general rules must be narrowly crafted.

vi. Consent to What? Stem Cells and Supermarkets: The “Fresh vs. Frozen” Debate

The debate around the use of fresh embryos in hESC research touches on many of the issues discussed above, but also raises unique questions that merit its discussion separate from questions around the timing and withdrawal of consent.

In late 2005, Jeffrey Nisker and Angela White authored a commentary in the *Canadian Medical Association Journal* (CMAJ) that sparked a debate around the use of fresh embryos in stem cell research.¹¹⁰ Nisker and White worried that at best, physicians and researchers may be confused about the propriety of approaching their patients with requests for fresh embryos and at worst, this practice would contravene professional and ethical obligations owed by physicians to their patients. The authors drew particular attention to the fact that the first Canadian scientist to derive stem cell lines, Dr. Andras Nagy, used fresh embryos in his research. Ultimately, they called for a moratorium on the donation of fresh embryos to stem cell research until professional and/or regulatory intervention takes place to guide the practice. Nisker and White should be commended for their obvious commitment to the protection of women’s interests in the context of research on human embryos. Their article raises some interesting points that certainly merit further consideration.

I have a few concerns, however, with their characterization of the issues at play in relation to the donation of fresh human embryos for stem cell research. My concerns are threefold: (i) the research done by Dr. Andras Nagy does not appear to give rise to the concerns identified by Nisker and White, given the factual realities of the research; (ii) the stance taken by the authors risks being viewed as paternalistic; and (iii) the authors single out conflicts of interest in stem cell research for heightened scrutiny without acknowledging the reality that the very same conflicts exist in other health research contexts, and that ethical guidelines permit such participation provided that procedural safeguards are adhered to by researchers.

As Dr. Nagy explained in response to the CMAJ commentary,¹¹¹ his use of fresh human embryos for the derivation of stem cells complied with the rigorous 2005 CIHR Guidelines.¹¹² The guidelines permit the use of fresh (or frozen) embryos no longer required for reproductive purposes. Given that the fresh embryos used by Nagy were in fact no longer required for reproductive use (they would have been destroyed had they not been used for research),¹¹³ Nisker and White’s concern with Nagy’s research in particular may be misplaced. The reason for the worries raised by Nisker and White has everything to do with the timing of and methods by which IVF patients are approached to donate their embryos for research purposes; nothing really turns on the bare question of whether the embryos are fresh or frozen.

With respect to the notion that women may not “understand and appreciate” the potential harms that may result from the donation of fresh embryos, in my view, this risks underestimating women’s capacity to make their own decisions. Nisker and White are to be lauded for raising the complex ethical terrain that must be navigated when IVF patients are approached about embryo donation,¹¹⁴ but it is important not to overstate the case. Provided that women are appropriately informed of the risks to their chances of pregnancy, as well as the risks inherent in future IVF cycles, there seems to be no reason in principle to assume that women cannot make a reasoned decision about their own participation. With respect to the concern related to who approaches the patient to request embryo donation, again, in the Nagy research, embryo donors were approached only by their physicians, not by the researchers themselves.

Finally, Nisker and White raise the question whether patients should ever be permitted to donate fresh embryos, given the reduced chance of pregnancy and increased chance of harm. In raising this question, the authors seem to imply that there is something extraordinary about stem cell research that makes conflicts of interest more worrisome, and the consent process less reliable, than in other contexts, including, for example, research protocols that call for payment of healthy volunteers to test investigational drugs for safety. I am sympathetic to their point that physicians should generally not approach patients to request the donation of fresh embryos for research purposes, but I worry that this implication in turn creates the perception that women do not have the capacity to participate in reproductive health related research because the danger of harm is too great. This is distressing because it might further marginalize women as potential research subjects,¹¹⁵ and might also reduce the likelihood of much-needed research into women’s reproductive health.



The “fresh embryo” debate has recently resurfaced in Canada, with comments made by Francoise Baylis before the House of Commons Standing Committee on Health. Baylis was commenting on the proposed consent Regulations under the *AHR Act*, and noted that she would like to see the Regulations address this issue. In her testimony, she stated that

... the research use of embryos should be limited to frozen-thawed embryos or fresh embryos not suitable for transfer. This is because donating healthy, fresh embryos created for reproductive purposes to research is not in women’s self-interest. If there are further IVF attempts, donating fresh embryos to research can, one, decrease the chance of pregnancy and child-bearing; two, increase the psychological stress experienced as a result of IVF; three, increase the number of risky or painful procedures; four, increase the social disruption that IVF causes; and five, increase the financial burden of infertility treatment. Moreover, donating fresh embryos to research is not in women’s other regarding interests.¹¹⁶

Subsequent to this meeting of the Standing Committee on Health, the composition of the AHRA was announced by the federal government. Baylis is among those appointed to the Agency which will grant licenses to individuals and entities who wish to use embryos in the clinical and /or research setting. Concerns have been raised among the Canadian stem cell research community, given the conservative views of a number of the appointees.¹¹⁷ Since the announcement of the composition of the AHRA Board of Directors, Baylis has been asked to explain her views in the media on a number of occasions,¹¹⁸ and has reiterated her concerns around the use of fresh embryos in research.

In a study recently published in the *Journal of Obstetricians and Gynecologists Canada*, Nisker and colleagues have asserted that there should be an extended waiting period between the time of gamete donation and embryo creation for reproductive purposes and requesting re-consent to the donation of surplus embryos for use in stem cell research.¹¹⁹ Although the Nisker study does not mention fresh embryos, the conclusions reached by the authors appear to support the argument that fresh embryos should not be used in research. The difficulty with this conclusion is that the authors have offered little by way of explanation as to why they reach it.

Although I share many of the concerns that have been raised in relation to the use of fresh embryos in research,¹²⁰ I am reluctant to support the call by Baylis and Nisker for a ban on the use of fresh embryos in research. Both assert that the need for a ban is grounded in women’s best interests, and it may well be the case that it will rarely be in women’s best interests to donate fresh embryos for use in research. But if we exclude the possibility that women may decide to donate fresh embryos in research – embryos that they do not wish to use, cryopreserve or donate to another couple – we are essentially stating that someone other than the woman in question is better placed to (i) determine her best interests and (ii) make this reproductive decision for her. I am extremely uncomfortable with the implications of such a move, given the historical lack of respect accorded to women’s reproductive decision making.

Imagine a woman who is undergoing a full IVF cycle for the third time. She and her partner have two children already, conceived through IVF, and have decided that, whatever the outcome, this will be their final attempt at conception. The couple does not wish to cryopreserve any excess embryos that remain at the completion of this cycle. They have been relatively successful in obtaining and fertilizing eggs in their other two cycles, and they are aware that it is highly likely that they will have more embryos after this cycle than they would wish to transfer back to the woman’s uterus. They are veterans of infertility treatment as well as scientifically literate, and have read with interest the news of embryonic stem cell research. They would like to donate any embryos that they do not use themselves to stem cell research.

The position taken by Baylis and Nisker would preclude such a decision because, in their view, it cannot be in this woman’s best interests to donate surplus fresh embryos. This position also seems to imply that the embryos cannot be discarded or donated to another couple for reproductive use (again, freezing the embryos is what Nisker and Baylis suggest is in the best interests of the woman), which means that the couple will be forced to pay for cryopreservation even though they do not wish to retain the embryos. Moreover, they may experience psychological harm as a result of knowing that they have cryopreserved embryos that they had no wish to keep.

Nisker *et al.* claim that their “...consultations and the response of the first 40 couples invited to donate cryopreserved embryos to hESC research suggest that a significant time interval, likely several years after the IVF treatment



cycle, should..." elapse before potential donors are contacted and asked to re-consent to donate embryos to research. Their findings were as follows: 40 couples were contacted and asked to re-consent to the use of their cryopreserved embryos in stem cell research. In all cases, embryos had been cryopreserved for at least five years. Of the 40 couples contacted, 23 responses were received. Twenty-two couples agreed to donate their embryos to the study. One couple no longer wished to donate their embryos to research. Of the non-responding couples, only one package was returned as "undeliverable" by Canada Post.

The authors assert that, because the non-responding couples were "patients with a reliable history of communication with the IVF unit to reconfirm or change their 'designation to research' status," it is unlikely that the reason for their lack of response was that they found it inconvenient to respond.¹²¹ In my view, there is no foundation for any conclusion respecting the failure of these couples to respond, given that the couples themselves have offered no explanation. No one can be certain that they even read the contents of the envelope they received, let alone that they have had a change of heart about donating embryos to research. In her testimony before the Standing Committee on Health, Baylis offered the Nisker study as evidence that "45% of couples who had specifically designated their frozen embryos for donation to research changed their minds."¹²² She explained that this conclusion is supportable (even though in fact Nisker *et al.* do not conclude that the non-responders changed their minds about donating to research) because "[i]t was made very clear that if we did not hear back from them, our understanding was that we were not to act on the consent and that we would not act on that consent."¹²³

Perhaps a way around the "fresh embryo" problem is to require the separation of the two distinct decisions – whether or not to cryopreserve and whether or not to donate to research. As long as the woman or couple have made an informed choice not to cryopreserve the embryos that remain after any given IVF cycle, there is no reason why they cannot be approached to donate those embryos for research purposes.

Conclusion

While there are some important distinctions between hESC research and other health research using human subjects, for the most part these differences do not demand a wholly distinct approach to consent in the hESC context. And, to the extent that they do demand a distinct set of rules, it is arguable that the hESC research context requires more, not less, rigorous consent rules. In some cases, consent requirements in Canadian law and policy seem to be unjustified and potentially illegitimate. In particular, I am referring to the virtual exclusion of gamete donor from the consent process, the limited right to withdraw afforded to embryo and gamete donors, and the requirement that infertility physicians not be involved in the consent process.

Based on the above discussion of consent-related issues, a brief summary of my recommendations for further discussion is outlined below.

1. Who Should Give Consent?

Gamete donors should be given more of a role to vary or withdraw their consent to stem cell research; this is particularly the case given that donors from whose human reproductive material stem cell lines are created will have to be re-contacted and asked for updated health information before such stem cell lines can be used in clinical trials.¹²⁴

2. When Should Consent Be Obtained?

A two-stage consent process, as specified in the CIHR Guidelines, should be explicitly adopted in the *AHR Act* consent Regulations. Consent should be obtained at the time of gamete donation and again at the time of the planned research use of the embryos.

3. Who Should Obtain Consent?

Consideration should be given to whether the exclusion of the infertility clinician from the research consent process is justified. In the absence of evidence that the conflicts of interest are somehow more profound in the hESC context than in health research more generally, physicians should not be excluded from this process.



4. Withdrawal of Consent

The fact that a stem cell line has been created should not bar withdrawal of consent by gamete and embryo donors. As in other health research, the right to withdraw consent must be available to donors for as long as possible. If, for example, cell lines are anonymized, withdrawal of consent will no longer be possible. But up to that point, donors should be permitted to withdraw consent to the continued use of their genetic material.

5. Consent to the Donation of Fresh Embryos?

In general, it will not be appropriate for physicians to ask their patients to donate fresh embryos if those embryos could be frozen for the future use of the couple. But, in my view, donation of fresh embryos to research should not be prohibited. Where patients make it clear to their physicians that they do not intend to freeze embryos that are additional to what they can use in a particular IVF cycle, it may be permissible to consider donation to research. This may be the case, for example, where a couple has decided that a given IVF cycle will be their last, or has decided that they will not cryopreserve post-PGD embryos that are affected by a particular genetic condition. We may question the wisdom of such decisions by IVF patients, but we must ultimately respect their right to make their own reproductive decisions.

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1. James A. Thomson *et al.*, “Embryonic Stem Cell Lines Derived from Human Blastocysts” (1998) 282 *Science* 1145.
2. President’s Council on Bioethics, *Human Cloning and Human Dignity: An Ethical Inquiry* (Washington, D.C.: President’s Council on Bioethics, 2002) at 258-266, 267-276; Robert Orr, “The Moral Status of the Embryonic Stem Cell: Inherent or Imputed?” (2002) 2:1 *American Journal of Bioethics* 57; Richard M. Doerflinger, “Ditching Religion and Reality” 2002 2:1 *American Journal of Bioethics* 31.
3. John Robertson, “Ethics and Policy in Embryonic Stem Cell Research” (1995) 9:2 *Kennedy Institute of Ethics Journal* 109; Michael J. Meyer & Lawrence J. Nelson, “Respecting What We Destroy: Reflections on Human Embryo Research” (2001) 31:1 *Hastings Center Report* 16; Rosario Isasi & Bartha M. Knoppers, “Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries” (2006) 13 *Euro. J. Health L.* 9.
4. Robertson, *ibid.*
5. Suzanne Holland, “Contested Commodities at Both Ends of Life: Buying and Selling Gametes, Embryos, and Body Tissues” (2001) 11:3 *Kennedy Institute of Ethics Journal* 263; Donna Dickenson, “Property and Women’s Alienation From Their Own Reproductive Labour” (2001) 15:3 *Bioethics* 205; Cynthia Cohen, “Selling Bits and Pieces of Humans to Make Babies: ‘The Gift of the Magi’ Revisited” (1999) 24:3 *Journal of Medicine and Philosophy* 288.
6. Françoise Baylis, “Embryological Viability” (2005) 5:6 *American Journal of Bioethics* 17 [Baylis, “Embryological Viability”]; Françoise Baylis & Jocelyn Downie, “An Embryonic Debate: The Importance of Shedding more Light than Heat on Stem Cell Research” (2005) 13:2 *Literary Review of Canada* 11 [Baylis & Downie, “An Embryonic Debate”].
7. Canadian Institutes for Health Research, *Guidelines for Human Pluripotent Stem Cell Research*. (Ottawa: The Institutes, 2005), online: <www.cihr-irsc.gc.ca/e/28216.html>.
8. *Assisted Human Reproduction Act*, S.C. 2004, c. 2 [AHR Act].
9. National Institutes of Health, *Directives for Human Experimentation, Nuremberg Code*, online: National Institutes of Health <<http://ohsr.od.nih.gov/guidelines/nuremberg.html>>.
10. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of



Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Public Works and Government Services Canada, 1998) at s.10 [TCPS].

11. Debra Mathews *et al.*, "Integrity in International Stem Cell Research Collaborations" (2006) 313 *Science* 921.
12. *Supra* note 10 at s. 9. It bears mention that the TCPS draws heavily on the final report of the Royal Commission on New Reproductive Technologies, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Supply and Services Canada, 1993). But in 1993, when the Royal Commission drafted and issued its report, hESC research was not on the horizon, and research using human embryos was in its earliest stages. It is therefore questionable whether the public opinion cited by the Royal Commission in support of its conclusions remains representative of current sentiment around the use of gametes and embryos in clinical or research applications.
13. Hank T. Greely, "Human Embryonic Stem Cells: The Emerging Ethical Issues" (Public Lecture, Health Law Institute Seminar Series, Edmonton, Alberta, 2005).
14. Timothy Caulfield & Tania Bubela, "Why a Criminal Ban?: Analyzing the Arguments Against Somatic Cell Nuclear Transfer in the Canadian Parliamentary Debate" (2007) 7:2 *American Journal of Bioethics* 51; President's Council on Bioethics, *Monitoring Stem Cell Research* (Washington, D.C.: President's Council on Bioethics, 2004); R. Alta Charo, "Passing on the Right: Conservative Bioethics is Closer than it Appears" 2004 32:2 *J. Law, Med. & Ethics* 307.
15. President's Council on Bioethics, *ibid.*
16. John Robertson "Crossing the Ethical Chasm: Embryo Status and Moral Complicity" (2002) 2:1 *American Journal of Bioethics* 33.
17. Isasi & Knoppers, *supra* note 3; D. Gareth Jones & C.R. Towns, "Navigating the Quagmire: The Regulation of Human Embryonic Stem Cell Research" (2006) 21:5 *Human Reproduction* 1113.
18. *Ibid.*
19. *Supra* note 5.
20. Margaret Jane Radin, *Contested Commodities: The Trouble with Trade in Sex, Children, Body Parts, and Other Things* (Cambridge, Mass.: Harvard University Press, 1996); Stephen Wilkinson, "Biomedical Research and the Commodification of Human Tissue" (2005) 1:1 *Genomics, Society & Policy* 27; Margaret Lock, "The Alienation of Body Tissue and the Biopolitics of Immortalized Cell Lines" (2001) 7 *Body & Society* 63; Lori Andrews & Dorothy Nelkin, *Body Bazaar: The Market for Human Tissue in the Biotechnology Age* (New York: Crown Publishers, 2001).
21. Insoo Hyun, "Fair Payment or Undue Inducement?" (2006) 422:10 *Nature* 629; Donna L. Dickenson, "The Lady Vanishes: What's Missing from the Stem Cell Debate" (2006) 3:1-2 *Journal of Bioethical Inquiry* 43; Bernard Lo *et al.*, "Informed Consent in Human Oocyte, Embryo, and Embryonic Stem Cell Research" (2004) 82:3 *Fertility and Sterility* 559; David Magnus & Mildred K. Cho, "Issues in Oocyte Donation for Stem Cell Research" (2005) 308 *Science* 1747; Henry T. Greely, "Moving Human Embryonic Stem Cells from Legislature to Lab: Remaining Legal and Ethical Questions" (2006) 3:5 *PLoS Medicine* e143, 0571.
22. Hyun, *ibid.*; Annick Delvigne & Serge Rozenberg, "Epidemiology and Prevention of Ovarian Hyperstimulation Syndrome (OHSS): A Review" (2002) 8:6 *Human Reproduction Update* 559.
23. Helen Pearson, "Health Effects of Egg Donation May Take Decades to Emerge" (2006) 442 (10) *Nature* 607-8; Linda Giudice, Eileen Santa & Robert Pool, eds., *Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research: Workshop Report* (Washington, D.C.: The National Academies Press, 2007).
24. See e.g. Lousie A. Brinton *et al.*, "Ovulation Induction and Cancer Risk" (2005) 83 *Fertility and Sterility* 261.
25. Françoise Baylis *et al.*, "Cryopreserved Human Embryos in Canada and their Availability for Research" (2003) 25:12 *Journal of Obstetrics and Gynaecology Canada* 1026; Catherine A. McMahon *et al.*, "Embryo Donation for Medical Research: Attitudes and Concerns of Potential Donors" (2003) 18:4 *Human Reproduction* 871 [McMahon *et al.*, "Embryo Donation for Medical Research"]; Gabor T. Kovacs, Sue A. Breheny & Melinda J. Dear, "Embryo Donation at an Australian University In-vitro Fertilisation Clinic: Issues and Outcomes" (2003) 178:3 *Medical Journal of Australia* 127. Although a recent Swedish study notes that 92% of couples chose to donate to research rather than discard supernumerary embryos: Kerstin Bjuresten & Outi Hovatta, "Donation of Embryos for Stem Cell Research – How Many Couples Consent?" (2003) 18:6 *Human Reproduction* 1353. In this study, the authors report on donation of both fresh and



cryopreserved embryos. In the fresh embryo context, couples are asked about donation only in relation to embryos that are not of sufficient quality to be transferred to the woman's uterus or frozen. The longest cryopreservation time permitted under Swedish law is 5 years, after which embryos must be discarded or donated to research. There is no option to donate embryos to third parties for reproductive use. Thus, in this study, the only disposition options available were "discard" or "donate to research."

26. Susan C. Klock, Sandra Sheinin & Ralph R. Kazer, "The Disposition of Unused Frozen Embryos [letter]" (2001) 345 *New England Journal of Medicine* 69.
27. Robert D. Nachtigall *et al.*, "Parents' Conceptualization of their Frozen Embryos Complicates the Disposition Decision" (2005) 84:2 *Fertility and Sterility* 431.
28. *Ibid.*; Catherine A. McMahon *et al.*, "Mothers Conceiving through In Vitro Fertilization: Siblings, Setbacks, and Embryo Dilemmas" (2000) 10 *Reproductive Technology* 131 [McMahon *et al.*, "Mothers Conceiving through In Vitro Fertilization"]; McMahon *et al.*, "Embryo Donation for Medical Research," *supra* note 25.
29. In the Canadian context, embryos may not be created for research purposes, except in very limited circumstances relating to assisted reproduction procedures (s. 5(1)(b), *AHR Act*). Moreover, somatic cell nuclear transfer is illegal, in that creating a human clone using any technique is prohibited (s. 5(1)(a), *AHR Act*). Stem cell research in Canada can therefore only be performed using embryos that were originally created for reproductive purposes, and the only possible donors involved in this scenario are those who donate gametes for reproductive use, and women or couples who donate embryos that are no longer required for reproductive purposes.
30. Greely, *supra* note 21.
31. Magnus & Cho, *supra* note 21.
32. *Ibid.*
33. Baylis, "Embryological Viability," *supra* note 6; Baylis & Downie, "An Embryonic Debate," *supra* note 6.
34. Roger Brownsword, "What the World Needs Now: Techno-Regulation, Human Rights and Human Dignity" in Roger Brownsword, ed., *Human Rights* (Oxford: Hart Publishing, 2004) 203; Roger Brownsword, "Stem Cells and Cloning: Where the Regulatory Consensus Fails" (2005) 39 *New Eng. L. Rev.* 535; Timothy Caulfield & Audrey Chapman, "Human Dignity as a Criterion for Science Policy" (2005) 2 *PLoS Medicine* e244; Timothy Caulfield & Roger Brownsword, "Human Dignity: A Guide to Policy Making in the Biotechnology Era?" (2006) 7 *Nature Reviews: Genetics* 72; Ruth Macklin, "Dignity is a Useless Concept" (2003) 327 *British Medical Journal* 1419.
35. Caulfield & Brownsword, *ibid.* at 72.
36. *Supra* note 9; World Medical Association, "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects" (2000) 284:23 *Journal of the American Medical Association* 3043 [WMA]; TCPS, *supra* note 10.
37. Rosamond Rhodes, "Rethinking Research Ethics" (2005) 5 *American Journal of Bioethics* 7; Ezekiel J. Emanuel, David Wendler & Christine Grady, "What Makes Clinical Research Ethical?" (2000) 283:20 *Journal of the American Medical Association* 2701.
38. Erin Nelson, "The Fundamentals of Consent" in Jocelyn Downie, Timothy Caulfield & Cynthia Flood, eds., *Canadian Health Law and Policy*, 2d ed., (Toronto: Butterworths, 2002) 111; Timothy Caulfield, Ubaka Ogbogu & Rosario Isasi "Informed Consent and Embryonic Stem Cell Research: Are we Following Basic Consent Principles?" (2007) 176 *Canadian Medical Association Journal* 1722.
39. WMA, *supra* note 36 at Art. 22; TCPS, *supra* note 10 at Art. 2.2, 8.6; Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks, Title 45, Code of Federal Regulations, Part 46 – Protection of Human Subjects (45 CFR 46) (Washington, D.C.: DHHS, 18 June 1991) [Common Rule] at §46.116(a)(8); Council of Europe, "Additional Protocol to the Convention on Human Rights in Biomedicine, Concerning Biomedical Research" (Strasbourg, 1 January 2005), online: <<http://conventions.coe.int/treaty/en/Treaties/Html/195.htm>> at Art. 14.1; United Nations Educational, Scientific and Cultural Organization, *Universal Declaration on Bioethics and Human Rights* (2005), online: <http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html> at Art. 6.1.
40. In limited circumstances, research may be carried out without individualized consent, *supra* note 9 at Art. 2.1(c), explanatory notes.
41. *Ibid.* at Art. 2.2, explanatory notes.
42. This discussion will proceed on the basis that subjects who participate in embryonic stem cell research are competent to consent to research participation. There



are numerous additional safeguards built into the TCPS where participation by incompetent subjects is contemplated. In addition, the potential participation in research of incompetent subjects gives rise to complex legal issues.

43. *Supra* note 9 at Art. 2.2.
44. Nelson, *supra* note 38; Ellen I. Picard & Gerald B. Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 3d ed. (Toronto: Carswell, 1996).
45. *Ibid.*
46. Bernard M. Dickens, "Informed Consent" in Jocelyn Downie, Timothy Caulfield & Cynthia Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Toronto: Butterworths, 2002) 129; *Reibl v. Hughes* (1980), 114 D.L.R. (3d) 1 (S.C.C.).
47. Kathleen C. Glass & Trudo Lemmens, "Research Involving Humans" in Jocelyn Downie, Timothy Caulfield & Cynthia Flood, eds., *Canadian Health Law and Policy*, 2d ed. (Toronto: Butterworths, 2002) 459; *Halushka v. University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 (Sask. C.A.) [*Halushka*]; *Weiss v. Solomon* (1989), 48 CCLT 280 (Que. Sup. Ct.) [*Weiss*].
48. *Halushka, ibid.*
49. *Weiss, supra* note 47 at para. 109: "La Cour doit donc conclure qu'en matière de recherche purement expérimentale, le médecin doit révéler tous les risques connus même rares ou éloignés et à plus forte raison si ceux-ci sont d'une conséquence grave."
50. Glass & Lemmens, *supra* note 47 at 487.
51. Canadian Institutes for Health Research, *Updated Guidelines for Human Pluripotent Stem Cell Research* (Ottawa: The Institutes, 2006), online: <<http://www.cihr-irsc.gc.ca/e/31488.html>> at Art. 5.
52. *Ibid.* at Art. 3.
53. *Ibid.* at Art. 8.1.1.
54. Erin Nelson, "Comparative Perspectives on the Regulation of Assisted Reproductive Technologies in the United Kingdom and Canada" (2006) 43:4 *Alta. L. Rev.* 1023.
55. *Human Fertilisation and Embryology Act*, (U.K.) 1990, C. 37.
56. Health Canada website: <http://www.hc-sc.gc.ca/english/lifestyles/reproduction/noi_e.html>.
57. *Supra* note 8 at ss. 70, 71.
58. *Supra* note 56.
59. *Supra* note 8 at s. 3.
60. *Supra* note 7, 51. Canadian Institutes for Health Research, *Updated Guidelines for Human Pluripotent Stem Cell Research*, June 29, 2007 (Ottawa: The Institutes, 2007), online: <<http://www.cihr-irsc.gc.ca/e/34460.html>>.
61. Françoise Baylis & Natalie Ram, "Eligibility of Cryo-preserved Human Embryos for Stem Cell Research in Canada" (2005) 27:10 *Journal of Obstetrics & Gynaecology Canada* 949.
62. Timothy Caulfield, "Bill C-13 *The Assisted Human Reproduction Act*: Examining the Arguments Against a Regulatory Approach" (2002) 11:1 *Health L. Rev.* 20.
63. A similar regulation-making process is found in the *Tobacco Act*, S.C. 1997, c.13, s. 42.1.
64. *Supra* note 8 at s. 66(1).
65. *Ibid.* at s. 67(1).
66. *Supra* note 60 at Art. 8.3.1.
67. *Ibid.* at Art. 8.1.1.2.
68. Canada, Governor-in-Council, *Draft Assisted Human Reproduction (Section 8 Consent) Regulations* (2006), Copy on file with author [Regulations].
69. Canada, House of Commons, Standing Committee on Health, *Fifth Report of the 39th Parl, 1st Sess.* (29 January 2007), online: <<http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?COM=10481&Lang=1&SourceId=189141>>.
70. Canada, Senate, Standing Committee on Social Affairs, Science and Technology, *Proceedings of the Standing Senate Committee on Social Affairs, Science and Technology, Issue 15 - Ninth Report of the Committee* (14 February 2007), online: <http://www.parl.gc.ca/39/1/parlbus/commbus/senate/Com-e/soci-e/15rp-e.htm?Language=E&Parl=39&Ses=1&comm_id=47>.
71. *Assisted Human Reproduction (Section 8 Consent) Regulations*, S.O.R./2007-137, online: <<http://canadagazette.gc.ca/partII/2007/20070627/pdf/g2-14113.pdf>>.
72. *Supra* note 8 at ss. 8 (1) and (3).
73. *Supra* note 61.
74. *Ciarlariello v. Schacter*, [1993] 2 S.C.R. 119.
75. TCPS, *supra* note 10 at Art. 8.6.
76. Given that anonymous gamete donation is permitted, it is legitimate to ask why gamete donors should have an ongoing role in decision-making about donation of embryos for use in research. A donor who wishes to remain anonymous may appear to have relinquished all control over the future use of their gametes. This may indeed be the case for some, but perhaps not all, gamete donors. At the very least, it would be useful to ask gamete donors at the time of donation whether they would like to be contacted should their gametes



be used to create embryos that might be donated to research.

77. Søren Holm, "Who Should Control the Use of Human Embryonic Stem Cell Lines: A Defence of the Donors' Ability to Control" (2006) 3 Bioethical Inquiry 55.
78. *Kass v. Kass*, 696 N.E.2d 174 (N.Y. 1998); *J.B. v. M.B.*, 783 A.2d 707 (N.J. 2001); *A.Z. v. B.Z.*, 725 N.E.2d 1051 (Mass. 2000); *In re the Marriage of Litowitz v. Litowitz*, 48 P.3d 261 (Wash. 2002); *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992); *Evans v. Amicus Health Care Limited & Others* [2003] EWHC 2161 (Fam); aff'd *Evans v. Amicus Health Care Limited & Others*, [2004] EWCA Civ 727; *Evans v. The United Kingdom* 6339/05 (7 March 2006), online: <<http://cmiskp.echr.coe.int/tkp197/view.asp?item=1&portal=hbk&action=html&highlight=evans%20%7C%20embryo&sessionid=6851437&skin=hudoc-en>>.
79. Health Canada, Seeking Input on a Proposed Approach for Regulations Concerning Section 8 (Consent) and the Section 3 Definition of an In vitro Embryo Donor under the Assisted Human Reproduction Act (Ottawa: Health Canada, 2004), online: <http://www.hc-sc.gc.ca/hl-vs/alt_formats/hpb-dgps/pdf/reprod/consent_e.pdf>.
80. Klock, Shenin & Kazer, *supra* note 26; Nachtigall *et al.*, *supra* note 27.
81. *Supra* note 60 at Art. 8.3.2.
82. *Ibid.*
83. International Society for Stem Cell Research (ISSCR), *Draft Guidelines for the Conduct of Human Embryonic Stem Cell Research* (30 June 2006), online: <<http://www.isscr.org/StaticContent/StaticPages/ISSCRTaskForceGuidelinesDRAFT6-30-06.pdf>> at Art. 11.2.
84. *Supra* note 71 at ss. 3, 4, 12, 13.
85. TCPS, *supra* note 10 at Art. 8.6.
86. Caulfield, Ogbogu & Isasi, *supra* note 38.
87. *Supra* note 60, Art. 8.3.2. It should be noted as well that Art. 8.3.7 of the Guidelines states that physicians who provide fertility treatment and pregnancy termination services are not to be part of a stem cell research team.
88. *Ibid.* at Art. 8.3.3.
89. American Society for Reproductive Medicine, Ethics Committee, "Donating Spare Embryos for Embryonic Stem Cell Research" (2002) 78:5 Fertility and Sterility 957 [ASRM]; American Association for the Advancement of Science and Institute for Civil Society, *Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research* (Washington, DC: American Association for the Advancement of Science, 1999); 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); Jeffrey Nisker & Angela White, "The CMA Code of Ethics and the Donation of Fresh Embryos for Stem Cell Research" (2005) 173:6 Canadian Medical Association Journal 621.
90. Lo *et al.*, *supra* note 21 at 562.
91. *Norberg v. Wynrib*, [1992] 2 S.C.R. 318; *McInerney v. McDonald*, [1992] 2 S.C.R. 138.
92. TCPS, *supra* note 10 at Arts. 4.1, 2.4(e).
93. Caulfield, Ogbogu & Isasi, *supra* note 38.
94. Timothy Caulfield & Glenn Griener, "Conflicts of Interest in Clinical Research: Addressing the Issue of Physician Remuneration" (2002) 30:2 J. Law, Med. & Ethics 305.
95. Hyun, *supra* note 21; Leah E. Hutt, "Paying Research Subjects: Historical Considerations" (2003) 12:1 Health L. Rev. 16.
96. *Supra* note 60 at Art. 8.3.7.
97. Lo *et al.*, *supra* note 21.
98. *Ibid.*
99. Bjursten & Hovatta, *supra* note 25.
100. Patricia Zettler, Leslie E. Wolf & Bernard Lo, "Establishing Procedures for Institutional Oversight of Stem Cell Research" (2007) 82:1 Academic Medicine 6.
101. Thus, even if the embryo has not actually been used in research when the researcher is notified that the donor(s) wish to withdraw consent, the withdrawal will not be effective if the researcher has already begun to thaw the embryo for use in research.
102. As noted earlier, the *AHR Act* does not apply to stem cell lines, or to any derivatives thereof. Arguably, then, the ambit of the *Act* cannot extend to withdrawal of consent past the point of the creation of a stem cell line. Now that a stem cell line exists, and the embryo no longer exists, there is no further role for the *Act*.
103. Caulfield, Ogbogu & Isasi, *supra* note 38.
104. Committee on Guidelines for Human Embryonic Stem Cell Research, National Research Council, Board on Life Sciences, Board on Health Sciences Policy, Earth and Life Studies, Institute of Medicine, *Guidelines for Human Embryonic Stem Cell Research* (Washington, DC: National Academies Press, 2005) Recommendation 17; *supra* note 83 at Art. 11.2; *Hu-*



- man Fertilisation and Embryology Act*, (U.K.) 1990, c.37 at Sch. 3, s. 4.
105. Caulfield, Ogbogu & Isasi, *supra* note 38.
 106. UK Biobank Ethics and Governance Framework, Version 2.0 (May 2006), online: <<http://www.ukbiobank.ac.uk/docs/EGF%20Version02%20May%202006.pdf>>; German National Ethics Council, *Biobanks for Research: Opinion* (Berlin: Nationaler Ethikrat, 2004), online: <http://www.ethikrat.org/_english/publications/Opinion_Biobanks-for-research.pdf>; TCPS, *supra* note 10.
 107. Caulfield, Ogbogu & Isasi, *supra* note 38 at 10.
 108. WMA, *supra* note 36 at Art.5; Council of Europe, *supra* note 39 at Art. 3; UNESCO *supra* note 39 at Art. 3; *supra* note 77.
 109. McMahan *et al.*, “Mothers Conceiving through In Vitro Fertilization, *supra* note 28; McMahan *et al.* “Embryo Donation for Medical Research,” *supra* note 35; Nachtigall *et al.*, *supra* note 27.
 110. Lo *et al.*, *supra* note 21 at 562.
 111. Margaret Munro, “Moratorium Urged on use of Fresh Embryos: Women at Risk – Ethicists” *The National Post* (13 September 2005) A1.
 112. *Supra* note 7.
 113. Munro, *supra* note 111; Canadian Press, “Ethicist: Embryo Research Should be Done Cautiously” CTV News online (12 September 2005), online: <http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/1126574891508_10/?hub=Health>.
 114. Christine Overall, “Frozen Embryos and ‘Father’s Rights’: Parenthood and Decision-making in the Cryopreservation of Embryos” in Joan C. Callahan, ed., *Reproduction, Ethics and the Law: Feminist Perspectives* (Bloomington, Ind.: Indianapolis University Press, 1995) 178; Susan Sherwin, “New Reproductive Technologies” in Susan Sherwin, *No Longer Patient: Feminist Ethics & Health Care* (Philadelphia: Temple University Press, 1992) 117; Baylis & Downie, *supra* note 6.
 115. Françoise Baylis, Jocelyn Downie & Susan Sherwin, “Reframing Research involving Humans” in Susan Sherwin, ed., *The Politics of Women’s Health: Exploring Agency and Autonomy* (Philadelphia, PA: Temple University Press, 1998) 19; Mita Giacomini & Françoise Baylis, “Excluding Women from Medical Research: Reasons and Rejoinders” (2003) 3:10 *Clinical Researcher* 12.
 116. House of Commons, Standing Committee on Health, 1st Sess., 39th Parl., no. 033. Evidence (12 December 2006), online: <<http://cmte.parl.gc.ca/cmte/CommitteePublication.aspx?SourceId=188386>>.
 117. Carolyn Abraham, “Critics Troubled by New Fertility Panel” *The Globe and Mail* (23 December 2006), online: <<http://www.theglobeandmail.com/servlet/story/RTGAM.20061223.wxrepro23/BNStory/specialScienceandHealth/home>>; Gloria Galloway, “Ottawa Rejects Concerns over Fertility Panel” *The Globe and Mail* (28 December 2006), online: <<http://www.theglobeandmail.com/servlet/story/RTGAM.20061228.wxrepro28/BNStory/National/home>>.
 118. See e.g. Norma Greenaway, “New Debate Emerges over Stem Cells” *The National Post* (3 January 2007) 4.
 119. Jeffery Nisker, Angela White, Francis Tekpetey & Valter Feyles, “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.
 120. ASRM, *supra* note 89.
 121. Nisker *et al.*, *supra* note 119 at 906.
 122. *Supra* note 116.
 123. *Ibid.*
 124. *Supra* note 77; Caulfield, Ogbogu & Isasi, *supra* note 38.

