

# Regulating Consent to Human Embryo Research: A Critique of Health Canada's Proposal

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In March 2004, the *Assisted Human Reproduction (AHR) Act* received Royal Assent.<sup>1</sup> The law includes an explicit prohibition on the creation of human embryos for research. Consequently, the only embryos available for research use are those created, but no longer required, for reproductive purposes. This legislative requirement explicitly transforms Canadian IVF clinics into partners in the research enterprise, as they are, by law, the sole providers of human embryos for research use. A key issue for IVF providers, embryo researchers, and policy-makers in moving forward under the AHR Act is consent.

In November 2004, Health Canada, which is responsible for creating regulations under the AHR Act, issued a Consultation Document entitled, *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*. The Consultation Document introduced Health Canada's proposed approach to a variety of issues pertaining to consent under the AHR Act and sought public input on the efficacy and ethical acceptability of the proposed approach to regulations.

The Consultation Document outlines proposed consent regulations for the use of gametes (sperm and eggs) and embryos in three domains: for one's own reproductive use, for third party reproductive use, and for use in research. A particularly difficult consent issue concerns third party use

of gametes, where gametes are used to create embryos for someone other than the person from whom the gametes were obtained. According to the Consultation Document, when gametes are donated to a third party, the consent is not only for the reproductive use of human gametes, but also for "all possible future uses."<sup>2</sup> With this approach, a gamete donor has no ability to direct or control the future use of her donated gametes. The gametes will originally be used for reproductive purposes, but, beyond that, the donor has no say. Specifically, the gamete donor has no choice with regard to the future use of her genetic material, including whether it is used in research and, if so, for what kinds of research.

Health Canada's proposed approach to the regulation of consent to third party use of gametes is both problematic public policy and possibly illegal.<sup>3</sup> The proposed regulation does not satisfy the core ethical principle of free and informed consent, which under current Canadian policy requires that a person who consents to any intervention understand and accept the "nature and goals"<sup>4</sup> of that intervention. The AHR Act explicitly identifies free and informed consent as one of its declared principles.<sup>5</sup> This paper will delineate requirements for consent to third party use of gametes in Canada, critically examine Health Canada's proposed approach to regulations under this rubric, and then critically evaluate three alternative approaches to consent to third party use of gametes.



## Instruments for Regulation Evaluation: Defining the Ideal

An ideal model for consent to third party use of gametes would comply with all legal requirements, be consistent with current Canadian scholarship on consent, and impose the least burdensome requirements possible. Pragmatically, the consent process should not be so burdensome that it effectively precludes the future research use of embryos created using third party gametes. Nor should the consent process be so open-ended that it discourages potential gamete donors from making donations for infertility treatment because they fear the unrestricted future use of their genetic material.

Consent to donation of gametes for third party use must emanate from a free and informed choice. Several landmark court rulings, including *Halushka v University of Saskatchewan*,<sup>6</sup> *Reibl v Hughes*,<sup>7</sup> *Hopp v Lepp*,<sup>8</sup> and *Weiss v Solomon*,<sup>9</sup> have issued judgments affirming the autonomy and inviolability of patient and research subject and the correlated necessity for consent to be both informed and freely given. In *Hopp*, which considered these issues in the context of therapy, the Court emphasized the requirement of informed consent, stating:

The underlying principle is the right of a patient to decide what, if anything, should be done with his body....It follows, therefore, that a patient's consent, whether to surgery or to therapy, will give protection to his surgeon or physician only if the patient has been sufficiently informed to enable him to make a choice whether or not to submit to the surgery or therapy. The issue of informed consent is at bottom a question whether there is a duty of disclosure, a duty by the surgeon or physician to provide information and, if so, the extent or scope of the duty.<sup>10</sup>

In defining the scope of necessary disclosure under informed consent, Chief Justice Laskin, writing for the Court in *Hopp*, stated, "I am far from persuaded that the surgeon should decide on his own not to warn of the probable risk of hearing or other impairment if the course of treatment contemplated is administered. A surgeon is better advised to give the warning, which may be coupled with a warning of the likely consequence if the treatment is rejected."<sup>11</sup> Both *Hopp* and *Reibl* made clear that doctors must disclose to their patients all "material risks" of treatment.

More on point, *Halushka* and the more recent *Weiss* case considered consent in the context of medical research. *Halushka* established that "in order for a consent to be effective it must be an informed consent, freely given, and it is the duty of a doctor to give a fair and reasonable explanation of the proposed treatment including the probable effect thereof and any special or unusual risks."<sup>12</sup> *Halushka* continued, noting, "the duty imposed upon those engaged in medical research ... to those who offer themselves as subjects for experimentation ... is at least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient."<sup>13</sup> *Weiss* strengthened this latter statement from *Halushka*, holding that the law imposes a more exacting standard for obtaining free and informed consent in the context of research than in the context of therapy.<sup>14</sup> The *Weiss* court also reaffirmed the duty of disclosure set forth in *Hopp* and *Reibl* – a duty to disclose all "material risks," including those that are transitory discomforts or rare but serious complications.<sup>15</sup> In arriving at its ruling, the court in *Weiss* relied not only on *Halushka*, but also on articles 19 and 20 of the *Civil Code of Quebec*, which state that competent individuals may donate tissues for purposes of research, but only with consent and only in circumstances in which the donation of tissue or participation in research will not impose more risks than potential benefits.<sup>16</sup> From these legal sources, it follows that the duty of disclosure and requirements of informed consent are demanding and rigorous, and that the duties and requirements that exist in the context of human subjects research are more onerous than those that apply in circumstances involving therapeutic interventions.

Emerging from this common and civil law background are several policy documents that advance specific requirements for consent. Most germanely, the AHR Act identifies "the principle of free and informed consent ... as a fundamental condition of the use of human reproductive technologies...."<sup>17</sup> The *Tri-Council Policy Statement (TCPS)* further clarifies free and informed consent, stating that it requires that the donor understand and accept the "nature and goals"<sup>18</sup> of the intervention to which she is consenting. Without an understanding of the nature and goals of the intervention(s) to which a donor is consenting, her consent cannot properly be said to be *informed*.<sup>19</sup> The nature and goals of assisted reproduction using donor gametes are very different from those of most embryo research. Embryo research encompasses a broad range of activities, including stem cell research, research to develop abortifacients, and research on infertility, among others.



Gamete donors committed to helping others conceive children through *in vitro* fertilization (IVF) may be morally opposed to embryo research. Were the proposed regulations to come into force as is, these prospective donors would face two choices, neither satisfactory: 1) refrain from donating their gametes; or 2) donate their gametes for reproductive use, and, as an unfortunate corollary, donate their gametes for possible future use in embryo research. The latter choice, in particular, arguably constitutes a subtle form of donor coercion. The prospective donors committed to assisting the infertile are obliged to consent to interventions that they may not support (i.e., research) if they want to consent to a distinctly different intervention that they do support (i.e., assisted reproduction).

The TCPS provides additional guidance for obtaining free and informed consent specifically in the context of secondary use of genetic material. Here, the TCPS advocates either “a comprehensive consent form, which allows the research subject to choose from a number of options (e.g., use of the material only in the present study, use restricted to the condition, or other clearly specified use) or a more limited consent form, which specifies arrangements to maintain contact with the subject regarding future uses.”<sup>20</sup> The TCPS represents core Canadian values in connection with research involving humans (including tissues and embryos<sup>21</sup>); therefore, it is critical that the regulations formulated for section 8 of the AHR Act be consistent with the TCPS.

Consent to third party use of gametes must also be consistent with the 2002 CIHR Guidelines for stem cell research.<sup>22</sup> The AHR Act explicitly incorporates these Guidelines in its definition of consent, stating, “‘consent’ means fully informed and freely given consent that is given in accordance with the applicable law governing consent and that *conforms to the provisions of the Human Pluripotent Stem Cell Research Guidelines released by the Canadian Institutes of Health Research in March, 2002*, as detailed in the Regulations.”<sup>23</sup> If consent by gamete donors is not obtained in a manner consistent with the 2002 CIHR Guidelines, then human embryos created using donor gametes will be legally ineligible for any use.<sup>24</sup> As regards the research use of such embryos, the 2002 CIHR Guidelines state, “where ‘donor’

gametes have been used to create the embryos, the gamete providers must have originally given free and informed consent to the unrestricted research use of any embryos created when these embryos were no longer required for reproductive purposes....”<sup>25</sup> Under this requirement, consent to the reproductive use of donor gametes is not substituted for consent to research use of donor gametes. Donors who consent to the third party reproductive use of their gametes retain the power to consent to or refuse the later research use of their genetic material. At the time of donation, donors may therefore consent to reproductive uses only or to reproductive and future research uses.

Of note, on June 7, 2005, CIHR issued updated guidelines for stem cell research in Canada that amend several of the requirements for consent to the research use of embryos.<sup>26</sup> Most pertinently, the 2005 CIHR Update requires disclosure of possible future uses of embryos prior to gamete collection, but it does not require decision-making at this time.<sup>27</sup> Conversely,

the 2002 CIHR Guidelines require decision-making about the future disposition of embryos no longer wanted for reproduction prior to gamete collection. However, the 2005 CIHR Update subsequently states that, at the time of anticipated research use of embryos, “A renewal of the consent provided by the gamete providers (if the gamete providers are not the same individuals as the embryo providers), is not required provided that appropriate consent for the unrestricted research use of the embryos was given at the time of gamete donation.”<sup>28</sup> The reference here to a prior research consent introduces considerable ambiguity and presumes a consent that the 2005 CIHR Update never describes or explicitly requires, as the only consent that can be known to have been obtained from gamete donors is to the reproductive use of embryos created with donor gametes. It is unclear whether this ambiguity was introduced purposefully to facilitate easier access to embryos created with donor gametes, or whether the ambiguity is the product of a failure to appreciate the distinction between consent to reproductive use of embryos created with donor gametes and consent to research use of such embryos.

In any case, the 2005 CIHR Update does not influence the legal or public policy requirements for consent to third party

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use of gametes because the AHR Act explicitly and only names the 2002 CIHR Guidelines in its definition of consent. In the absence of an act of Parliament, no changes to the 2002 CIHR Guidelines with respect to consent constitute changes to the legislation. Given the considerable ambiguity of requirements for consent to third party use of gametes in the 2005 CIHR Update and the legal force of the 2002 CIHR Guidelines, the analysis that follows will consider the implications of Health Canada's proposal solely in light of the 2002 CIHR Guidelines.

## **Evaluating Health Canada's Proposed Approach to Consent**

Health Canada's proposed approach to consent to third party use of gametes requires that gamete donors consent not only to the reproductive use of their genetic material, but also to "all possible future uses."<sup>29</sup> The pragmatic benefits of this approach, in terms of not having categories of embryos to track over time, are obvious – namely the ease with which this approach could be introduced and implemented, the reduced maintenance costs, and the lower probability of error. For instance, in the case of reducing the probability of error, if donors provide consent to all possible future uses of their gametes, then there are no categories of embryos (available for research versus not available for research) that need to be tracked. This administrative streamlining of the consent process and its attendant paperwork may simplify access to donor embryos for researchers.

However, there are also pragmatic considerations that argue against requiring such broad consent from gamete donors; most importantly, the proposed, sweeping consent could limit the number of gametes donated for infertility treatment. Research indicates that only 2% of embryos cryopreserved in Canadian IVF clinics are available by consent for research purposes.<sup>30</sup> As this number may reflect the willingness of individuals to make their genetic material available for research purposes, potential donors opposed to embryo research might choose not to donate their gametes at all and thereby risk them being used for research. This outcome would further limit the number of third party gametes available to IVF patients for reproductive purposes. Given that donor gametes, especially eggs, are already in extremely short supply and that the elimination of payments for gamete donation specified in the AHR Act<sup>31</sup> will likely reduce the number of available donor gametes further, driving away potential donors by requiring that they consent to all possible future uses of their gametes is not in the best

interest of potential donors, infertility patients, or even researchers.

Moreover, Health Canada's proposed approach to consent to third party use of gametes is inconsistent with current Canadian policy. The proposed regulation under section 8 does not provide opportunity for potential donors to understand and accept the "nature and goals"<sup>32</sup> of potential future research uses of their genetic material. In substituting consent to therapy for consent to research, Health Canada's proposed approach to consent under section 8 of the AHR Act undermines the principle of free and informed consent described in the AHR Act, the requirements for consent articulated in the 2002 CIHR Guidelines for stem cell research, and the consent requirements stipulated in the TCPS, both generally and in the context of secondary use of genetic material.

## **A Few Alternatives**

At the very least, evaluation of Health Canada's proposed approach to consent to third party use of gametes demonstrates that separating consent to reproductive use from consent to research use of donated reproductive materials is required. In this vein, there are several alternatives to the approach set forth in Health Canada's consultation document. Previously established policy documents and practices in Canada and elsewhere as well as the literature on consent for secondary use of tissue or genetic material in research<sup>33</sup> offer three alternative models for addressing consent for third party use of gametes:

- At the time of consent to therapy, request blanket consent<sup>34</sup> for research; or
- At the time of consent to therapy, request authorization to re-contact for research use, so that project-specific consent may be solicited; or
- At the time of consent to therapy, request tiered consent for possible future research.

Each of these policy options improves on Health Canada's proposed approach to consent because each preserves donor choice – the right of the gamete donor to consent to reproductive use of her genetic material is independent of her consent to or refusal of their future use in research. Both consent to and refusal of future research use of gametes and resulting embryos are legitimate choices, and both must therefore be protected.



## Choosing Between Alternatives

There are several benefits to Model 1, which identifies a system of blanket consent/refusal for future research use of embryos created using third party gametes. It improves on Health Canada's proposed approach by separating consent to therapy from consent to research. Blanket consent for research conforms to the model set forth in the 2002 CIHR Guidelines for stem cell research. As such, it is consistent with the requirements for consent in that document. Moreover, blanket consent for research imposes few pragmatic difficulties. Tracking of gametes donated for third party reproductive use would need to note only whether gamete donors consented to or refused the future research use of their gametes (and resulting embryos).

However, while blanket consent to research improves on Health Canada's proposed approach by protecting donor choice respecting the future use of the donor's genetic material, a system of blanket consent to research presents some of the same difficulties as Health Canada's proposal. According to the TCPS, appropriate models for consent to secondary use of genetic material include, "comprehensive consent form, which allows the research subject to choose from a number of options ... or a more limited consent form, which specifies arrangements to maintain contact with the subject regarding future uses."<sup>35</sup> Blanket consent for research conforms to neither of these suggested models. As noted earlier, embryo research encompasses a broad range of activities, and donors who share in the nature and goals of some research projects may not share in the nature and goals of others. Thus, like Health Canada's proposed approach to section 8 regulations, in the context of consent to research, blanket consent impermissibly demands consent that may not be fully informed and that may oblige consent to research projects that are morally objectionable to some. As a general model of consent, blanket consent is overly broad.

Like Model 1's system of blanket consent to research, Model 2, which requests authorization to re-contact donors for future consent to research use of embryos created using

their gametes, separates consent to reproductive use of gametes from research use. Although consent to research under a re-contact model is significantly more demanding than required under the 2002 CIHR Guidelines for stem cell research, re-contact is consonant with the nature and goals of consent under the 2002 CIHR Guidelines. A re-contact model of consent also improves on blanket consent in that it presents the gamete donor with a greater ability to make her wishes respecting the research use of her gametes known. A re-contact model conforms to a model of consent suggested in the TCPS: "a more limited consent form, which specifies arrangements to maintain contact with the subject regarding future uses...." Re-contact for consent does not oblige gamete donors to consent to any, some, or all projects of embryo research. In this respect, a re-contact model protects consent as both freely given and informed.

However, a re-contact model poses significant pragmatic difficulties. Requesting permis-

sion to re-contact gamete donors for consent to research use of their genetic material requires that donors maintain accurate and up-to-date contact information with some authority responsible for overseeing the movement of human gametes and embryos in and among IVF clinics and embryo researchers. At least for some research projects, the administrative demands of such a system make the re-contact model pragmatically ill advised.<sup>36</sup>

Moreover, given that the primary motivation for gamete donation is reproductive, a re-contact model for future research use may also be burdensome to the original goals of donation. Many donors who undertake donation to assist infertile couples in realizing their reproductive goals may not wish to be repeatedly contacted by researchers seeking their consent for a variety of unrelated research proposals, even if they are willing to allow their gametes to be used in some or all types of research. Such repeated re-contact may place an undue burden on gamete donors.<sup>37</sup>

Recognizing the difficulties of Models 1 and 2, Model 3, which is a model of tiered consent, attempts to find a middle ground that preserves the benefits of these approaches while minimizing their disadvantages. Tiered consent is conso-

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nant with the nature and goals of consent under the 2002 CIHR Guidelines, and it conforms to a model of consent suggested in the TCPS: “comprehensive consent form, which allows the research subject to choose from a number of options...” Tiered consent does not oblige gamete donors to consent to any, some, or all categories of embryo research. Furthermore, the inclusion of an option for re-contact strengthens the ability of the potential donor to make her wishes known. In this respect, tiered consent protects consent as both freely given and informed.<sup>38</sup>

The precise options under a tiered consent process need not be defined in the regulations, although Health Canada could choose to do so. Alternatively, such determinations could be made by Research Ethics Boards. Most often, in presenting a gamete donor with a menu of research categories to which she may consent, one option provided under tiered consent permits unrestricted research use (as under Model 1), while another provides authorization for re-contact (as under Model 2). In addition, discrete research objectives may be identified to enable donors to make embryos created using their gametes eligible for future research without having to consent to unrestricted use or unwanted re-contact. In thinking about appropriate options for embryo research to which gamete donors may consent, Health Canada (or other decisional bodies) might take note of the acceptable purposes of embryo research set forth in the United Kingdom’s Human Fertilisation and Embryology Act 1990:

- (i) To promote advances in the treatment of infertility
- (ii) To increase knowledge about the causes of congenital disease
- (iii) To increase knowledge about the causes of miscarriages
- (iv) To develop more effective techniques of contraception
- (v) To develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.<sup>39</sup>

In 2001, new cloning regulations approved by the British Parliament introduced three additional research categories:

- (vi) To increase knowledge about the development of embryos
- (vii) To increase knowledge about serious disease; or
- (viii) To enable such knowledge to be applied in the development of treatments to combat serious disease.<sup>40</sup>

This list of potential research categories is not exclusive or necessarily complete – it is merely meant to be illustrative.

Tiered consent processes that incorporate blanket consent and authorization for re-contact as options available to donors will have the same limitations as these two discrete models. However, while these other consent models solely endorse blanket consent or authorization to re-contact as a single option that gamete donors must select in order to consent to the future research use of their genetic material, a tiered consent process includes these options as simply two options among several. Thus, any potential burdens and risks are chosen by the gamete donor.

It is also possible that, because authorization to re-contact is one option among several, tiered consent might be conducted in the absence of an option for re-contact. The removal of a re-contact option under tiered consent might, of course, be possible only under limited, strictly enforced circumstances, for instance research projects in which the pragmatic difficulties of re-contact are too great to be successfully undertaken and the potential harms to donors of a less precise consent mechanism are minimal.<sup>41</sup> Thus, although tiered consent imposes additional pragmatic constraints in comparison to blanket consent to research or Health Canada’s proposed approach to regulations, these pragmatic requirements are not as intractable as those faced under a re-contact model, nor are they restrictive to such a degree so as to paralyse research using embryos created with donor gametes.

## Conclusions and Recommendation

Health Canada has proposed an approach to regulation of section 8 of the AHR Act with respect to consent to third party use of gametes that violates the principle of free and

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informed consent outlined in the AHR Act and entrenched in Canadian common law and other relevant policy documents governing research involving humans, most notably the TCPS and the 2002 CIHR Guidelines. Health Canada's proposed approach yields a model of consent that is neither informed nor free. It is problematic from both a policy-making and legal perspective to exclude gamete donors from the decision-making process with respect to embryo research, which would be the unfortunate result of Health Canada's proposed regulation of consent under the AHR Act.

Three alternative models for consent to gamete donation have been proposed and evaluated. Each model allows donors to control (to varying degrees) the future use of their genetic material. In this respect, all three models improve upon Health Canada's proposed model. Having said this, it is still possible to distinguish between the three models. Blanket consent to research may constitute an illegally broad model resulting in consent that is not truly free or informed. Meanwhile, the re-contact model threatens to cripple research through pragmatic requirements while potentially placing an undue burden on donors with continuous re-contact. Tiered consent provides the best opportunity for Health Canada to meet its public policy and legal obligations, consistent with the values identified in the AHR Act.

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1. *Assisted Human Reproduction Act*, S.C. 2004, c. 2 [AHR Act].
2. 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: Assisted Human Reproduction Implementation Office - Health Canada, 2004) at 10, 13, online: Health Canada <<http://www.hc-sc.gc.ca/english/lifestyles/reproduction/consent.html>> [Emphasis original] [Health Canada]
3. The Government of Quebec has brought a reference to the Court of Appeal of that province, seeking a judicial assessment of the constitutional validity of ss. 8-12 of the AHR Act. In particular, Parliament's jurisdiction to legislate in regard to the matters governed by these provisions of the Act is being questioned. This paper will not attempt to assess the reference in regard to s. 8 of the AHR Act or predict its outcome. Rather, it will assume the constitutionality of s.8, and instead focus on the consistency of Health Canada's proposed regulations under this section with the AHR Act itself, and with other policy and legal documents.
4. Medical Research Council of Canada, 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*, 1998 (with 2000, 2002 updates) (Ottawa: Public Works and Government Services, 1998) at s. 2.4, online: Interagency Advisory Panel on Research Ethics <[http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003\\_E.pdf](http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf)> (date accessed: 6 July 2005) [TCPS].
5. *AHR Act*, *supra* note 1 at s. 2.
6. [1965] 52 W.W.R. 608 (Sask, C.A.).
7. [1980] 2 S.C.R. 880.
8. [1980] 2 S.C.R. 192.
9. [1989] 48 C.C.L.T. 280 (Que. S.C.)
10. *Supra* note viii.
11. *Ibid.*
12. *Supra* note vi.
13. *Ibid.*
14. *Supra* note ix at paras 89-93.
15. *Ibid.* at paras 91-93.
16. *Civil Code of Quebec*, C.c.Q., 1991, c. 64, online: Canadian Legal Information Institute <<http://www.canlii.org/qc/laws/sta/ccq/20050111/whole.html>> (date accessed: 6 July 2005).  
"19. A person of full age who is capable of giving his consent may alienate a part of his body *inter vivos*,



provided the risk incurred is not disproportionate to the benefit that may reasonably be anticipated.

“A minor or a person of full age who is incapable of giving his consent may, with the consent of the person having parental authority, mandatory, tutor or curator and with the authorization of the court, alienate a part of his body only if that part is capable of regeneration and provided that no serious risk to his health results.

“20. A person of full age who is capable of giving his consent may submit to an experiment provided that the risk incurred is not disproportionate to the benefit that can reasonably be anticipated.”

17. *AHR Act*, *supra* note i at s. 2.
18. *TCPS*, *supra* note iv at s. 2.4.
19. *Weiss* affirms the absolute requirement of disclosure in the context of research: regardless of the desires of potential research participants, researchers are required to disclose all “potential hazards.” This requirement is mandated in order to ensure compliance with the Declaration of Helsinki. (*Weiss v Solomon*, *supra* note ix at paras. 91-93.)
20. *TCPS*, *supra* note iv at s. 8.6.
21. *Ibid.* at s. 1.1(b).
22. Canadian Institutes of Health Research, *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* (4 Mar 2002), online: Canadian Institutes of Health Research <<http://www.cihr-irsc.gc.ca/e/1487.html#?>> (date accessed: 6 July 2005) [*2002 CIHR Guidelines*].
23. *AHR Act*, *supra* note i at s. 3 [Emphasis added].
24. Under a straight reading of the *AHR Act*’s definition of consent in section 3 of the Act, it seems that compliance with the 2002 *CIHR Guidelines* for stem cell research is required for consent to any action involving human reproductive material – embracing not only stem cell research, but also all other types of embryo research as well as therapeutic interventions. Health Canada has advanced an interpretation of section 3 that restricts the application of the 2002 *CIHR Guidelines*’ requirements of consent to circumstances involving research to derive human embryonic stem cells (Health Canada, *supra* note ii at 14). This alternative reading of section 3 is much narrower than the straight reading of section 3. However, Health Canada’s interpretation is not legally required – neither Parliament nor the Courts have spoken definitively about which interpretation of section 3 is to be legally preferred, and the straight-text interpretation of section 3 is a reasonable reading of the text. Thus, the broader, straight-text interpretation will be favoured in this analysis.
25. *2002 CIHR Guidelines*, *supra* note xxii at s. 7.1.1.
26. Canadian Institutes of Health Research, *Updated Guidelines for Human Pluripotent Stem Cell Research* (7 June 2005), online: Canadian Institutes of Health Research <<http://www.cihr-irsc.gc.ca/e/28216.html#?>> (date accessed: 6 July 2005) [*2005 CIHR Update*].
27. *Ibid.* at s. 8.3.1.
28. *Ibid.* at s. 8.3.2.
29. *Health Canada*, *supra* note ii.
30. Francoise Baylis *et al.*, “Cryopreserved Human Embryos in Canada and Their Availability for Research” (2003) 25 *Journal of Obstetrics and Gynaecology of Canada* 1026. The precise figure is 2.3% for clinics that offer research as an option and 1.9% overall.
31. *AHR Act*, *supra* note i at s. 7.
32. *TCPS*, *supra* note iv at s. 2.4.
33. For example, see: *TCPS*, *ibid.* at s. 8.6; National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (Rockville, MD: National Bioethics Advisory Commission, 1999), online: National Bioethics Advisory Commission <<http://www.georgetown.edu/research/nrcbl/nbac/hbm.pdf>> (date accessed: 6 July 2005) [*NBAC*].
34. “Blanket consent” refers to consent that covers a broad range of interventions. More precisely, in this instance, “blanket consent” refers to consent to all possible future research uses, with a separate consent for reproductive uses.
35. *TCPS*, *supra* note iv at s. 8.6.
36. PN Furness & ML Nicholson, “Obtaining explicit consent for the use of archival tissue samples: practical issues” (2004) 30 *Journal of Medical Ethics* 561.
37. People Science & Policy Limited, *Biobank UK: A question of trust: A consultation exploring and addressing questions of public trust* (London: People Science & Policy Limited, 2002), online: UK Biobank <<http://www.ukbiobank.ac.uk/docs/consultation.pdf>> (date accessed: 6 July 2005).
38. The legal status of tiered consent is not uncontroversial. For instance, although the National Bioethics Advisory Commission in the United States recommended tiered consent for obtaining consent to future use of tissues in research, some commissioners expressed concerns that tiered consent may not meet legal thresholds for disclosure (*NBAC*, *supra* note xxxii at 65). To date, no complete and rigorous analysis of the legal status of tiered consent in a Canadian context (or more generally) has been done. This paper will not attempt to provide such an analysis and will, instead,



limit itself to consideration of the regulatory requirements for consent set forth in the AHR Act and related documents.

39. Human Fertilisation and Embryology Authority, *Code of Practice*, 6<sup>th</sup> ed. (London: Human Fertilisation and Embryology Authority, 2003) at s. 10.2, online: Human Fertilisation and Embryology Authority <<http://www.hfea.gov.uk/HFEAPublications/CodeofPractice/Code%20of%20Practice%20Sixth%20Edition%20-%20final.pdf>> (date accessed: 6 July 2005).
40. *Ibid.*
41. Current Canadian policies provide working examples of similar protocols. The TCPS allows for some research projects to proceed in the absence of informed

consent (*supra* note iv at s. 2.1(c)). Such allowance must be approved by a Research Ethics Board, and the research project must meet strict criteria. Likewise, the *Personal Information Protection and Electronic Documents Act* (S.C. 2000, c. 6, s. 7.2(c)) permits, under strict conditions set forth in the legislation, research to be conducted in the absence of consent or knowledge of the person whose personal information is being used. Although the removal of an option authorizing re-contact would not necessarily make consent obtained through tiered consent uninformed, such tiered consent would limit to some extent the degree to which gamete donors control the uses to which their genetic material is put.

