

# Is research in Canada Limited to “Surplus” Embryos?

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## Introduction

From the moment Canada’s *Assisted Human Reproduction Act* (then known as Bill C-56) was introduced to Parliament in May 2002, much public debate focused on those few provisions that would affect embryonic stem cell research. Specifically, debate centered around the Bill’s prohibitions against creating a cloned embryo and against creating an embryo for “any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures.”<sup>1</sup> By these two prohibitions, the Bill effectively prohibited the creation, by cloning or other means, of embryos specifically for use in many kinds of research, including stem cell research. Contravention of these prohibitions became a criminal offence when the Bill became law on March 29, 2004, with guilty persons liable for fines of up to \$500,000, ten years imprisonment, or both.<sup>2</sup>

It has been assumed that the prohibitions in the *Assisted Human Reproduction Act* [*the Act*] limit embryo research to what are sometimes called “unused,” “spare,” or “surplus” embryos. That is, that the Act limits research to embryos originally created in the course of fertility treatment that were not in fact used by the woman or couple undergoing fertility treatment and that are now in frozen storage pending destruction or donation to another woman or couple.<sup>3</sup> While it is clear that such surplus embryos exist in Canada (although the numbers are much lower than is often suggested, simply because many frozen embryos are not yet surplus<sup>4</sup>), it is *not* clear that the Act limits research to these surplus embryos. As this commentary will show, a strict reading of the Act permits the creation of embryos for certain kinds of research as well as the conduct of research on

embryos that are not-yet-surplus, including on fresh embryos that might otherwise be frozen for later use in a pregnancy attempt.

## The Assisted Human Reproduction Act

The Act primarily serves to regulate the provision of assisted reproductive services. However, because it became law at a time of great scientific interest in, and significant debate over, embryonic stem cell research, much of the parliamentary and public debate accompanying the passage of the Act focused on two of its prohibitions. These prohibitions are contained in paragraphs (a) and (b) of section 5(1) of the Act and they outlaw the creation of a cloned embryo and the creation of an embryo for “any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures.”<sup>5</sup> The prohibitions were seen by some critics as hindering the progress of scientific research (particularly stem cell research), as inappropriately using criminal sanctions to regulate scientific research,<sup>6</sup> and as instituting cumbersome prohibitions instead of flexible regulation.<sup>7</sup> These same provisions were criticized by other groups and individuals for not containing a blanket ban on the use of embryos in research, and for thus implicitly condoning the intentional destruction of human life for the sake of scientific research.<sup>8</sup>

In defending both the prohibition contained in section 5(1)(b) and the absence of a complete prohibition on the research use of embryos, Canada’s Health Minister, Anne McLellan, argued in the House that “[i]t would be up to the



couple to choose whether their unused embryos would be discarded or donated either for research or to other infertile Canadians.<sup>9</sup> In discussion with the media, McLellan asked reporters: “Do you know what happens to surplus embryos? Do you know what happens? They go in the garbage.”<sup>10</sup> In both these comments, McLellan assumed that the Act would limit research to surplus embryos as defined above: that is, to embryos originally created in the course of fertility treatment that were not in fact used by the woman or couple undergoing fertility treatment and that were in frozen storage pending destruction (McLellan did not mention the possibility of donation to another woman or couple). Yet, the Act contains no provision to that effect.

What the Act does do in section 5(1)(b) is stipulate the only three legitimate reasons for creating human embryos: to create a human being, to improve assisted reproduction procedures, or to provide instruction in assisted reproduction procedures. Strictly interpreted, the first reason requires that anyone creating an embryo do so with the intention that the embryo be transferred to a woman in the hopes of eventual live birth of a child.<sup>11</sup> The second and third reasons act as exceptions to the first, permitting the creation of embryos that are not intended to eventually lead to a live birth, provided those embryos are intended for use to improve assisted reproduction procedures or to provide instruction in assisted reproduction procedures. “Improve” and “provide instruction in” are not defined in the Act, but “assisted reproduction procedure” is defined to include the alteration, manipulation, treatment, or use of an *in vitro* human embryo for the purpose of creating a human being.<sup>12</sup> These exceptions to the prohibition against creating embryos for non-reproductive purposes could capture, for example, the creation of embryos for use in research aimed at improving methods of injecting sperm into eggs or the creation of embryos for use in testing equipment or instructing trainees in methods of freezing and thawing embryos. Therefore, under the Act, embryos can be created for defined non-reproductive purposes including particular kinds of research. Nevertheless, much research that uses human embryos, including most (although not all)<sup>13</sup> embryonic stem cell research, will not fall under the terms of sec-

tion 5(1)(b) of the Act because it does not aim to improve assisted reproduction.<sup>14</sup>

By limiting the purposes for which embryos may be created, the Act limits the embryos that may be used in research to those that were originally created for assisted reproduction or for assisted reproduction improvement or instruction. Thus, researchers, including embryonic stem cell researchers, must seek embryos either from women and couples who are undergoing, or who have undergone, assisted reproduction or from fertility clinics that created the embryos for improvement or instruction purposes (under the Act, clinics need to obtain consent from donors before creating embryos for these purposes).<sup>15</sup> There is no data available on how many embryos are created in Canada for use in improving or providing instruction in assisted human reproduction [AHR] procedures. In fact, anecdotal evidence indicates that clinics do not typically create embryos for this purpose,<sup>16</sup> and survey data shows that clinics use embryos donated by women

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and couples (including because such embryos were not considered suitable for transfer) to improve procedures or provide instruction.<sup>17</sup> I will therefore proceed on the assumption that *most* embryos donated to research will originally have been created for the reproductive use of women and couples, rather than for improving or providing instruction in assisted human reproduction procedures even while I note the possibility of these embryos for subsequent use in other kinds of research.

Importantly, the Act does not say anything about *when* women and couples may donate their embryos to research. There is no requirement in the Act that women and couples complete their assisted reproduction before they donate embryos to research or that these embryos be otherwise destined for destruction or donation to another woman or couple. By comparison, the CIHR *Updated Guidelines for Human Pluripotent Stem Cell Research [CIHR Guidelines]* require that embryos used in embryonic stem cell research be “no longer required for [reproductive] purposes.”<sup>18</sup> Similarly, Australia’s *Research Involving Human Embryos Act 2002* limits research to “excess ART embryos,” which are



defined as embryos created for use in the assisted reproductive technology treatment of a woman and that are now excess to the needs of the woman or couple for whom they were created.<sup>19</sup>

It is not clear why the drafters of the Canadian legislation did not include language such as that found in the CIHR Guidelines or the Australian legislation as no explicit discussion of this consequence is found in the various official explanations accompanying the bill.<sup>20</sup> The Legislative Summary accompanying Bill C-6 (the last of the three bills that would become the Act) used the term “excess” in referring to the embryos that would be available for research under the Act, noting that “[t]here was also considerable debate on whether research on so-called “excess” *in vitro* embryos should be allowed. Clause 5(1)(b) prohibits the “creation” of *in vitro* embryos for any purpose other than creating a human being or improving or providing instruction in AHR procedures, but it does not prohibit their subsequent “use,” whether for research or other purposes. Such uses would come under the controlled activity category in clause 10(2) and would thus require a licence and compliance with the regulations.”<sup>21</sup> However, this discussion, like that of the Minister cited above, also appears to assume that embryos used in research under the Act would be “excess” or surplus embryos, although the Act contains no provision to that effect. Indeed, on a strict interpretation of the Act, women or couples can create embryos specifically for use in certain kinds of research, and they can also donate fresh or frozen embryos originally created for reproductive purposes to research before they have completed assisted reproduction, including embryos that are not-yet-surplus.

## Compatibility with CIHR Guidelines

In its *Updated Guidelines for Human Pluripotent Stem Cell Research*, CIHR limits human pluripotent stem cell research (otherwise and hereafter known as embryonic stem cell research) to embryos that “whether fresh or frozen, were originally created for reproductive purposes and are no longer required for such purposes.”<sup>22</sup> Thus, unlike the provisions of the *Assisted Human Reproduction Act*, the CIHR Guidelines restrict research to embryos that meet the definition of surplus set out above.<sup>23</sup>

This provision of the CIHR Guidelines applies to all research involving human embryonic stem cells that is funded by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council, and

the Social Sciences and Humanities Research Council (“the Agencies”) or that is conducted under the auspices of an Institution that receives any funding from the Agencies. However, the CIHR Guidelines do not apply to other kinds of research involving human embryos and they do not apply to embryonic stem cell research conducted privately (without funding from the Agencies and outside an institution receiving Agency funds). Therefore, although the CIHR Guidelines restrict the use of not-yet-surplus embryos in some of the embryo research currently conducted in Canada, they will not affect all Canadian embryo research.<sup>24</sup>

Having established that the Act does not restrict embryo research to surplus embryos, the remainder of this commentary will consider some of the scientific reasons for seeking donation of not-yet-surplus embryos to stem cell research as a particular example of embryo research. I will then consider four scenarios involving donation of not-yet-surplus embryos to research, explaining why donation of not-yet-surplus embryos to research could be attractive to some women and couples and showing that a deeper consideration of the provisions of the Act affecting research use of embryos is necessary in each case before determining legality.

## Donation to research of fresh (and recently frozen) embryos

The donation of embryos to research before completion of assisted reproduction may seem unlikely: why would anyone still undergoing arduous and expensive fertility treatment not save each and every embryo for possible later transfer? Yet a number of scientific and financial issues at play in stem cell research in particular suggest that researchers may be interested in accessing not-yet-surplus embryos and that women and couples in treatment may be interested in donating not-yet-surplus embryos to research. Specifically, supplies of frozen surplus embryos may not be sufficient to meet the demands of stem cell research, and fresh embryos or recently frozen embryos may be more likely to yield stem cells than those frozen several years ago. In addition, popular interest in stem cell research, the opportunity for “embryo sharing” agreements to reduce the costs of fertility services, and the practice of not freezing embryos on which preimplantation genetic diagnosis [PGD] has been carried out all raise the possibility that Canadian women and couples might wish to donate not-yet-surplus embryos to research.



In the laboratory, human embryos are created as part of assisted reproduction by a procedure called *in vitro* fertilization [IVF]. For IVF to occur, women must undergo hyperstimulation to produce a large number of eggs (many more than they would produce in a natural cycle). These eggs are then removed from the woman and fertilized in the laboratory with sperm to create human embryos. One, two, or three<sup>25</sup> of these highest quality embryos<sup>26</sup> are then transferred to the woman in the hopes of achieving a pregnancy. Because a woman undergoing IVF routinely requires numerous cycles before she achieves pregnancy or abandons treatment, those fresh embryos that are not transferred in the initial cycle, but are of sufficient quality, are usually frozen for her later use.

A 2003 survey of Canadian fertility clinics with a response rate of 54% found that just over 15,000 frozen human embryos were stored in Canadian fertility clinics.<sup>27</sup> A similar United States survey, also published in 2003, with a response rate of 79% found that just under 400,000 frozen embryos were stored in U.S. clinics.<sup>28</sup> These large numbers might suggest that there are many frozen embryos available for research.<sup>29</sup> Yet both surveys reported that most of these frozen embryos are designated for the woman or couple's future use – the woman or couple may, for example, be in the midst of IVF treatment or they may have achieved pregnancy but be planning to use the frozen embryos for a subsequent pregnancy attempt. Only 2% of the frozen embryos in Canada and 2.8% of the frozen embryos in the United States have been donated to research. Thus, numbers of frozen embryos are far greater than numbers of surplus embryos, which are also far greater than numbers of frozen embryos that have been donated to research.

According to the Canadian survey, those frozen embryos that are not slated for future use by the women or couples will be disposed of in a number of ways: some will be destroyed or allowed to perish; some will be donated to other women or couples; some will be donated to a variety of different research projects, including fertility research and stem cell research; and some will be stored indefinitely (many clinics store embryos indefinitely, apparently reluc-

tant to discard them even when clients have only paid for a finite storage period).<sup>30</sup> In sum, very few embryos currently in frozen storage in Canadian fertility clinics are, or are likely to become, available for research use – the majority are not yet surplus, and of those that are surplus and have been donated to research, some, but not all, will be donated to stem cell research. Thus, the small number of frozen embryos available for stem cell research use may encourage researchers to seek alternative sources of embryos.

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In addition to limited availability of frozen surplus embryos, researchers may have scientific reasons for seeking donation of not-yet-surplus fresh or recently frozen embryos. Because it may be years before clinics and their patients can say for certain that frozen embryos will not be used by the women or couples for whom they were created, surplus frozen embryos that are donated to research may have been frozen many years ago.

Embryos do not age while they are frozen (they remain at the developmental stage at which they were frozen). Nevertheless, some research shows that frozen embryos are less likely to progress to the blastocyst stage required for embryonic stem cell derivation than fresh embryos<sup>31</sup> and that embryos frozen more than two years ago are less likely to survive the thawing process and progress to blastocyst stage than those frozen more recently.<sup>32</sup>

In recent years, freezing methods have improved<sup>33</sup> and there is a trend towards freezing embryos at a later stage in their development,<sup>34</sup> so that the freeze-thaw rate for recently-frozen embryos is often higher than for embryos frozen two, five, or ten years ago. Therefore, researchers, and specifically embryonic stem cell researchers, might prefer to use fresh embryos or embryos that were frozen very recently over those frozen several years ago. However, it is likely that few of these scientifically preferable embryos can accurately be described as surplus: although they were originally created for use in assisted reproduction in accordance with the Act, many of these embryos may yet be used by the woman or couple for whose reproductive use they were created.



## ***Ethical arguments about donation to research of not-yet-surplus embryos***

The major ethical argument against using in research embryos that were originally created as part of assisted human reproduction but that are not-yet-surplus is that such use can reduce the chances of pregnancy, thus causing the woman or couple physical, emotional, and financial harm.<sup>35</sup> Donating fresh embryos to research rather than freezing them for later transfer will more quickly exhaust the woman or couple's supply of embryos for transfer. Once the supply of frozen embryos is exhausted, the woman or couple must either abandon IVF treatment or create more embryos (requiring either the woman or a donor to undergo additional egg retrieval cycles).

Egg retrieval cycles are costly, time consuming and painful – each cycle involves the woman undergoing medical tests, taking strong medications to stimulate egg production including daily, self-administered injections, and undergoing egg retrieval by either inserting a hollow needle through the woman's vagina or by laparoscopic surgery. Risks of the stimulation and egg-collection process include hot flashes, headaches, sleeplessness, mood alteration, ovarian hyper-stimulation syndrome, nausea, vomiting, pain, bleeding, and infection. There is even a controversy over a possible danger of ovarian cancer from the medications.<sup>36</sup> Many women also find hormonal stimulation, egg retrieval, and embryo transfer to be psychologically difficult.<sup>37</sup>

Commentators have also argued that physicians who facilitate, accept, and solicit donation of not-yet-surplus embryos to research risk breaching the obligations inherent in the doctor-patient relationship.<sup>38</sup> According to this argument, physicians are obliged to act so as to maximize the chances of their patients achieving pregnancy while simultaneously minimizing physical and emotional (and arguably financial) harm. They should, therefore, only solicit embryos for donation where the embryo would not otherwise be frozen for later transfer to the woman or, if already frozen, where the woman making the donation has completed fertility treatment and is unlikely to use the frozen embryo for additional treatment in the future.<sup>39</sup> Additional concerns arise when physicians solicit embryos for research in which they are involved or for research to be performed by a colleague or friend, including concerns over conflict of interest and undue influence.

However, there is also a strong argument that the doctor-patient relationship is well served by physicians who facilitate, accept, and arguably even solicit, the donation of their patients' not-yet-surplus embryos to stem cell research. According to this argument, if complete and accurate information is provided (including that donation may reduce pregnancy chances), offering patients the option of donating to the research before treatment is complete allows patients more choices about what should happen to their embryos. This practice allows patients to choose whether and when to donate embryos to stem cell research, and therefore respects their autonomy,<sup>40</sup> arguably thereby facilitating a better doctor-patient relationship in which the patient is aware of her options and has more control.

## ***Donation of not-yet-surplus embryos to research: four possible scenarios***

In a nation such as Canada that prohibits the creation of embryos for research use (other than research to improve assisted reproduction procedures)<sup>41</sup> there are at least four possible scenarios whereby women or couples undergoing fertility treatment might seek to donate embryos to research that are arguably not-yet-surplus, although not all of them conform to other provisions of the Act or to the current version of the CIHR Guidelines.<sup>42</sup>

The woman or couple are motivated by altruism to donate a portion of their fresh embryos to research;

The woman or couple have entered into an agreement with their fertility clinic or with researchers whereby the cost of undergoing fertility treatment is waived or reduced in exchange for their agreement to donate some of their fresh embryos to research ("embryo sharing");

The women or couple have had PGD performed on all their embryos and have decided to donate to research (rather than freeze) all, or a proportion of, those embryos in which no genetic abnormality was uncovered but which are not needed for immediate transfer (sufficient other "healthy" embryos are available for immediate transfer);

The woman or couple is opposed to freezing embryos (for religious or other reasons) and so donates those not immediately transferred to research.



### 1. Donation for altruistic reasons

In this scenario, women or couples currently undergoing fertility treatment agree to donate some of their fresh or frozen embryos to research immediately following embryo creation. For example, a couple may create eight “healthy” embryos and agree to transfer two to the woman, to freeze two for later use, and to donate the remaining four embryos to stem cell research. They may wish to donate these four not-yet-surplus embryos to research because they feel that the research is worthwhile and because they are happy for their reproductive effort to serve more than simply their desire to become parents. Ethically, there is a very strong argument that because women and couples have dispositional authority over their embryos, they ought to be permitted to make considered and autonomous decisions as to the fate of their embryos (see above).

Although studies have shown that few currently frozen embryos have been donated to stem cell research in particular, rates of donation may rise if more clinics begin offering such donation (some Canadian clinics do not yet offer women and couples the option of donating embryos to any kind of research<sup>43</sup>) and if public support for stem cell research increases such that more women and couples seek to assist stem cell research in the course of their assisted reproduction. For example, a couple undergoing fertility treatment might decide to donate a portion of their embryos to stem cell research because they believe that such research shows great promise in the treatment of life threatening and fatal illnesses.

Embryos thus donated would not meet the definition of surplus because at the time of donation they would be of sufficient quality to be frozen and later transferred to the woman. Legally, if the decision to donate is made before the embryos are created, creating these embryos may contravene section 5(1)(b) of the Act because at the time of creation it would be clear that some of the embryos would not be used for fertility purposes.<sup>44</sup> One way around this legal hurdle might be to seek donation immediately following the creation of the embryos, when the woman or couple is

deciding how many embryos to transfer, discard, and freeze.<sup>45</sup>

### 2. Donation under embryo sharing programs

According to this scenario, women and couples might receive cheaper or free fertility treatment in exchange for donation of a number or proportion of their embryos to research. Although there are currently no reports of scenario 2 taking place in Canada, the existence of egg sharing programs in other nations indicates that such a scenario warrants serious consideration.

Egg sharing programs operate to reduce or eliminate the cost of fertility treatment. In exchange for reduced treatment costs, the woman undergoing treatment donates a portion of her eggs to another woman or women in the fertility program. These programs are common enough in the United States and the United Kingdom to be the subject of an American Society for Reproductive Medicine ethics committee report<sup>46</sup> and Human Fertilisation and

Embryology Authority guidelines.<sup>47</sup> Similar “embryo sharing programs” might operate to reduce or eliminate the costs of fertility treatment in exchange for women and couples agreeing to donate a portion of their fresh embryos to research.

However, the legality of both egg and embryo sharing programs in Canada is doubtful. The Act prohibits the “purchase” of eggs and embryos,<sup>48</sup> where purchase “includes to acquire ... in exchange for property or services.”<sup>49</sup> Therefore, it seems likely that the provision of reduced or free treatment (a service) in exchange for donation would constitute “purchase” of eggs or embryos and be prohibited under the Act.

In Canada, an embryo sharing program might also contravene the prohibition in section 5(1)(b) against creating embryos for “any purpose other than creating a human being or improving or providing instruction in assisted reproduction.”<sup>50</sup> As in scenario 1, this legal issue arises particularly if the parties in such a program have agreed in advance of cre-

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ation of the embryos that some of the embryos created would, in fact, be used in research and not to create a human being. Practically, it might be impossible to approach women or couples about participating in embryo sharing programs after their embryos have been created simply because the decision to begin fertility treatment may be contingent on the reduced cost offered by such a program.

I will not explore in detail here the ethical and other legal issues raised by the possibility of embryo sharing programs as a way of both reducing the cost of fertility treatment and generating embryos for research use. However, I do note that in addition to the autonomy argument presented in scenario 1, the major ethical argument in favour of embryo sharing programs is that they provide IVF treatment to women and couples who might otherwise not be able to afford such treatment. In a negative vein, such agreements, like all the scenarios considered here, reduce the number of embryos available for later transfer to the woman and thereby reduce the chances of pregnancy.

### 3. Donation following PGD

PGD is a process whereby embryos are biopsied and then tested for various genetic conditions. Generally, women or couples will have all of their sufficiently high quality embryos biopsied and tested before deciding which ones to transfer. PGD generally yields three main “kinds” of embryos: those that are deemed healthy (“unaffected”) and are transferred, those that are unaffected but are not initially transferred, and those that are “affected.” Affected embryos are not frozen for later use by the woman or couple and so could be immediately discarded or donated to research.<sup>51</sup> Such affected embryos might properly be considered surplus to the woman or couple’s reproductive needs since they will never be used to create a pregnancy.

The second kind of embryo (unaffected but not immediately transferred) is usually not frozen. Early PGD research showed that biopsied embryos generally do not survive the thawing process (researchers theorized that this poor survival was due to the hole created by the biopsy).<sup>52</sup> Survival rates were so low that many physicians recommended that patients not freeze their unaffected biopsied embryos, but instead discard them or donate them to research.<sup>53</sup> Low success rates freezing biopsied embryos, therefore, made it arguable that unaffected biopsied embryos not immediately transferred nevertheless met the definition of surplus.

However, new research shows that a modified cryopreservation method increases the survival of frozen biopsied embryos.<sup>54</sup> Therefore, it may be clinically effective to freeze unaffected biopsied embryos for later thawing and transfer, making the argument that such embryos are surplus weaker than it was in the past. Nevertheless, freezing unaffected biopsied embryos is not yet routine practice in Canada. Under the Act, donation of biopsied embryos to research would not contravene section 5(1)(b) of the Act, because the embryos would originally have been created for fertility purposes.

### 4. Donation rather than freezing

In scenario 4, the woman or couple may refuse to freeze any embryos not immediately transferred. Reasons for the decision could include not wanting to ever have to make a decision about what to do with frozen surplus embryos, inability to pay for frozen storage of embryos (storage fees average around \$300/year<sup>55</sup>), or because freezing embryos goes against religious or other beliefs. Nisker and White<sup>56</sup> have supposed that a woman who for religious reasons refuses to freeze embryos not immediately transferred may operate under a value system that also would prohibit donation to research, although they could not find any reports of such women. Although perhaps unlikely, the possibility of a woman or couple refusing freezing but seeking to donate to research should be considered.

It is not clear whether the embryos in this scenario meet the definition of surplus. On the one hand, like many of the unaffected biopsied embryos described in scenario 3, those embryos not immediately transferred will in fact be discarded or donated to another couple (or, as proposed here, to research). In this sense, they are surplus. On the other hand, as in scenario 1 above, the woman or couple has not completed fertility treatment and the embryos not transferred immediately could be frozen and used in a later pregnancy attempt, but for the woman or couple’s preferences.

Again, if the preferences of the women or couples are known before the embryos are created, it could be argued that creation of any more embryos than are likely to be implanted contravenes section 5(1)(b) of the Act (that is, because some of the embryos would have been created in the knowledge that they would not be used for one of the mandated purposes but would instead be used in research).



## Conclusion

Under the Act, embryos cannot be created for any purpose other than to create a human being or to improve or provide instruction in assisted reproduction procedures. Therefore, embryos cannot be created for the purpose of use in research, other than research aimed at improving assisted reproduction procedures. However, after an embryo is created (for either of the three purposes listed in section 5(1)(d) of the Act), it may be donated to research, including to stem cell research.

The Act does not stipulate when donation of embryos to research may take place. As detailed above, the assumption that embryos donated to research will be spare or surplus embryos may be false. The Act does not require that embryos be surplus before they are donated to research, where surplus is understood to mean that the embryos were originally created in the course of fertility treatment but were not in fact used by the woman or couple undergoing fertility treatment and are now in frozen storage pending destruction or donation to another woman or couple. In fact, under the Act, embryos may be used in research before they become surplus, provided other requirements of the Act are followed, including that embryos may not be purchased (as would arguably occur under an embryo sharing program).<sup>57</sup>

For a variety of scientific reasons, researchers, particularly stem cell researchers, may prefer fresh or recently frozen embryos over embryos frozen more than a year or two ago. Many of these fresh or recently frozen embryos will not be surplus. Nevertheless, use of these not-yet-surplus embryos in research will often be permitted under the Act. For example, the fresh embryos of women or couples motivated to donate by a desire to assist in research or because they are opposed to freezing may not meet the definition of surplus but may still be used in research provided it can be shown that all of the embryos were originally created for the purpose of creating a human being. Similarly, unaffected (healthy) embryos on which PGD has been conducted may be donated to research rather than frozen for later use. In these three cases, donation would need to be solicited following the creation of the embryos in order to avoid creating embryos with the intention (or knowledge) that any of them would be used for purposes other than other specified in section 5(1)(d). Donation of fresh embryos to research under an embryo sharing program would not be permitted under the Act because such a program would contravene the Act's prohibition against purchasing embryos, which extends to exchanging embryos for services.

Practically, many Canadian researchers seeking embryos for use in stem cell research will need to comply not just with the Act but also with the CIHR Guidelines, which currently restrict donation to embryos that are "no longer required" for fertility purposes. However, in research not covered by the CIHR Guidelines, use of some not-yet-surplus fresh or frozen embryos will be possible and should be carefully considered.

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1. *Assisted Human Reproduction Act*, S.C. 2004, c. 2 [*the Act*].
2. *Ibid.*, s. 60.
3. This description will serve as my working definition of "surplus embryos."
4. Françoise Baylis *et al.*, "Cryopreserved Human Embryos in Canada and Their Availability for Research" (2003) 25:12 *Journal of Obstetrics Gynaecology Canada* 1026 at 1028.
5. *Supra* note 1 at s. 5(1)(a)-(b).
6. Abdallah Daar *et al.* "Ban cloning, not its life-saving cousin" *The Globe & Mail* (9 May 2002) A21; Timothy Caulfield, "Clones, Controversy, and Criminal Law: A Comment on the Proposal for Legislation Governing Assisted Human Reproduction" (2001) 39:2 *Alta. L. Rev.* 335 at 337.
7. Timothy Caulfield, "Bill C-13, The Assisted Human Reproduction Act: Examining the Arguments Against a Regulatory Approach" (2002) 11:1 *Health L. Rev.* 20 at 23.
8. See for example, House of Commons Debates, 188 (21 May 2002) at 1030 (Robert Merrifield).
9. House of Commons Debates, 188 (21 May 2002) at 1025 (Hon. Anne McLellan).
10. Tim Harper "New bill backs stem-cell research" *The Toronto Star* (10 May 2002) A.03.
11. "Human being" is not defined in the Act. The Canadian *Criminal Code* defines "human being" in section 223: "(1) A child becomes a human being within the meaning of this Act when it has completely pro-



ceeded, in a living state, from the body of its mother, whether or not (a) it has breathed; (b) it has an independent circulation; or (c) the navel string is severed.” For current purposes, therefore, it is not enough to intend that the embryo created develop into a foetus, but it must be intended to lead to a live birth. *Criminal Code*, R.S.C. 1985, c. C-46.

12. See definition of “assisted reproduction procedure” in section 3 of the Act, which refers to controlled activities described in section 10 of the Act, *supra* note 1.
13. Unreported research from the Centre for Stem Cell Biology in Sheffield presented at the European Society for Human Reproduction and Embryology’s (ESHRE) annual conference in June of 2005 found that some human embryonic stem cells (hESCs) have similar genetic profiles to primordial germ cells and could therefore be used to generate eggs and sperm. Centre for Stem Cell Biology, News Release, “Stem Cell hope for fertility treatment” (20 June 2005), online: Centre for Stem Cell Biology <<http://cscb.shef.ac.uk/News/Article275.htm>>.
14. Some embryonic stem cell research does aim to improve assisted human reproduction, see for instance research presented at the European Society of Human Reproduction and Embryology conference in Copenhagen in June of 2005 as reported by James Meikle “Sperm and eggs could be created from stem cells, says new study” *The Guardian* (20 June 2005), online: *The Guardian* <[http://www.guardian.co.uk/uk\\_news/story/0,,1510299,00.html](http://www.guardian.co.uk/uk_news/story/0,,1510299,00.html)>. Embryonic stem cell research may also result in collateral benefits for assisted human reproduction, see Carl T. Hall “Stem cell research may be a boon to fertility clinics: Insight gleaned in lab could help couples conceive” *San Francisco Chronicle* (21 February 2005) A6.
15. The Act clearly specifies that consent must be obtained from gamete donors for the creation of embryos for all the purposes listed at section 5(1)(b), but it does not specify whether consent to subsequent donation of such embryos to other research must also be obtained from the original gamete donors. The specifics of consent are to be laid out in regulations. *Supra* note 1 at s. 8.
16. Conversation with Dr. Jeffery Nisker, Professor of Obstetrics-Gynaecology, University of Western Ontario, November 19, 2005.
17. A 2003 survey of Canadian IVF clinics indicates that the majority of clinics that offer donation of embryos to research use at least some of those donated embryos for practicing or testing clinic procedures or freezing techniques, IVF research, basic research (such as research on chromosomal abnormalities), and staff training. It therefore appears that clinics often obtain embryos for improvement or instruction from women and couples who are undergoing fertility treatment. The same survey found that some clinics make similar use of fresh or thawed embryos that are considered unsuitable for transfer. See *supra* note 4 at 1029.
18. Canadian Institutes of Health Research, “Updated Guidelines for Human Pluripotent Stem Cell Research, June 7, 2005” at Guideline 8.1.1, online: Canadian Institutes of Health Research <<http://www.cihr-irsc.gc.ca/e/28216.html>>.
19. *Research Involving Human Embryos Act 2002*, s. 9 (Commonwealth of Australia).
20. The Act was introduced as Bill C-56 on 9<sup>th</sup> May 2002, it was then reintroduced as Bill C-13 on 9<sup>th</sup> October 2002, and then finally as Bill C-6 on 11<sup>th</sup> February 2004, after which it was passed by the House and the Senate and received royal assent on 29<sup>th</sup> March 2004. Each time it was introduced it was accompanied by a legislative summary, none of which considered in any detail the consequences of not specifying that an embryo be surplus before it be donated to research.
21. Monique Hébert, Nancy Miller Chenier, and Sonya Norris, “Bill C-6: Assisted Human Reproduction Act,” (Legislative Summary: LS-466E), 17<sup>th</sup> February 2004.
22. *Supra* note 18. Under the CIHR Guidelines, embryos must also have been donated with the free and informed consent of the persons “for whom the embryos were originally created for reproductive purposes” and any gamete donors, as well as neither the embryos nor any donor gametes may have been obtained through “commercial transactions.”
23. I say “likely” because it is not clear yet how “no longer required for [reproductive] purposes” will be interpreted by CIHR. It may be that the phrase will be interpreted to include only those embryos that were not used by the woman or couple undergoing fertility treatment and that are now in frozen storage pending destruction or donation to another woman or couple. On the other hand, the phrase could be interpreted more widely to include embryos that could in fact be frozen and later transferred to the woman but that the woman does not or couple do not wish to freeze and/or later transfer. That is, the phrase could be given a more subjective interpretation, with “required” being determined by the woman or couple’s wishes.
24. The Act does incorporate an earlier version of the CIHR Guidelines in its definition of consent, which is defined 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,” *supra* note 1 at s. 3. However, the Act does not similarly incorporate other provisions of the Guidelines, such as guideline 8.1.1 restricting the source of embryos for use in research, *supra* note 18.

25. The number of embryos transferred depends on the woman’s wishes, her health, her age, clinic practice, and any applicable legislation or regulations (the Act itself does not contain any provisions limiting the number of embryos that may be transferred in any one cycle, although such limitations may be contained in future regulations made under the Act). In the UK, regulations stipulate that no more than 2 or 3 embryos be transferred, depending on the woman’s age, see parts 8.20 and 8.21 of the Human Fertilisation and Embryology Authority, *Code of Practice – 6<sup>th</sup> Edition*, (London: The Human Fertilisation and Embryology Authority, 2003).
26. “Quality” is a clinical assessment of the chances that an embryo will implant and lead to a successful pregnancy. It is an assessment generally made after consideration of the morphology (appearance) of the embryo, see Andrea Borini *et al.*, “Artificial reproductive technology achievements for optimizing embryo quality” (2004) 1034 *Annals N.Y. Academy of Science* 252 at 252.
27. *Supra* note 4 at 1028.
28. David I. Hoffman *et al.*, “Cryopreserved embryos in the United States and their availability for research” (2003) 79:5 *Fertility and Sterility* 1063 at 1066. For similar proportions of frozen embryos to embryos donated to research, see Bradley J. Van Voorhis *et al.*, “Establishment of a successful donor embryo program: medical, ethical, and policy issues” (1999) 71:4 *Fertility and Sterility* 604 at 606.
29. In the second U.S. Presidential debate, Senator John Kerry argued that the large number of frozen embryos stored in U.S. fertility clinics justified a policy of federal support for the derivation of new embryonic stem cell lines, see Senator John Kerry, “The Second Bush-Kerry Presidential Debate” (8 October 2004), online: Commission on Presidential Debates <<http://www.debates.org/pages/trans2004c.html>>.
30. *Supra* note 4 at 1029. See also the public outcry in the United Kingdom when nearly 3,000 embryos were destroyed in 1996 in accordance with the storage limitation of five years contained in section 14(4) of the *Human Fertilization and Embryology Act 1990* (U.K.), R. G. Edwards & Helen K. Beard, “Destruction of cryopreserved embryos: UK law dictated the destruction of 3000 cryopreserved human embryos” (1997) 12:1 *Human Reproduction* 3 at 4.
31. D. H. Edgar *et al.*, “Survival and development potential of stored human early cleavage stage embryos” (2004) 115: Suppl 1 *European Journal of Obstetrics & Gynecology Reproductive Biology* S8 at S10; Hoffman *et al.*, *supra* note 26 at 1068.
32. Hoffman *et al.*, *ibid.*
33. Gary D. Smith & Cristine Ane Silva E. Silva, “Developmental consequences of cryopreservation of mammalian oocytes and embryos” (2004) 9:2 *Reproductive Biomedicine Online* 171.
34. Lucinda L. Veeck *et al.*, “High pregnancy rates can be achieved after freezing and thawing human blastocysts” (2004) 82:5 *Fertility and Sterility* 1418 at 1425.
35. Harm may also arguably be caused to any egg donor, who would be required to undergo additional cycles in order to produce more eggs than if the woman or couple had frozen all sufficient quality embryos not immediately transferred. I will not consider here the argument that destroying embryos in research is ethically wrong. The permissibility of destructive research on embryos is already established under the Act subject to certain conditions, although I acknowledge that this practice has been the major focus of ethical debate over embryonic stem cell research.
36. Josephine Johnston “The Women Behind Cloning” *The Washington Post* (8 March 2004) A19.
37. Asha Emsley Randal, “The Personal, Interpersonal, and Political Issues of Egg Donation” (2004) 26:12 *Journal Obstetrics Gynaecology Canada* 1087 at 1089.
38. 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.
39. As mentioned above, where the woman or couple donates as part of an embryo sharing program there may be an argument that donation enables access to IVF and thus actually enhances, rather than diminishes, the woman’s chances of achieving pregnancy even while the program ensures that less embryos are available for later transfer.
40. A significant body of ethics and legal literature supports the right of patients to exercise their autonomy in the health care setting. See for example Tom L. Beauchamp & James F Childress, *Principles of Bio-*



*medical Ethics*, 4th ed. (Oxford: Oxford University Press, 1994) and World Medical Association, *World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, 18th WMA General Assembly, (June 1964), online: World Medical Association

<<http://www.wma.net/e/policy/b3.htm>>. See also the principle of consent as recorded at section 2(d) of the Act, as well as section 8(1) of the Act stipulating “No person shall make use of human reproductive material for the purpose of creating an embryo unless the donor of the material has given written consent, in accordance with the regulations, to its use for that purpose that the consent of donors is necessary to create embryos,” and section 8(3) stipulating “No person shall make use of an *in vitro* embryo for any purpose unless the donor has given written consent, in accordance with the regulations, to its use for that purpose.” *Supra* note 1.

41. *Supra* note 1.

42. Donation of “low quality” fresh, frozen, or recently thawed embryos to research is not considered. As explained above, the quality of embryos created *in vitro* is assessed before deciding which embryos to transfer immediately to the woman and which to freeze for later use. Embryos are usually ranked according to their appearance and one or more of those with the highest ranking are immediately transferred. Most of the remaining embryos are frozen for later use, except those of such a low quality that they will never be transferred, which may be immediately discarded, donated to research (including possibly stem cell research), or used for testing of laboratory equipment, etc. Even while the woman or couple are still undergoing fertility treatment, these very low-quality embryos meet the definition of surplus because there is no possibility of them being transferred to the woman even if other transfers fail to result in a pregnancy. Because they are of such low quality, use of these surplus embryos may present difficulties for researchers. Low quality embryos are less likely to develop to the blastocyst stage needed for stem cell derivation and may not provide high-quality stem cell lines. See S. Munné *et al.*, “Chromosome abnormalities in human arrested preimplantation embryos: a multiple-probe FISH study” (1994) 55:1 *American Journal of Human Genetics* 150; Susan J. Pickering *et al.*, “Preimplantation genetic diagnosis as a novel source of embryos for stem cell research” (2003) 7:3 *Reproductive Biomedicine Online* 353 at 353.

43. *Supra* note 4 at 1028.

44. *Supra* note 1 at s. 5(1)(b). It should be noted that clinics are always aware that some of the embryos they create might not be used for fertility purposes because some of the embryos they create are usually of such low quality that they will never be transferred to a woman. Also, clinics are aware that women may achieve pregnancy or complete fertility treatment before using all the embryos.

45. As with all scenarios explored in this paper, I am not advocating for this scenario but am rather using it as a way of exploring the impact of the Act.

46. The Ethics Committee of the American Society for Reproductive Medicine, “Financial incentives in recruitment of oocyte donors” (2004) 82: Suppl. 1 *Fertility Sterility* 240.

47. *Supra* note 25 at Appendix A (Guidance for Egg-Sharing Arrangements).

48. *Supra* note 1 at s. 7.

49. *Ibid.* note 1 at s. 7(4).

50. *Ibid.* note 1 at s. 5(1)(b).

51. In the United Kingdom several research projects have used embryos that were biopsied as part of PGD but were not transferred to the women because they carried genetic defects (that is, affected surplus embryos). See Pickering, *supra* note 42 at 361.

52. H. Joris *et al.*, “Reduced survival after human embryo biopsy and subsequent cryopreservation” (1999) 14:11 *Human Reproduction* 2833 at 2833. See also M.C. Magli *et al.*, “Impact of blastomere biopsy and cryopreservation techniques on human embryo viability” (1999) 14:3 *Human Reproduction* 770 at 772 [Magli].

53. Magli, *ibid.* For a different opinion regarding whether cryopreservation should be preserved given the low survival rate following thawing, see Michael Lee & Santiago Munné, “Pregnancy after polar body biopsy and freezing and thawing of human embryos” (2000) 73:3 *Fertility and Sterility* 645 at 647.

54. Helena Jericho *et al.*, “A modified cryopreservation method increases the survival of human biopsied cleavage stage embryos” (2003) 18:3 *Human Reproduction* 568 at 569.

55. *Supra* note 4 at 1029.

56. *Supra* note 38 at 622.

57. *Supra* note 1 at s. 7.

