PRB 06-35E

Library of Parliament Bibliothèque du Parlement

ASSISTED HUMAN REPRODUCTION AND INFORMED CONSENT

Elizabeth Kuruvila
Law and Government Division

10 November 2006

PARLIAMENTARY INFORMATION AND RESEARCH SERVICE
SERVICE D'INFORMATION ET DE RECHERCHE PARLEMENTAIRES

TABLE OF CONTENTS

Page

CANADA

LIBRARY OF PARLIAMENT
BIBLIOTHÈQUE DU PARLEMENT

ASSISTED HUMAN REPRODUCTION AND INFORMED CONSENT

INTRODUCTION

On 17 September 2005, Health Canada published the proposed Assisted Human Reproduction (Section 8) Regulations pursuant to the *Assisted Human Reproduction Act* (Act).(1) As a result of the public consultation process, the regulations were amended, and a revised version was presented to the House and referred to the Standing Committee on Health on 27 October 2006. The regulations were then presented to the Senate on 30 October 2006.(2)

The Assisted Human Reproduction (Section 8) Regulations are the first set of proposed regulations made pursuant to the Act. They are necessary to enforce the prohibitions under section 8 of the Act, which are the only prohibitions under the Act that are currently not in force. Section 8 deals with written consent that must be obtained from the donor in order to use human reproductive material for the creation of an embryo or the use of an *in vitro* embryo(3) for any purpose. This section also provides that human reproductive material shall not be removed posthumously from the donor's body without the prior written consent of the donor. Specifically, section 8 reads:

> (1) 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.
>
> (2) No person shall remove human reproductive material from a donor's body after the donor's death for the purpose of creating an

(1) S.C. 2004, c. 2. For a detailed discussion of this Act's provisions, see Monique Hébert, Nancy Miller Chenier and Sonya Norris, *Bill C-13: Assisted Human Reproduction Act*, LS-434E, Parliamentary Information and Research Service, Library of Parliament, Ottawa, rev. 16 April 2003.

(2) Section 66 of the Act requires that any proposed regulations shall be laid before Parliament and referred to the appropriate committee of each House.

(3) The Act refers to an *in vitro* embryo as one that exists outside the body of a human being (section 3).

> embryo unless the donor of the material has given written consent, in accordance with the regulations, to its removal for that purpose.
>
> (3) 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.

It is important to note that consent required under section 8 is in addition to "the requirements for a valid consent to medical treatment set out in both the common law and any provincial statutes."(4) Health Canada officials have stated that the consent provisions in section 8 are not about the consent for procedure in relation to assisted human reproduction.(5)

This paper is organized into four parts. The first deals with informed choice in the context of assisted human reproduction. This is followed by a discussion of the consent framework under the *Assisted Human Reproduction Act*. The next part examines the proposed regulations made under section 8. The paper concludes with a discussion of problematic issues.

INFORMED CHOICE AND ASSISTED HUMAN REPRODUCTION

A. "Informed Choice" Versus "Informed Consent"

Medical practice places much emphasis on obtaining informed consent from a patient with respect to his/her treatment and care. The legal principles relating to informed consent to medical treatment are grounded in common law and have also been legislated in some provinces.(6)

It is generally accepted nowadays that the term "informed choice" or "informed decision-making" is preferable to "informed consent" because the former terms leave room for consent or refusal by the patient, while the latter implies consent only. As one medical writer has observed:

---

(4) Glenn Rivard and Judy Hunter, *The Law of Assisted Human Reproduction*, LexisNexis Butterworths, Markham, Ont., 2005, p. 50.

(5) Francine Manseau, testimony before the House of Commons Standing Committee on Health, *Evidence*, 10 May 2005.

(6) Section 3 of the *Assisted Human Reproduction Act* defines consent as being given "in accordance with the applicable law governing consent," thus incorporating the applicable provincial law as well as common law relating to consent.

> Perhaps the term "informed consent" is a misnomer that contributes to its own misapplication. "Informed decision making" may be a preferable and more accurate expression. Emphasizing "informed" stresses the central importance of the process itself: the effective communication between physician and patient with the intention of empowering patients to make well-informed decisions. Consent is not necessarily the goal. A patient's refusal of treatment may be the result of a process performed exceptionally well.(7)

In the context of assisted human reproduction, the 1993 Royal Commission on New Reproductive Technologies defined informed choice as "a decision about a particular course of action made after receipt of sufficient information about the non-medical and medical options."(8) Considering the direct implications of assisted human reproduction for basic human dignity, individual autonomy, and moral and religious values, informed choice or consent is especially important in such cases. It has been stated that "[t]he right to decide the fate of the genetic material by the gamete providers or intentional parents is considered a fundamental right."(9) The use of genetic material or embryos without the consent of the donor may be considered a serious breach of individual autonomy and human dignity.

In its December 2001 report entitled *Assisted Human Reproduction: Building Families*, the House of Commons Standing Committee on Health specifically identified informed choice as one of five overarching considerations to be used in assessing legislation regulating assisted human reproduction. The Committee summarized its importance in this context as follows:

> [I]nformed choice can lead to either informed refusal or informed consent. We want individuals participating in assisted human reproduction to be able to choose freely on the basis of full information of risks as well as benefits pertaining to medical, legal, ethical, social, or psychological implications. For the resulting children, they must be able to rely on the involved adults. For participating adults, this can mean having full understanding of short-term as well as long-term ramifications including the

(7) Jay M. Baruch, "Informed Consent and Advance Directives," *Journal of the American Podiatric Medical Association*, Vol. 94, 2004, pp. 198-205 (p. 198).

(8) *Proceed With Care*, Final Report of the Royal Commission on New Reproductive Technologies, Vol. 2, Minister of Government Services, 1993, p. 1161 (cited hereafter as *Proceed With Care*).

(9) Guido Pennings, "What Are the Ownership Rights for Gametes and Embryos?" *Human Reproduction*, Vol. 15, No. 5, 2000, pp. 979-986 (p. 979).

> consequences for others who may be involved. We want to ensure that consent is given freely for all aspects of assisted human reproduction such as treatment, donation, and research. We also want continual assessment of the consent that is given and an acknowledgement that, for most activities, consent may be withdrawn at any time.(10)

The *Assisted Human Reproduction Act* uses the term informed consent as opposed to informed choice. Both terms are used interchangeably in this paper.

B. The Elements of Informed Choice in Assisted Human Reproduction

The Royal Commission on New Reproductive Technologies recognized the importance of informed consent in assisted human reproduction. It commissioned a research paper that outlined the key elements of a morally valid choice as intentionality, understanding and voluntariness. The paper also noted that an informed choice must not be subject to force, fraud, deceit, duress, or other forms of constraint or coercion, and briefly described the process for obtaining informed consent:

> Informed decision making for both research and therapy is a process that generally begins with disclosure of relevant information and culminates with a choice to authorize or to refuse a particular intervention. In the interim, the prospective research subject or the patient presumably tries to understand and assess the information disclosed, then weighs the consequences associated with each option so as to make a choice that is consistent with his/her life goals, objectives, values, beliefs, or other factors.(11)

In its 1993 report, *Proceed With Care*, the Commission stated that full information and appropriate counselling are prerequisites to making an informed choice, and that prior to a request for consent the following information should be given to patients:

- full information about all the procedures involved;
- non-medical alternatives to creating a family;

---

(10) House of Commons Standing Committee on Health, *Assisted Human Reproduction: Building Families*, December 2001, p. 6 (cited hereafter as *Building Families*).

(11) Françoise Baylis, *Assisted Reproductive Technologies: Informed Choice*, New Reproductive Technologies: Ethical Aspects, Research Studies of the Royal Commission on New Reproductive Technologies, Ottawa, 1993, pp. 48-49.

- the treatment, costs and benefits; and
- possible outcomes – both negative and positive.(12)

THE CONSENT FRAMEWORK UNDER THE *ASSISTED HUMAN REPRODUCTION ACT*

In section 2(*d*), the Act states that "the principle of free and informed consent must be promoted and applied as a fundamental condition of the use of human reproductive technologies."

In its 2001 report, the Health Committee had urged that the legislation dealing with assisted human reproduction include a clear definition of informed choice. The Committee recommended that the following components be included in the definition and in subsequent regulations:

> (a) Mandatory independent counselling for all assisted human reproduction;
>
> (b) The provision of such counselling be made a condition of any licence;(13)
>
> (c) Consent be obtained at all stages of all processes; and
>
> (d) Consent may be withdrawn at any time, except as regards the retention and disclosure of medical records and personal identifying information where an offspring is involved.(14)

A. Definition of Consent Under the Act

Section 3 of the Act defines consent as follows:

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

---

(12) *Proceed With Care*, pp. 460, 462.

(13) Under the Act, certain activities related to assisted human reproduction can be performed only with a licence obtained from the Human Reproduction Agency of Canada. Such activities, known as controlled activities, include the alteration, treatment or manipulation of any human reproductive material to create an embryo; and the obtaining, storage, transfer, import or export of an *in vitro* embryo for any purpose. The Human Reproduction Agency of Canada has not yet been established.

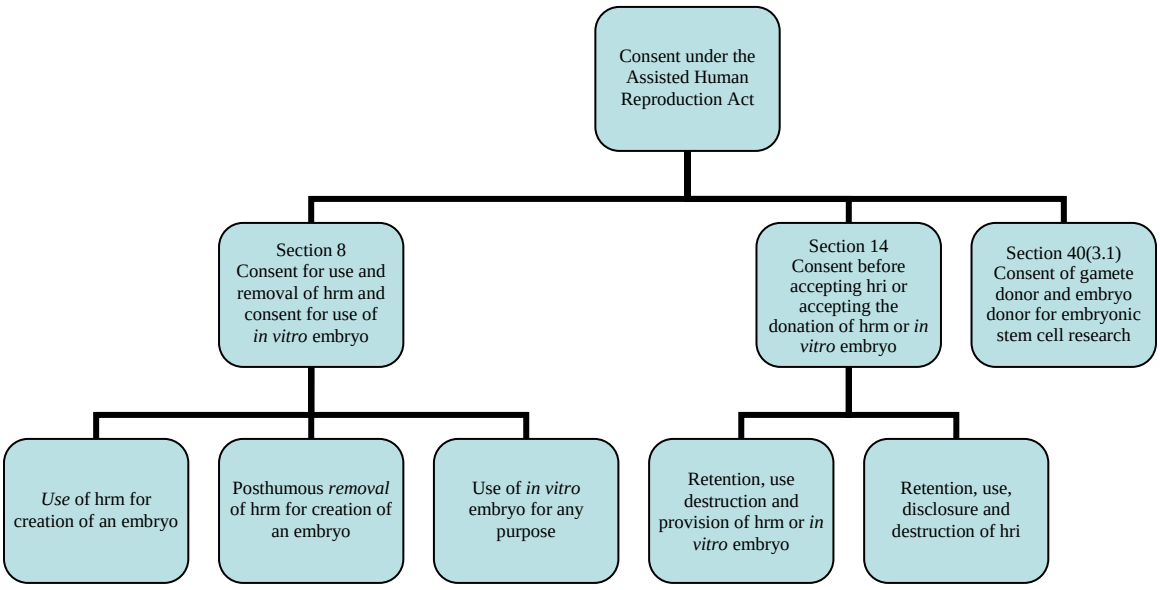
(14) *Building Families*, Recommendation 36.

One of the guiding principles of the *Human Pluripotent Stem Cell Research Guidelines* issued by the Canadian Institutes of Health Research(15) (CIHR) is free and informed consent provided voluntarily and with full disclosure of relevant information. It must be noted that while the Act deals only with derivation of stem cells from human embryos, the CIHR guidelines deal with research using stem cells derived from human embryos as well as research using existing human embryonic stem cell lines that have already been derived. The Act specifically refers to the guidelines issued in March 2002; however, the guidelines were revised in June 2005 and again in June 2006.(16)

B. Specific Provisions Dealing With Consent

As Figure 1 illustrates, sections 8, 14 and 40 of the Act deal with informed consent. It is important to note that none of these sections have yet been brought into force.

Figure 1: The Consent Framework Under the Act



Note: In this diagram, *hrm* refers to human reproductive material and *hri* refers to health reporting information.

(15) CIHR, the federal funding agency for health research in Canada, was established in 2000. It provides funding for a wide variety of research, including biomedical research and clinical science research.

(16) The June 2006 version of the guidelines is available on the CIHR Web site at http://www.cihr-irsc.gc.ca/e/31488.html.

Section 8 of the Act requires written consent for the use of human reproductive material for embryo creation; for the posthumous removal of human reproductive material to create an embryo; and for the use of an *in vitro* embryo.

Section 14 provides that health reporting information must be collected from a person before accepting the donation of human reproductive material or an *in vitro* embryo. This section further provides that before accepting health reporting information or accepting the donation of human reproductive material or an *in vitro* embryo, the person's written consent must be obtained regarding the:

- retention, use, provision to others and destruction of human reproductive material or an *in vitro* embryo; and
- retention, use, disclosure and destruction of health reporting information.

In summary, while section 8 deals with consent before *using* or *posthumously removing* for use the human reproductive material and *using* the *in vitro* embryo, section 14 deals with consent before *accepting* the donation of human reproductive material or an *in vitro* embryo, or *accepting* the health reporting information.

Section 40(3.1) of the Act requires written consent from the original gamete provider and the embryo provider before a licence can be issued for embryonic stem cell research.

PROPOSED CONSENT REGULATIONS UNDER SECTION 8 OF THE ACT

The stated purpose of the proposed regulations "is to specify the basic requirements necessary to activate the section 8 prohibitions under the *Assisted Human Reproduction Act* and, in so doing, help to protect the reproductive autonomy of donors of human reproductive material and *in vitro* embryos."(17) As stated earlier, these regulations are essential for the enactment of the prohibitions in section 8 of the Act. The related Regulatory Impact Analysis Statement (RIAS) states that: "These prohibitions [under section 8 of the Act], approved by Parliament through its passage of the Act, would not be enforceable without the

(17) Regulatory Impact Analysis Statement, *Canada Gazette*, Part I, 17 September 2005, pp. 3037-3038, http://canadagazette.gc.ca/partI/2005/20050917/pdf/g1-13938.pdf.

Regulations. … [T]he statute itself is dependant upon the Regulations in order to be implemented."[18]

The regulations are divided into three parts that correspond to the three parts in section 8:

- Part I – Consent for the use of human reproductive material for the creation of an embryo;
- Part II – Consent for the posthumous removal of human reproductive material to create an embryo; and
- Part III – Consent for the use of an *in vitro* embryo for any purpose.

All three parts of the regulations deal with information that must be provided to the donor before a valid consent is obtained, and with effective withdrawal of consent by the donor. Parts I and III also deal with the potential uses of human reproductive material or an *in vitro* embryo.[19]

The regulations also contain transitional provisions and coming into force provisions.

A. Part I: Use of Human Reproductive Material for Embryo Creation

1. Information to Be Given to the Donor Before Obtaining Consent

The following information must be provided to the donor before obtaining his/her written consent for the use of human reproductive material for the creation of an embryo:

- the human reproductive material will be used for certain prescribed purposes in accordance with the donor's consent (see the section below regarding potential uses);
- the withdrawal of consent by the donor must be in writing and must also comply with other requirements prescribed in the regulations;
- if the human reproductive material is taken from the donor's body after his/her death, it will be used for certain purposes in accordance with the donor's consent;
- embryos in excess of reproductive needs might be created with the human reproductive material; and

(18) RIAS, p. 3046.

(19) See the Appendix for a summary table of potential uses of human reproductive material and *in vitro* embryos under the proposed regulations.

- if the human reproductive material is used for the reproductive use of a third party or the spouse or common-law partner at the time of the donor's death and there are embryos that are in excess of the needs of such persons, the excess embryos will be used in accordance with their consent. An exception is made when embryos are to be used to improve assisted human reproductive procedures or to provide instruction for such procedures; in this case, the embryos will be used in accordance with the consent given by the donor of the reproductive material.

2. Potential Uses of Human Reproductive Material

A person who donates human reproductive material for the creation of an embryo must give written consent stating that the material may be used for one or more of the following purposes:

- the donor's own reproductive use, while the donor is alive;
- after the donor's death, the reproductive use of the spouse or common-law partner of the donor at the time of death;
- reproductive use of a third party;
- improving assisted reproduction procedures; and
- providing instruction in assisted reproduction procedures.

3. Effective Withdrawal of Consent

When the human reproductive material is intended for the reproductive use of a third party, the written withdrawal of the consent will be effective only if it is made before the third party acknowledges in writing that the material has been designated for his/her reproductive use. For all other uses, a written withdrawal will be effective if it is provided before the human reproductive material is used.

B. Part II: Posthumous Removal of Human Reproductive Material for Embryo Creation

A person who removes human reproductive material from a donor after his/her death, for the purpose of creating an embryo, must have written consent stating that the donor had received the following information in writing before consenting to the removal:

- the human reproductive material will be removed in accordance with the donor's consent to create an embryo for certain prescribed purposes;

- if the donor wishes to withdraw consent it should be in writing and it will be effective only if it is provided before the removal of human reproductive material; and

- human reproductive material removed posthumously cannot be used unless consent for use of the material is provided in accordance with Part I of the regulations (discussed earlier).

An embryo derived from human reproductive material that has been posthumously removed can be used for the reproductive use of the spouse or common-law partner at the time of the donor's death, but not for the reproductive use of a third party. The embryo could also be used to improve assisted human reproductive procedures and provide instruction in such procedures.

It should be noted that in the case of posthumous removal of human reproductive material, two consents must be obtained:

- consent to remove the human reproductive material; and

- consent to use the human reproductive material.

Obtaining the two consents is important to fulfil the requirements of the Act. Section 8(1) of the Act states that: "No person shall *make use of* human reproductive material" except under certain conditions (emphasis added). On the other hand, section 8(2) of the Act, which deals with posthumous donation of human reproductive material, states that: "No person shall *remove* human reproductive material" (emphasis added).

The withdrawal of consent for posthumous removal of human reproductive material will be effective only if the person who removes the human reproductive material is notified in writing, before the actual removal of the material.

C. Part III: Consent Regarding the Use of an *In Vitro* Embryo

1. Definition of Donor

The definition of "donor" in Part III of the regulations is very important. With certain exceptions, donor refers to the *person/couple for whose reproductive use the embryo was created*. In other words, the donor of the sperm or ovum may not be the donor of

the *in vitro* embryo in all cases. The donor of the sperm or ovum does, however, become the donor of the *in vitro* embryo when the embryo is created for his/her own reproductive use.

In addition, when an *in vitro* embryo is donated for the improvement of assisted human reproduction procedures or to provide instruction in such procedures, the donor of the human reproductive material is considered the donor for the purposes of certain provisions of the regulations. These provisions deal with information that must be provided to the donor of the embryo before a valid consent is obtained; consent from the donor of the embryo regarding the potential uses; and withdrawal of consent by the donor of the embryo.

The following persons, depending on their status at the time the embryo was created, may be considered donors.

- In the case of an individual for whose reproductive use the embryo was created, and who has no spouse or common-law partner at the time, the individual is considered the donor.
- In the case of a couple who are spouses or common-law partners at the time the embryo is created, the couple is considered the donor, regardless of the source of the human reproductive material. However, if the embryo is created using the reproductive material from one of the individuals in a couple, that individual becomes the donor of the embryo if, before the use of the embryo, that individual is no longer a spouse or common-law partner.

2. Information to Be Given to the Donor Before Obtaining Consent

The following information must be provided to the donor in writing before obtaining his/her consent for use of the *in vitro* embryo:

- the embryo will be used for certain prescribed purposes in accordance with the donor's consent (see the following section regarding potential uses); and
- the withdrawal of consent by the donor must be in writing and must also comply with other requirements prescribed in the regulations.

3. Potential Uses of an *In Vitro* Embryo

The donor of an *in vitro* embryo must give his or her written consent stating that the embryo shall be used for one or more of the following purposes:

- the donor's own reproductive use;
- reproductive use of a third party;

- improving assisted human reproduction procedures;
- providing instruction in assisted human reproduction procedures; and
- a specific research project.

If an *in vitro* embryo is to be used for a specific research project, for the improvement of assisted human reproduction procedures or to provide instruction in such procedures, the written consent of the donor of the human reproductive material is also necessary, unless he or she has already consented to that use as the donor of the embryo. If the embryo is donated by a couple, their mutual and compatible consent is required in order to use the embryo.

A recent case before the European Court of Human Rights highlights the importance of obtaining mutual consent from a couple before using an *in vitro* embryo.(20) On 12 July 2000, the applicant and her then partner commenced *in vitro* fertilization (IVF) treatment. As a result, six embryos were created using eggs and sperm obtained from the applicant and from her partner. These embryos were consigned to storage. Both the applicant and her partner had given consent to use their eggs and sperm for the IVF treatment. They had also consented to the storage of any *in vitro* embryos developed from the IVF process.

Subsequent to the creation and storage of the embryos, the applicant's ovaries had to be removed as part of treatment for cancer. She was advised to wait for two years before implanting any of the embryos into her uterus.

The couple later separated. The applicant's partner notified the clinic of the separation and advised them that the embryos in storage should be destroyed. The applicant sought an injunction in the British courts requiring that her partner restore his consent to the use and storage of the embryos. The applicant lost her case in the High Court and the Court of Appeal. Subsequently, the European Court of Human Rights held that the provisions of the European Convention on Human Rights were not violated in this case. In her submissions to the European Court, the applicant had emphasized that the embryos in storage were her only chance to have a biological child.

(20) *Evans* v. *The United Kingdom*, Application No. 6339/05, 7 March 2006.

4. Effective Withdrawal of Consent

The withdrawal of consent by the donor of an *in vitro* embryo will be effective only if the person who intends to make use of the embryo is notified in writing:

- before the actual use, in cases where the embryo is for the reproductive purposes of the donor;
- before the third party acknowledges in writing that the embryo has been designated for his/her own reproductive use, in cases where the embryo is to be used for the reproductive purposes of a third party;
- in cases where the embryo is to be used to improve assisted human reproduction procedures or provide instruction in such procedures, the withdrawal must be made before the later of the following occurrences:
  - it is acknowledged in writing that the embryo has been designated for such purposes; or
  - the beginning of the process of thawing the embryo for such purposes;
- in cases where the embryo is to be used for a specific research project, the withdrawal must be made before the latest of the following occurrences:
  - it is acknowledged in writing that the embryo has been designated for research;
  - the beginning of the process of thawing the embryo for research; or
  - the creation of a stem cell line using the embryo.

SOME PROBLEMATIC CONSENT ISSUES

The proposed regulations do not address all aspects related to informed consent under the Act. In this context, Health Canada has made the following observations in the RIAS.

- "Forthcoming regulatory proposals under other sections of the Act will complement the section 8 regulations."(21)
- "… Health Canada is developing two non-regulatory instruments, including an interpretation or user's guide and a sample consent form that clinics can use or adapt for their own purpose."(22)
- "Specifying only the essential information required to be provided to donors was deemed necessary to give effect to the section 8 prohibition while ensuring that potential penalties

(21) RIAS, p. 3052.

(22) *Ibid.*, p. 3047.

under the Act were proportional to the obligations imposed by that section and the proposed Regulations."[23]

This part of the paper briefly discusses certain points that have not been addressed in the proposed regulations under section 8. Some of these questions were raised during Health Canada's public consultation process. The questions, and Health Canada's responses, have been included in the RIAS.

A. Counselling

The proposed regulations do not refer to counselling services to be provided before the donor's informed consent is requested. Even though section 8 does not make counselling services mandatory, such services may be necessary to ensure that "informed" consent has been obtained.

In this regard, Health Canada agrees that counselling is important and notes that section 14 of the Act makes it mandatory to make counselling services available to a person before the donation of human reproductive material or an *in vitro* embryo. The RIAS further states that "[s]ection 8 of the Act can only address the unauthorized use of *in vitro* embryos."[24]

B. Process of Obtaining Consent

The process of obtaining consent is also important in order to ensure that the consent is freely obtained. The person who obtains consent, the nature of the consent (written versus oral), the place where the consent is obtained and the time available for thoughtful consideration before giving consent are important factors that must be considered. For instance, if the physician treating the couple requests their consent to the use of any surplus embryos for research, the donor(s) may feel pressured to give consent in order to ensure continuation of treatment. These issues may possibly be addressed in subsequent non-regulatory instruments.

(23) *Ibid.*, p. 3046.

(24) *Ibid.*, p. 3052.

C. Destruction and Storage of Embryos

Before a donor of an *in vitro* embryo gives informed consent to the embryo's use for research, it is important for the donor to realize that the embryo will be destroyed in the process. Likewise, it may be important that a donor receive information about storage and destruction of human reproductive material or an *in vitro* embryo before giving informed consent. However, Health Canada has noted that "section 8 Regulations do not address the storage or destruction of human reproductive material or *in vitro* embryos, as these are not considered 'uses.' Future regulatory proposals under other sections of the Act will address when and how human reproductive material or *in vitro* embryos may be disposed of."(25) The RIAS goes on to state that "forthcoming regulatory proposals under section 10 will address *in vitro* embryo storage time limits and destruction."(26)

D. "Use" for the Purposes of Withdrawal of Consent

In most cases, an effective withdrawal of consent for the use of human reproductive material or an *in vitro* embryo can be made before the material is "used." However, the regulations are not clear as what constitutes "use" for the purpose of withdrawal. It may be important to clarify this matter.

The consent framework of the *Assisted Human Reproduction Act* including section 8 is complex and involves various legal and ethical issues and it may be challenging to deal with all of the problematic issues in the first set of regulations. While it is important to finalize and implement regulations relating to informed consent as early as possible, it is also important that such regulations be finalized only after effective public and parliamentary debates on the matter.

(25) *Ibid.*, p. 3046.

(26) *Ibid.*, p. 3050.

APPENDIX

Potential Uses of Human Reproductive Material and *In Vitro* Embryos Under the Proposed Regulations

Human Reproductive Material Obtained From Living Donor	Human Reproductive Material Removed Posthumously	*In Vitro* Embryos
Reproductive use of donor		Reproductive use of donor
Reproductive use of spouse or common-law partner, following the death of the donor	Reproductive use of spouse or common-law partner	
Reproductive use of third party		Reproductive use of third party
Improving assisted human reproduction procedures	Improving assisted human reproduction procedures	Improving assisted human reproduction procedures
Providing instruction in assisted human reproduction procedures	Providing instruction in assisted human reproduction procedures	Providing instruction in assisted human reproduction procedures
		A specific research project