Health Canada
Santé 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*

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Canada

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1. Introduction and Context

An Act respecting assisted human reproduction and related research (the Act) became law on March 29, 2004. This Act governs the area of assisted human reproduction (AHR). The Act prohibits certain ethically unacceptable activities, like human cloning. In addition, it provides a mechanism to oversee acceptable activities, such as *in vitro* fertilization (IVF), thus helping to protect the health and safety of Canadians, as well as a mechanism to oversee AHR-related research. The Act will eventually lead to the establishment of the Assisted Human Reproduction Agency of Canada, responsible for licensing, inspecting and enforcing activities controlled under the Act.

Many pieces of legislation require the support of regulations in order to be fully implemented. Like statutes, regulations have binding legal effects. A regulation must be consistent with its enabling Act and cannot go beyond the scope of the Act. Generally, regulations serve to complement and fill in the details of the policy framework set out in a statute and to establish rules and procedures that are within the scope of the statute.

The task of developing proposals for the regulations which will support the AHR Act rests with Health Canada.

Throughout the development of the AHR regulations, Health Canada plans to undertake public involvement activities to ensure that interested parties have an opportunity to present their views, concerns and recommendations. At present, consultations are planned to be held over the next three years to develop the components for the regulatory framework under the AHR Act.

The consultations will be held on the following subjects:

- Section 8 (consent – i.e., this document)
- Section 12 (reimbursement of expenditures)
- Section 10 (*in vitro* embryo research)
- Section 10 (clinical and laboratory practices, including clinical trials)
- Section 10 (preimplantation genetic diagnosis – PGD)
- Sections 14-19 (health reporting information – HRI)
- Section 14 (counselling)
- Administration of the licensing and inspection/ enforcement framework

The purpose of this paper is twofold: to inform Canadians, and to seek their views on the development of regulations concerning section 8 (consent) of the Act and concerning the definition of an *in vitro* embryo donor. Readers may find it helpful to have a copy of the AHR Act at hand for ease of reference[1].

The accompanying questionnaire and response form provides readers with the opportunity to respond to a series of questions posed by Health Canada. The comments or recommendations that readers might wish to provide will be considered in the development of regulations for section 8 (consent) and for the definition of an *in vitro* embryo donor. In order to develop regulations in a timely manner, please note that the deadline for receipt of comments is December 10, 2004.

[1] A copy of the Act can be found on the Health Canada web site: http://hc-sc.gc.ca/english/pdf/protection/ahr/C-6_4_RA.pdf

2. Background

2.1 *Assisted Human Reproduction Act* – An overview

An Act respecting assisted human reproduction and related research (the short title is *Assisted Human Reproduction Act*) has three primary objectives. First, to prohibit unacceptable practices such as human cloning. Second, to protect Canadians using AHR to help build their families without compromising their health and safety. Third, to ensure that AHR related research which may facilitate treatment for infertility and certain diseases, such as Alzheimer's, Parkinson's and cancer, takes place within a regulated environment.

The Act begins with a Declaration of Principles that sets out the broad principles on which the Act and future regulations are based. For example, the health and well-being of children born through the application of AHR technologies must be given priority in decisions respecting the use of such technologies. Also, the health and well being of women in particular must be protected in the application of these technologies. The Declaration also states the need to preserve and protect human individuality and diversity, and the integrity of the human genome. Further it is declared that free and informed consent is a fundamental condition of the use of AHR technologies. As well, the Act addresses the concerns raised by the commercialization of the reproductive capabilities of women and men.

The Act helps to protect Canadians by prohibiting certain unacceptable activities from taking place in Canada, such as:

- human cloning (all types, whether reproductive or therapeutic);
- germ-line alteration;
- payment to surrogates;
- payment to donors of egg, sperm, or *in vitro* embryos;
- creating chimeras; and
- using someone's reproductive material without their consent.

The Act establishes controlled activities that are prohibited unless carried out with a licence and in accordance with the regulations. Such controlled activities include AHR procedures like *in vitro* fertilisation, donor insemination and research involving the human *in vitro* embryo.

The Act will ensure that all research involving the use of a human *in vitro* embryo is strictly regulated. First, the Act will require persons, such as researchers, to obtain the fully informed written consent of *in vitro* embryo donors prior to using them. Second, an *in vitro* embryo can only be used if the Agency (when established) is satisfied that it's use is necessary for the purpose of the proposed research. Third, an embryo cannot be maintained outside the body of a woman past the 14th day of development which is the internationally accepted standard. Fourth, all such research will be licensed in accordance with the forthcoming regulations.

Finally, the Act provides for the establishment of the Assisted Human Reproduction Agency of Canada (the Agency). The Agency will become a recognized and knowledgeable source of reliable information on AHR-related issues. Its responsibilities will include inspecting clinics, issuing licences, maintaining a donor/offspring registry, and providing reliable information on AHR to Canadians.

The Act creates offences for contravention of its provisions, regulations, and the terms and conditions of a licence. Contravention could

result in a fine and/or imprisonment. Almost all AHR services provided by clinics fall under the category of controlled activities, which will be allowed with a licence obtained from the Agency. Once the Agency becomes operational and licences are issued, inspections of clinics will be conducted to verify that their activities are in compliance with the legislation. The Agency may use various enforcement measures, such as amendments to the terms of licences or the suspension or revocation of licences.

2.2 Coming into force

At the time the Act received Royal Assent (March 29, 2004) and became law, only section 78 of the Act came into force. Section 78 allows the remaining provisions of the Act to come into force at various times.

Most of the prohibitions (sections 5 through 9) came into force on April 22, 2004. The one exception is section 8, prohibits the use of reproductive material and the *in vitro* embryo without consent. It will be brought into force when accompanying regulations are made. The feedback received in response to the present document will help inform the development of these regulations.

The "controlled activities" sections (sections 10-13) and section 71 (the "grandfathering" provision) also came into force on April 22. The one exception is section 12, which deals with the reimbursement of receipted expenditures.

Provisions relating to the creation of the Agency will be brought into force at a date when the selection process for the President and Board of Directors has been completed and appointments are ready to be made. This is expected in 2005. The overall regulatory and licencing schemes are expected to be in place in 2007.

2.3 Section 8 (Consent) and the definition of an *in vitro* embryo donor

As mentioned above, section 8 of the Act, which prohibits the use of reproductive material and the *in vitro* embryo ***without*** consent, will be brought into force once the accompanying regulations have been developed.

The purpose of this document is to facilitate the informed participation of Canadians in the development of section 8 regulations. An overview of the consent issues related to the use of reproductive material is provided below. At this time, Health Canada is also interested in including Canadians in the development of a definition of an *in vitro* embryo donor as the Act refers to regulations to define this term. This is explained below.

Aside from section 8, there are other provisions of the Act which refer to consent, though in different contexts (as explained in 3.4 below). These provisions will be dealt with in a future consultation document.

2.4 Next steps

At the end of this document, readers will be provided with the opportunity to respond to a series of questions posed by Health Canada. The comments or recommendations that readers might wish to provide will be considered in the development of regulations for section 8 (consent) and the definition of an *in vitro* embryo donor. In order to develop regulations in a timely manner, please note that the deadline for receipt of comments is December 10, 2004.

Once the comments on this document have been compiled and analysed, a regulatory proposal together with a report on the consultations will be made available. In keeping with the Federal Regulatory Policy requirements, the proposals will

be drafted into regulations and the supporting Regulatory Impact Analysis Statement. The draft regulations will then be pre-published in Part I of the *Canada Gazette* for a public comment period. After final revisions are complete, there will be a formal publication of the regulations in Part II of the *Canada Gazette*.

2.5 Definitions

The following terms are used in this document and defined here for clarification:

- ***Donor – in relation to human reproductive material*** includes an individual from whose body human reproductive material was obtained for the purposes of reproduction. For example, it could be an individual who provides their sperm or eggs for use with their spouse or common law partner, or it could be an individual who provides sperm or eggs to others (i.e. third party donation);
- ***Donor – in relation to the in vitro embryo*** will be discussed below in sections 4 and 5;
- ***Embryo*** refers to a human embryo. As an embryo could be created inside (*in vivo*) or outside (*in vitro*) a woman's body, it is important to realize the distinction when reading this document. When this document refers to an embryo outside the body of a woman, the term "*in vitro* embryo" will always be used. However, when only the word "embryo" appears, this could mean either *in vivo* or *in vitro*;
- ***Human reproductive material*** in the Act refers to human sperm or eggs (also called gametes) or other human genes or cells. For ease of reference in this document, the specific terms, sperm and eggs, will often be used instead of human reproductive material as these are the reproductive materials used in most AHR procedures;
- ***Partner*** for purposes of this document, a partner could mean spouse or common-law partner; and
- ***Third-party*** means a person other than the donor's spouse or common-law partner, and may include two persons who are spouses or common-law partners.

3. Consent

3.1 Why consent is important

The requirement for free and informed consent is a core principle of the AHR Act. Consent is required to protect those involved in the donation and/or use of human reproductive materials and the human *in vitro* embryo. For example, sperm, eggs and *in vitro* embryos cannot be used unless the donors have given their consent in writing. All persons contemplating donating their human reproductive materials or *in vitro* embryo must be fully informed, in writing, of the requirements of the Act respecting the retention, use and destruction of their reproductive material or *in vitro* embryo.

3.2 What stakeholders and parliamentarians have said about informed consent

Throughout the development of the AHR Act, informed consent has generated commentary from stakeholders (i.e. interested parties) and parliamentarians as to the importance of this principle. From the 1993 Royal Commission to the House of Commons Standing Committee on Health hearings on the proposed legislation, the importance of fully informed and freely given consent was continually underscored.

For example, it its Final Report (1993), the ***Royal Commission on New Reproductive Technologies*** stated the following:

> "Researchers conducting interviews for the Commission were told that sperm donation is not necessarily a simple isolated act; some donors said they had not considered the full implications of DI [donor insemination] until years after donating. Some said they strongly regretted donating; some felt frustrated by the lack of access to basic information about the children born as a result of their donation. Many reported that they regarded donation very casually until they were married or had children of their own, when they began considering the implications of having a genetically linked child growing up elsewhere. Some donors also reported that their wives or partners were upset by their past donations and said they worried that their children should marry a half sibling unknowingly." (p.446, vol.1)

This issue was further discussed before the House of Commons Standing Committee on Health during its review of the legislative proposals (2001). In its recommendations, the Committee reiterated the importance of informed consent which they often associated with 'choice':

> Recommendation 3 (e): "the principle of free and informed choice as a fundamental condition of the use of assisted human reproduction must be promoted and applied."

The Committee also emphasized the importance of section 8:

> "Without full and informed consent for any controlled activity, participating adults could face unknown long-term harm. Consent must be freely given and be based on full understanding of the implications of providing one's personal reproductive material for use by others. The Committee strongly supports this prohibition on the use of reproductive materials and embryos without consent." (p.14)

3.3 The meaning of informed consent in terms of the AHR Act

In the context of the Act, it is important to distinguish between the consent given for the use of one's own reproductive material (e.g. sperm and eggs) to create an embryo from the consent

As defined in section 3 of the Act:

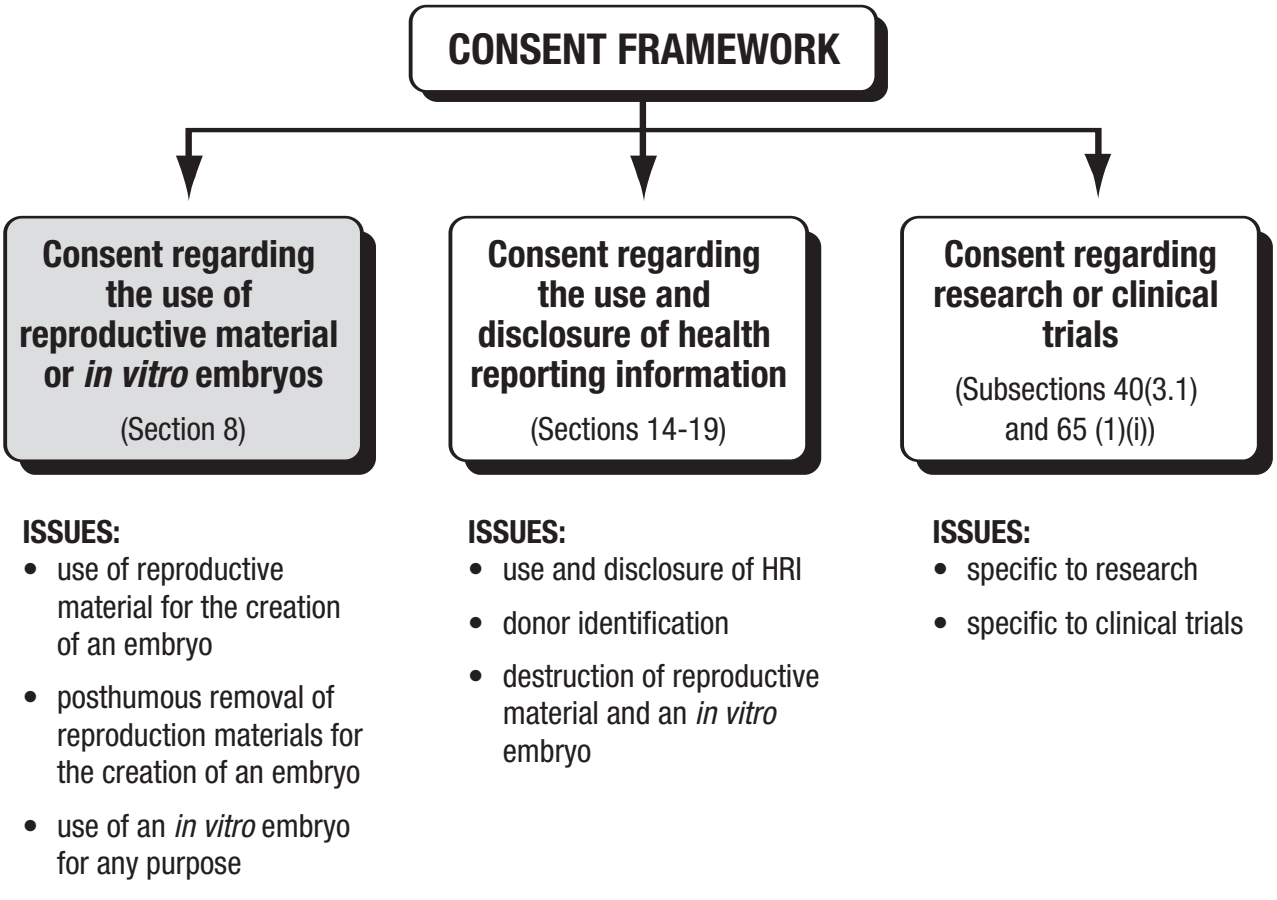
"consent" means fully informed and freely given consent that is given in accordance with the applicable law governing consent and that conforms to the provisions of the Human Pluripotent Stem Cell Research Guidelines released by the Canadian Institutes of Health Research in March, 2002, as detailed in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

given to undergo a medical procedure. Informed consent as it relates to a medical procedure is a separate matter between physicians and their patients and is beyond the scope of the Act.

The AHR Act defines consent in broad terms, making reference to "the applicable law governing consent". Generally, for a consent to be valid in law, the person giving consent (1) must have the capacity to consent, that is, be of sound mind and of the appropriate age; and (2) must do so freely, voluntarily, without undue pressure or influence. In addition consent must be informed, that is, the person must have sufficient information in order to make an informed decision to consent to whichever procedure or action is being contemplated.

3.4 The AHR Act's consent framework

The Act deals with informed consent in a number of provisions and in different contexts. These provisions provide the basis for the consent framework of the Act. Section 8 is only one component of this framework. In order to better understand the objectives of section 8 and situate them within the larger consent framework of the Act, a brief overview of the overall consent framework is outlined here (three major areas of the Act make reference to informed consent, as shown in the chart below).



The development of a regulatory proposal in relation to section 8 of the Act is the focus of this document. In this section, consent is required to prevent the misuse of reproductive material to create an embryo or the misuse of an *in vitro* embryo for any purpose.

As indicated in the chart, there are other provisions of the Act which pertain to informed consent. First, sections 14 to 19 refer to consent in the context of health reporting information[2]. For example, before health reporting information can be collected from an individual, there is an obligation to inform the individual in writing of the requirements of the Act and to obtain that individual's written informed consent. The Act states what type of information must be provided to obtain informed consent from an individual who donates human reproductive material or an *in vitro* embryo, or when an individual provides health reporting information:

> *s.14(2)(a): inform the person in writing of the requirements of this Act respecting, as the case may be, (i) the retention, use, provision to other persons and destruction of the human reproductive material or* in vitro *embryo, or (ii) the retention, use, disclosure and destruction of the health reporting information.*

Second, subsection 40 (3.1) deals with consent as it applies to research and clinical trials. In this context, consent has specific meaning and the Act draws on established guidelines for consent for research involving the *in vitro* embryo specifically to derive stem cells – i.e. the March 2002 *Canadian Institutes of Health Research's Human Pluripotent Stem Cell Research Guidelines*.

As this document is only intended to address section 8 and its regulatory requirements, issues pertaining to the other sections (i.e. sections 14 to 19 and subsection 40(3.1) where consent is addressed will be consulted upon at a later date.

It is important to note that as section 8 pertains to the ***use*** of human reproductive materials and *in vitro* embryos, it does not refer to their destruction. Issues surrounding consent to the destruction of human reproductive materials and the *in vitro* embryo will be dealt with in later consultations pertaining to sections 14 to 19 of the Act.

[2] Health reporting information is defined in section 3 of the Act as meaning information provided under the Act respecting "the identity, personal characteristics, genetic information and medical history of donors of human reproductive material and *in vitro* embryos, persons who have undergone assisted reproduction procedures and persons who were conceived by means of those procedures"; and "the custody of donated human reproductive materials and *in vitro* embryos and the uses that are made of them".

4. The Definition of a Donor

Donor of human reproductive material

As stated above in section 2.5, the definition of a donor includes an individual who makes use of their own reproductive material (often with a partner) with the intention of reproduction. However, it can also include an individual who provides their reproductive material to another person(s), for that person's reproductive purposes. The latter is referred to as third party donation.

Under the Act, a donor may be any individual from whose body human reproductive material was obtained, whether ***for their own use or for the use of others***.

Given that it takes the gametes (sperm, eggs) of two individuals to create an embryo, the man and woman who have provided their gametes for reproductive purposes are known as the donors.

A donor of reproductive material could be, for example:

- someone who provides sperm or eggs ***for their own reproductive use***, with or without a partner (e.g. sperm in the case of artificial insemination, or eggs for use in IVF); or
- someone who provides sperm or eggs ***for a third-party's reproductive use*** (e.g. sperm for use in donor insemination, or eggs for use in IVF – this is known as 'IVF with a donor's eggs').

Donor of an *in vitro* embryo

The Act states that a donor in relation to an *in vitro* embryo is as defined in the regulations (under the definition of "donor" in section 3). The authority to define an *in vitro* embryo donor in the regulations is found in paragraph 65(1)(a) of the Act. For further discussion of the definition of an *in vitro* embryo donor, please refer to item 5(3) below for proposed definitions.

5. The Issues: Section 8 Regulations (consent) and the Definition of *In Vitro* Embryo Donor

The purpose of the prohibitions in section 8 are to prevent the misuse of human reproductive materials and the *in vitro* embryo. Given that contravention of section 8 would be an offence with potentially significant penalties, it is important that the regulations relate closely to the scope and purpose of this section. For this reason, the regulations pertaining to section 8 will not deal with all of the information requirements pertaining to consent. Further requirements will be addressed in a separate set of regulations that will be developed later as part of the regulations under sections 14-19 of the Act.

In order to respect the principle of reproductive autonomy, a donor's consent is a ***mandatory*** condition of use under section 8. Only the individual donors may consent to the use of their reproductive materials and/or *in vitro* embryo.

Section 8 specifies three circumstances where consent must be obtained from the donor before sperm and/or eggs or an *in vitro* embryo may be used or before sperm and/or eggs may be posthumously removed. These three circumstances are as follows:

- (1) consent to the use of sperm and/or eggs to create an embryo;
- (2) consent to the removal of sperm or eggs from a donor's body posthumously for the purpose of creating an embryo; and
- (3) consent to the use of an *in vitro* embryo for any purpose.

Each of these circumstances is addressed separately below. Also addressed below are the details of how section 8 regulations and the definition regarding an *in vitro* embryo donor could be developed. Please note that in many cases, there are no policy options presented given the existence of other regulations and the constraints of the prohibitions to which these regulations will relate. Please see the chart at Annex A for a summary of the information provided below.

At the end of each of the following sections, questions relevant to that particular section are being posed. In the Questionnaire and Response form, all the questions are listed with some space to provide input.

Section 8 reads as follows:

(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 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.*

5.1 Consent to the *use* of human reproductive materials (hrm) for the purpose of creating an embryo

The Act prohibits the creation of an *in vitro* embryo for any purpose other than creating a human being or for improving or providing instruction in assisted human reproduction procedures (paragraph 5(1)(b)).

Subsection 8(1) makes it an offence for a person to use a donor's human reproductive material (i.e. sperm/or eggs) for the purpose of creating an embryo unless the donor of the material has given his or her written consent to that use.

For the purpose of subsection 8(1) of the Act, there are five scenarios under which consent would be required to use human reproductive material for the purpose of creating an embryo. It is proposed that the regulations would deal with the following scenarios:

- **For the donor's reproductive use**
  In situations where the fertility problems are complex (e.g. *in vitro* fertilization), treatments may involve the use of donated sperm and eggs to create an *in vitro* embryo. Or, for example, a couple could be undergoing a more simple procedure like artificial insemination using the male partner's sperm and thus trying to create an *in vivo* embryo. Regardless of the treatment type, donors must consent to the use of their sperm or eggs for the purpose of creating an embryo.

It is proposed that the regulations would outline that the donors must be informed prior to providing a consent, that his or her donation or any resulting *in vitro* embryo may not be used due to the presence of disease, lack of viability, or for some other reason in which case the human reproductive material or *in vitro* embryo may be disposed of.

- **For posthumous reproductive use by the donor's partner**
  The decision to donate sperm or eggs to create an embryo for one's reproductive use implies that the donor plans to participate in the rearing of the resulting child. However, using sperm and eggs to create an embryo following the death of a donor raises additional issues that must be considered. If a donor's spouse or common law partner wishes to create an embryo for their own use ***after*** the donor's death, the donor must have already consented to the use of their sperm or eggs for this purpose. The donor would therefore have consented separately – prior to death – to the posthumous use of their sperm or egg in order to create an embryo for the future use of their partner.

- **For third party reproductive use**
  The intention to donate sperm or eggs for the reproductive use of a third party is different than providing sperm or eggs for one's own reproductive use. Thus, a donor must specifically consent to the use of their sperm or eggs for the creation of an embryo for third party use.

It will be important and necessary for donors who provide their reproductive materials for third party use to understand that their consent in this context includes consent to ***all possible future uses***, as authorized under the Act, of any *in vitro* embryo created using their reproductive materials. That is to say that once they have provided their materials and these materials are assigned to a third party to create an *in vitro* embryo, it will be up to the third party to decide how the *in vitro* embryo should be used[3].

[3] For example, if a woman donates her eggs to a couple for use during their IVF treatment, once her eggs have been assigned to the other couple to create an *in vitro* embryo, she would no longer have a say as to the future use of the *in vitro* embryo, i.e. should they stay in storage, should they only be used for the couple's reproductive needs, should they be given to research. Such decisions would rest with the couple for whom the *in vitro* embryos were created and not the original donor.

- **For improving assisted human reproduction procedures**
  The Act allows for the creation and use of an *in vitro* embryo for the purpose of improving assisted reproduction procedures (s. 5(1)(b)). To ensure the safety of a procedure before using it in a clinical setting, tightly controlled research is required so that women, men and any resulting offspring are not subjected to AHR procedures which have not been properly tested. Given that the validation of AHR procedures sometimes results in the creation of an *in vitro* embryo, the consent must be obtained from the donors of the sperm and eggs used to create such an *in vitro* embryo.

- **For providing instruction in assisted human reproduction procedures**
  The Act also allows for the creation and use of an *in vitro* embryo to provide instruction in assisted human reproduction procedures (s.5(1)(b)). While most training for AHR procedures does not necessarily involve the manipulation of human sperm and eggs, there are some circumstances where human sperm and eggs will be used and their manipulation may result in the creation of an *in vitro* embryo. The creation of an *in vitro* embryo to assist in training for AHR procedures is permitted and consent is required from the donors of the sperm and eggs used to create the *in vitro* embryo for this purpose.

Question 1: Do you have any comments on the requirements for section 8 (consent) regulations regarding the ***use*** of human reproductive materials for the purpose of creating an embryo:

- for the donor's reproductive use;
- for posthumous reproductive use by the donor's partner;
- for third party reproductive use;
- for improving assisted human reproduction procedures; or
- for providing instruction in assisted human reproduction procedures.

Question 2: Specifically, do you have any comments on the proposal that prior to providing a consent, a donor must be informed that his or her donation or any resulting *in vitro* embryo may not be used due to the presence of disease, lack of viability, or for some other reasons in which case the human reproductive material or *in vitro* embryo may be disposed of?

5.2 Consent to the posthumous removal of human reproductive materials (hrm) from a donor's body for the purpose of creating an embryo

Subsection 8(2) makes it an offence for a person to remove sperm or eggs from a donor's body posthumously for the purpose of creating an embryo, unless the donor consented in writing to the removal for that purpose ***prior*** to death.

Under subsection 8(2), there are several instances for which consent would be required for the posthumous removal of sperm or eggs for the purpose of creating an embryo. Although posthumous removal of sperm or eggs is rarely requested, the requirement for obtaining consent would be to respect the wishes of the donor to provide their sperm or eggs for reproductive use. It is proposed to limit donation to the donor's partner for the partner's own reproductive use.

It is proposed that the regulations would outline the following:

- **For the donor's partner's own reproductive use**
  There are issues, such as the psychosocial impacts on the resulting child, that must be considered in the case where a donor's partner wishes to remove the donor's sperm or eggs posthumously in order to create an embryo for

their own use. Such issues would be discussed as part of the provision of counselling services which will be covered in other regulations. Under this scenario, a donor must have consented in writing to the posthumous removal of their sperm or eggs ***prior*** to their death and solely for the reproductive use of their partner.

It is proposed that the regulations would outline that the donors must be informed, prior to providing a consent, that his or her donation or any resulting *in vitro* embryo may not be used due to the presence of disease, lack of viability, or for some other reason in which case the human reproductive material or *in vitro* embryo may be disposed of.

- **For use by a third party**
  Under section 4 of the *Processing and Distribution of Semen for Assisted Conception Regulations (Semen Regulations)*[4] there is a mandatory six month minimum quarantine period required before donated sperm intended for use by third party in assisted conception can be used. This would prevent the posthumous removal of sperm from happening as the *Semen Regulations* state that the donor must be retested again at the end of the quarantine period which, in this instance, would not be an option. Similar health and safety concerns exist with the use of donated eggs. Future regulations under the Act will address these concerns.

- **For improving assisted human reproduction procedures**
  The health and safety concerns addressed under the *Semen Regulations*, for example, are not applicable in this circumstance given that any *in vitro* embryo created for this purpose would not be used for reproduction. The use of sperm and eggs to create an *in vitro* embryo for the purpose of improving assisted human reproduction procedures is permitted in the Act, although the donor's consent is required for its use for this purpose.

- **For providing instruction in assisted human reproduction procedures**
  As mentioned above, the health and safety concerns that are addressed under the *Semen Regulations*, for example, are similarly not applicable in this circumstance given that any *in vitro* embryo created for this purpose would not be used for reproduction. The use of sperm and eggs to create an *in vitro* embryo to provide instruction in assisted human reproduction procedures is permitted, although the donor's consent is required for its use for this purpose.

Question 3: Do you have any comments on the requirements for consent regarding the ***removal*** of human reproductive materials from a donor's body posthumously for the purpose of creating an embryo for:

- for the reproductive use of the donor's spouse/common law partner;
- for improving assisted human reproduction procedures; or
- for providing instruction in assisted human reproduction procedures.

Question 4: Do you have any comments on the proposal that prior to providing a consent, a donor must be informed that his or her donation or any resulting *in vitro* embryo may not be used due to the presence of disease, lack of viability, or for some other reasons in which case the human reproductive material or *in vitro* embryo may be disposed of?

[4] The *Processing and Distribution of Semen for Assisted Conception Regulations* can be found on the Justice Canada website: http://laws.justice.gc.ca. More information on these regulations can be found on the Health Canada-Inspectorate website: http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/gui_41_entire_e.html#3.

5.3 Consent by the donor to the use of an *in vitro* embryo for any purpose

Subsection 8 (3) makes it an offence for a person to use an *in vitro* embryo for any purpose unless the donor(s) of the *in vitro* embryo has provided written consent for that use. Prior to elaborating on this, the expression "*in vitro* embryo donor" must be defined. The Act states that the term donor in relation to an *in vitro* embryo is as defined in the regulations (see definition of "donor" in section 3 of the Act). The authority to define the term "*in vitro* embryo donor" in the regulations is found in paragraph 65(1)(a) of the Act.

As stated in the AHR Act's Principles in paragraph 2: (e)

- *persons who seek to undergo assisted reproduction procedures must not be discriminated against, including on the basis of their sexual orientation or marital status;*

This means that single individuals and same sex partners cannot be discriminated against. For this reason the definition of a donor of an *in vitro* embryo needs to take into consideration all of these possible scenarios.

It is proposed that there be four situations where consent would be required by the regulations for the use of an *in vitro* embryo, as described below:

- **For the donor's reproductive use**
  Consent must be given by the *in vitro* embryo donor(s) before it is used for his, her or their reproductive use.

Health Canada proposes that an "*in vitro* embryo donor" be defined to mean:

- **an individual *for whose reproductive use*** an *in vitro* embryo was created regardless of the source of the sperm and egg used to create the *in vitro* embryo; or
- **spouses or common law partners *for whose reproductive use*** the *in vitro* embryo was created, in which case both spouses or partners become the donor with regard to any further disposition of the *in vitro* embryo; or
- **a third party *for whose reproductive use*** an individual (other than the donor's spouse or common-law partner), or both spouses or both partners, donates *in vitro* embryos, in which case the third party becomes the donor with respect to any further disposition of the *in vitro* embryo.

- **For posthumous reproductive use by the donor's partner**
  The donor of an *in vitro* embryo must have consented ***prior*** to death to the use of their *in vitro* embryo for this purpose.

- **For third party reproductive use**
  In the event that a person(s) has *in vitro* embryos in excess of their reproductive needs, these *in vitro* embryos may be donated for third party reproductive use. However, the *in vitro* embryo donor(s) must consent to the use of their *in vitro* embryo(s) for this purpose.

It will be important and necessary for donors who provide their supernumerary *in vitro* embryos for third party reproductive use to understand that their consent in this context includes consent to ***all possible future uses***, as authorized by the Act,

of that *in vitro* embryo created using their reproductive materials. Once they have donated their *in vitro* embryo and it has been assigned to a third party, it will be up to the third party to decide how this *in vitro* embryo will be used[5].

- **For research**
  In the event that a person(s) has *in vitro* embryos in excess of their reproductive needs, these *in vitro* embryos may be donated for research purposes[6]. However, the *in vitro* embryo donor must consent to the use of their *in vitro* embryo(s) for this purpose.

  In particular, if an *in vitro* embryo is donated to research to derive stem cells, then a separate consent to that effect is required in order to conform to the March 2002 *Canadian Institutes of Health Research's Human Pluripotent Stem Cell Research Guidelines* as referred to in the Act (see definition of "consent" in section 3 and subsection 40(3.1) of the Act).

Where an *in vitro* embryo is created, it is proposed that the regulations would outline that the donors must be informed that their *in vitro* embryo may not be used due to the presence of disease, lack of viability or some other reasons in which case the *in vitro* embryo may be disposed of. Donors must be informed of this possibility, before providing consent to any use of their *in vitro* embryo.

However, they could then decide to consent to another purpose (e.g. research). In that instance, he or she may vary or withdraw his or her consent, provided that the person who has control of the *in vitro* embryo at the time of the withdrawal or variation of the consent is notified, in writing, of that withdrawal or variation of consent prior to the *in vitro* embryo being assigned to an individual or couple for their reproductive use or to a licensed researcher for research use.

[5] For example, if a couple donates their *in vitro* embryos to another couple for use during their IVF treatment, once the *in vitro* embryos have been donated and assigned to the second couple, the first couple would no longer have a say as to the future use of the *in vitro* embryos, i.e. should they stay in storage, should they be given to research. Such decisions would be for the second couple (and not the original *in vitro* embryo donors) to decide.

[6] Information about *in vitro* embryo research in the context of the Act, including examples of such research, can be found on the Health Canada website: http://hc-sc.gc.ca/english/protection/reproduction/research.html

Mutual Consent

In the above situations, it is important to note that where consent from two people is required, such as, for example, in the case of donation of an *in vitro* embryo by a couple, both parties' consent would need to be compatible. This would ensure that in cases of divorce, or death, one partner could not use the *in vitro* embryo without the matching consent of their ex-partner.

A donor may change or withdraw their consent as long as the *in vitro* embryo has not been used for its intended purpose. However, once they have donated their *in vitro* embryo to a third-party and the third party has provided written consent to the use of the *in vitro* embryo, neither "original" donor could alter their consent as it would be up to the third party to decide how this *in vitro* embryo would be used.

A fictionalized case scenario is given at Annex B to help explain the policy intent of the AHR Act that would be reflected in the regulations.

Question 5: Do you have any comments on the proposed definition of an *in vitro* embryo donor?

Question 6: Do you have any comments on the requirements for section 8 regulations (consent) regarding the ***use*** of an *in vitro* embryo as follows:

- for the donor's reproductive use; or
- for posthumous reproductive use by the donor's partner; or
- for third party reproductive use; or
- for research.

Question 7: Specifically, do you have any comments on the proposal that, in order to obtain informed consent, donors must be informed that:

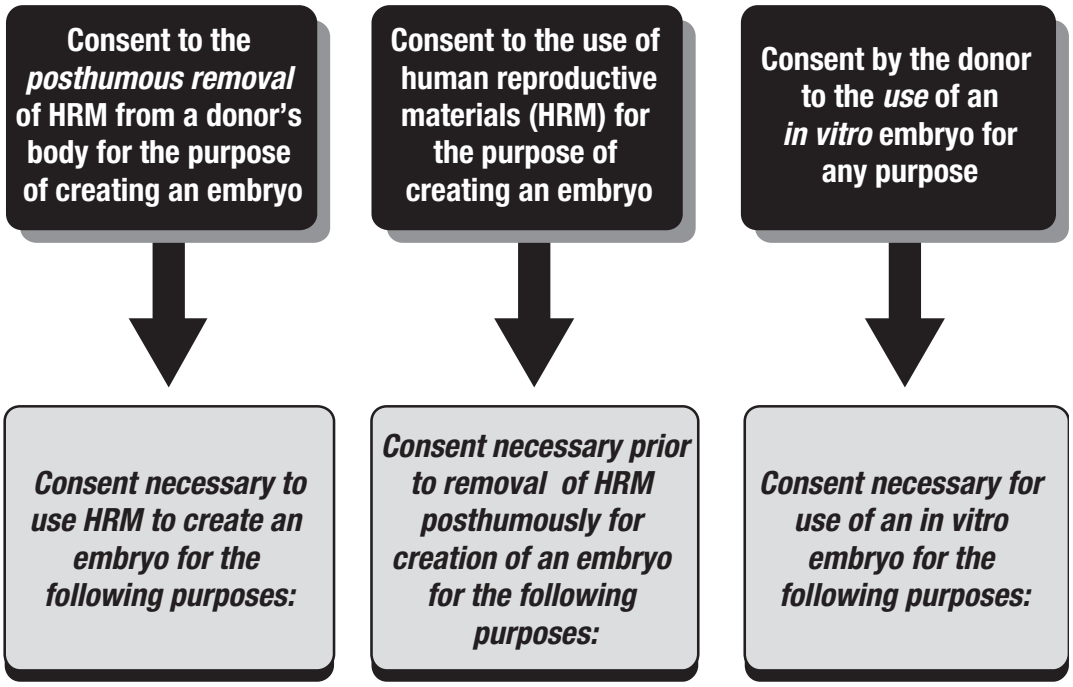
- their *in vitro* embryo may not be used due to the presence of disease, lack of viability or some other reasons in which case the *in vitro* embryo may be disposed of; and
- that he or she may vary or withdraw his or her consent, provided that the person who has control of the *in vitro* embryo at the time of the withdrawal or variation of the consent is notified, in writing, of that withdrawal or variation of consent prior to the *in vitro* embryo being assigned to an individual or couple for their reproductive use or to a licensed researcher for research use?

Question 8: Do you have any comments regarding the proposed requirement for mutual consent?

And finally, these general questions:

Question 9: For those directly engaged in providing AHR services, what impact do you foresee these regulations will have on your day-to-day operations?

Question 10: Do you have any general comments you wish to share with Health Canada concerning the issues raised in this document?



Donors own use	For the donor's own reproductive use For posthumous reproductive use by the donor's partner	For the donor's partner's own reproductive use	For the donor's own reproductive use For posthumous reproductive use by the donor's partner
Third Party use	For third party reproductive use	—	For third party reproductive use
Other	For improving AHR procedures For providing instruction in AHR procedures	For improving AHR procedures For providing instruction in AHR procedures	For research

Case Scenario – Who are the Donors if *in vitro* Embryos are Created?

This is a fictionalized case scenario to help explain the policy intent of the AHR Act that would be reflected in the regulations:

Ms. X – egg donor

Mr. Y – sperm donor

Mr. and Mrs. P – couple needing a donated *in vitro* embryo

Ms. X donates her eggs and consents to the creation of an embryo using her egg, for a third party reproductive use.

Mr. Y donates his sperm and consents to the creation of an embryo using his sperm, for a third party reproductive use.

Both **Ms. X and Mr. Y** sign individual consent forms. Both donors realize that once the eggs or the gametes have been assigned to a third party for the creation of an *in vitro* embryo, they can no longer change or withdraw their consents.

Mr. and Mrs. P need IVF and require donated *in vitro* embryos. They intend to use the *in vitro* embryos created with the gametes of Ms. X and Mr. Y.

Six *in vitro* embryos are created for **Mr. and Mrs. P** and two are transferred to Mrs. P's uterus. The remaining four *in vitro* embryos are cryopreserved for future use. Mrs. P gives birth to a child.

This chain of events follows:

- After a year, **Mr. and Mrs. P** seek a divorce.
- Mr. P does not want Mrs. P to use their stored embryos for IVF treatment. Mr. P withdraws his consent for Mrs. P's use of the *in vitro* embryos.
- Mrs. P wants to use the *in vitro* embryos for her own use but realizes she cannot without Mr. P's consent. However, Mrs. P decides that, if Mr. P consents, she would like the *in vitro* embryos to be donated to research or donated to another couple or individual for their IVF treatment.
- Mr. P agrees to the latter and both Mr. and Mrs. P sign consent forms agreeing to the donation of the *in vitro* embryos to a third party. Mr. and Mrs. P realize that once the *in vitro* embryos have been assigned, they can no longer change or withdraw their consents.