



## Information Sheet on 'Consent To Use' Regulations Section 8 of the Assisted Human Reproduction Act

The *Assisted Human Reproduction Act* (AHR Act) provides a mechanism to oversee activities such as *in vitro* fertilization and research related to assisted human reproduction, and prohibits ethically unacceptable activities such as human cloning. The Act helps protect the health and safety, human rights and dignity of Canadians.

The purpose of section 8 of the AHR Act is to ensure that human reproductive material for creating embryos and *in vitro* embryos are used only with the donor's written consent. The essential element of consent under the Act and the regulations concerns the use of human reproductive material or *in vitro* embryo. It is expected that future regulations will address elements that may impact on other aspects of consent, such as storage or destruction of human reproductive material and *in vitro* embryos, etc.

As of December 1, 2007, section 8 of the AHR Act requires all persons (e.g., clinics, physicians, nurses and laboratory personnel) making use of human reproductive material (sperm or eggs) to create an embryo, or making use of an *in vitro* embryo (an embryo that exists outside the human body) for any purpose, to have the written consent of the individual (i.e., the "donor") providing the human reproductive material or *in vitro* embryo. In addition, the regulations require that a person making use of the human reproductive material or *in vitro* embryo must have a document signed by the donor acknowledging that the donor received certain written information prior to the donor giving their consent to such use.

### **Human reproductive material (sperm or eggs) used to create an embryo**

The human reproductive material used to create an embryo will be used only in accordance with the consent to use of the donor, for one or more of the following purposes:

- the donor's own reproductive use,
- following the donor's death, the reproductive use of the person who is, at the time of the donor's death, the donor's spouse or common-law partner,
- the reproductive use of a third party,
- improving assisted reproduction procedures,
- providing instruction in assisted reproduction procedures.

### **Where *in vitro* embryos are to be created from the human reproductive material of a donor, the donor must also be informed that:**

- There may be more *in vitro* embryos created than are needed for the reproductive use of the individual or couple for whom they were created.
- If *in vitro* embryos are created for a third party's reproductive use, and there are embryos in excess of the third party's reproductive needs, the third party's consent is required for use of the excess embryos. Should the third party wish to donate those excess embryos for improving or providing instruction in assisted reproduction procedures or other research, then the person who donated the sperm or eggs to create the *in vitro* embryos must also have given their prior written consent for such use.
- In the event of the donor's death, any *in vitro* embryos, created from the donor's human reproductive material (with consent that it be used) for the surviving spouse/common-law partner's reproductive use, will be used according to the surviving spouse or partner's consent to use. However, should there be more embryos than were needed by the surviving spouse/partner

and he/she wishes to donate those excess embryos for improving or providing instruction in assisted reproduction procedures or other research, then the deceased donor must have also given their prior written consent for such use.

- If the donor's human reproductive material is used to create *in vitro* embryos for the reproductive use of a married couple or common-law partners, along with human reproductive material from one of the individuals in that couple, should that couple divorce or separate before the *in vitro* embryos are used, only that individual in the couple who has provided the human reproductive material needs to consent to how the embryos will be used.
- If the donor consents to the human reproductive material being used to create an *in vitro* embryo for the purpose of providing instruction in or improving assisted human reproduction procedures, no additional consent to use from the donor is required to permit the use of the embryo for that purpose.

### **In vitro embryos used for any purpose**

The *in vitro* embryo will be used only in accordance with the consent of the donor for one or more of the following purposes:

- the donor's own reproductive use,
- the reproductive use of a third party,
- improving assisted reproduction procedures,
- providing instruction in assisted reproduction procedures,
- a specific research project, the goal of which is stated in the consent to use.

### **Withdrawal of Consent to Use**

For a withdrawal of consent to use to be effective, the following conditions must be met:

- the withdrawal must be in writing,
- the clinic, physician, researcher or other person who will be using the human reproductive material or *in vitro* embryo must be notified of the withdrawal.
- For withdrawing consent to the use of human reproductive material for one's own reproductive use or that of the spouse or common-law partner, or improving or providing instruction in assisted reproduction procedures, the notice must be received before the material is used.
- For withdrawing consent to the use of human reproductive material for the reproductive use of a third party, the notice must be received before the third party has acknowledged in writing that the material has been designated for their reproductive use.
- For withdrawing consent to use an *in vitro* embryo for one's own reproductive use, the notice must be received before the use of the *in vitro* embryo.
- For withdrawing consent to use an *in vitro* embryo for the reproductive use of a third party, the notice must be received before the third party has acknowledged in writing that the embryo has been designated for their reproductive use.
- For withdrawing consent to use *in vitro* embryos for improving or providing instruction in assisted reproduction procedures, the notice must be received before the later of:
  - the person conducting the activity has acknowledged in writing the designation of the embryo for that activity, OR
  - the person conducting the activity has begun the thawing of the embryo for that activity.
- For withdrawing consent to use *in vitro* embryos for a specific research project, the notice must be received before the later of:

- the person conducting the activity has acknowledged in writing the designation of the embryo for that activity, OR
- the person conducting the activity has begun the thawing of the embryo for that activity; OR
- the creation of a stem cell line using the *in vitro* embryo.

### **Posthumous donations**

Before a physician can remove human reproductive material from a donor's body after death for the purpose of creating an embryo, the physician must have a written document signed by the donor, stating that before consenting to the removal of human reproductive material after death, the donor was informed in writing that:

- The human reproductive material will be removed after death only in accordance with the donor's consent to use the material to create an embryo, for one or more of the following purposes:
  - the reproductive use of the person who is, at the time of the donor's death, the donor's spouse or common-law partner,
  - improve assisted reproduction procedures,
  - provide instruction in assisted reproduction procedures.
- The donor may withdraw their consent to the posthumous removal and:
  - the withdrawal must be in writing,
  - the withdrawal is effective only if the person who intends to remove the human reproductive material is notified of the withdrawal before the removal of the material.
- Before removing the human reproductive material from a donor's body after death for a purpose above, in addition to the signed acknowledgement of information relating to removal on death, the physician must have both:
  - the donor's written consent to remove the human reproductive material; and
  - the donor's written consent to use of the human reproductive material.

### **Definitions**

**Common-law partner:** The individual who, at the relevant time, is cohabitating with the donor (or third party) in a conjugal relationship of at least one year prior to the relevant time.

**Donor:** In relation to reproductive material, "donor" means the individual from whose body the sperm or eggs were obtained, even if it is for the individual's own reproductive use.

In relation to an *in vitro* embryo, "donor" means the individual or couple for whose reproductive use the *in vitro* embryo has been created, regardless of the source material used to create the embryo.

***In vitro* embryo:** An embryo that exists outside the body of a human being.

**Reproductive Material:** Sperm or eggs obtained for the purpose of creating an embryo (including an *in vitro* embryo).

**Third Party:** In relation to reproductive material, "third party" means an individual or couple other than the donor of the reproductive material or the spouse/common-law partner of the donor.

In relation to an *in vitro* embryo, "third party" means an individual or couple (spouses or common-law partners) other than the individual or couple for whom the *in vitro* embryo has been created.