Health Canada Santé Canada

Assisted Human Reproduction Implementation Office

Consultation Background Paper Seeking Input Concerning Health Reporting Information Under the *Assisted Human Reproduction Act*

Couples Undergoing Procedures Using their Own Gametes

Fall 2006 Consultations

November 17, 2006

Canada

1. Subject

Regulations related to health reporting information (HRI) under the *Assisted Human Reproduction Act* (AHR Act) for couples undergoing procedures using their own human reproductive material (HRM) or *in vitro* embryos created with their own gametes.

The purposes of this paper are: to provide background information about the AHR Act and HRI; to highlight the topics of discussion during the upcoming consultations in November and December of 2006; and, to outline the factors that will guide how HRI could be regulated.

2. Purpose of Consultations

The purpose of the consultations is to seek comment on policy options being developed for regulations intended under the AHR Act. The discussions will focus on the HRI to be collected from couples undergoing procedures using their own gametes.

3. Introduction and Background

The AHR Act received Royal Assent on March 29, 2004. On April 22, 2004, most of the prohibitions under the AHR Act came into force. The Act also provides for the establishment of the Assisted Human Reproduction Canada (AHRC or 'the Agency'), that will oversee the area of assisted human reproduction in Canada.

The AHR Act has created an obligation on licensees to collect HRI about patients prior to accepting donations of HRM and performing an assisted reproduction procedure.

Section 3 of the AHR Act defines HRI as information provided under the Act respecting:

> *(a) 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*
>
> *(b) the custody of donated human reproductive materials and in vitro embryos and the uses that are made of them.*

The HRI will be collected only in order to meet the principles of the AHR Act and to enable the Agency to meet its obligations.

Principles of the AHR Act

Several principles found under section 2 of the AHR Act are important to guide the development of regulations concerning HRI, in particular, Parliament recognized:

- the need to protect and promote human health, safety, dignity and rights in the use of reproductive technologies and research;
- the health and well-being of all involved is to be protected and promoted, with priority given to children born from reproductive technologies and women who are directly and significantly affected; and,
- free and informed consent is a fundamental condition of the use of reproductive technologies.

Obligations of the Agency

Information will be required to be collected by licensees to allow the Agency to meet its obligations.[1] One of these obligations is to maintain a personal health information registry about donors, persons who undergo assisted reproduction procedures and of offspring conceived through AHR. The Agency may use HRI for the purposes of the administration and enforcement of the AHR Act, and for the identification of health and safety risks.

The AHR Act also restricts the Agency from disclosing HRI unless otherwise authorized. However, the Agency may need to disclose HRI in certain circumstances stipulated in the AHR Act, such as to comply with a subpoena compelling the production of information.

Controlled Activities

Pursuant to sections 10 to 12 of the AHR Act, a controlled activity means an activity that may not be undertaken, except in accordance with the regulations and a licence, to alter, manipulate or treat any HRM or an *in vitro* embryo. It also includes activities to obtain, store, transfer, destroy, import, or export reproductive material or *in vitro* embryos. The controlled activities that will be discussed during the consultations include: semen obtaining, semen analysis and processing, oocyte retrieval, controlled ovarian hyperstimulation, oocyte processing, IVF with insemination, IVF with intracytoplasmic sperm injection (ICSI), *in vitro* embryo culture and assessment, and, *in vitro* embryo transfer.

Donor

A donor, in relation to human reproductive material, is the individual from whose body it was obtained. A donor in relation to *in vitro* embryos, has been defined in proposed regulations as meaning the individual or couple for whom the *in vitro* embryo was created, regardless of the source of the HRM used to create the *in vitro* embryo.

Licensee

[1] To view the full obligations of the Agency, please refer to the AHR Act or see highlights in Appendix A

A licensee has obligations related to HRI under the AHR Act, some of which will be discussed during the consultations. The obligations are outlined in greater detail in the topics of discussion[2].

4. Topics of Discussion

Topic 1 : Collection of HRI related to medical history and genetic information, and to the custody and uses of HRM and *in vitro* embryos.

Subsection 14(1) the AHR Act stipulates:

> *A licensee shall not accept the donation of human reproductive material or an in vitro embryo from any person for the purpose of a controlled activity, and shall not perform a controlled activity on any person, unless the licensee has obtained from that person the health reporting information required to be collected under the regulations.*

Prior to accepting a donation or accepting HRI from a person, the licensee must also inform that person of the requirements of the Act relating to the retention, use, disclosure and destruction of HRI and obtain the written consent of the person regarding the application of these requirements.

Custody of HRM or *in vitro* embryos serves to identify who has obtained gametes and *in vitro* embryos, who has them in their possession, and to which donor it relates. The uses made of sperm, eggs or an *in vitro* embryo are linked to the type of controlled activity undertaken (e.g., IVF, ICSI), when it was performed and by whom.

Preliminary discussions with some practitioners performing assisted reproduction procedures have revealed that they collect a considerable amount of health information. The data collected, however, differs from one practitioner to another. Consequently, the regulations will establish the health information that will be considered HRI for the purposes of the AHR Act.

Accordingly, part of the consultation exercise will focus on obtaining stakeholder feedback on health information that would be considered HRI under the AHR Act.

Topic 2: Retention and destruction of HRI.

In subsection 16(2) the AHR Act stipulates:

> *A licensee or any other person that has control of the health reporting*

[2] To view the full obligations of the licensee, please refer to the AHR Act or see highlights in Appendix A .

information provided by a donor of human reproductive material or an in vitro embryo, by a person who has undergone an assisted reproduction procedure or by a person who was conceived by means of such a procedure, shall, at the request of the donor or that person, as the case may be, destroy that information in the circumstances and to the extent provided by the regulations, and shall inform the donor or that person that the destruction has occurred.

The time period that HRI must be retained by licensees and the circumstances and the extent to which a licensee can destroy HRI will have to be defined in regulations. Having a retention period established in regulations and the circumstances and the extent to which HRI can be destroyed will be essential when seeking a patient's informed consent for HRI.

One consideration in setting the retention period is that HRI could be retained to allow access in the event it is required to trace medical history if any health complications arise associated with assisted reproduction procedures. As the health of any offspring must also be considered, the HRI about the assisted reproduction procedures the couple has undergone could also be retained to assist physicians to diagnose any health conditions in offspring that may be associated with their conception from AHR.

It is also essential that the HRI related to the custody and the uses of reproductive material and *in vitro* embryos are retained and tracked for a minimal period of time. As some assisted reproduction procedures are relatively new and the risks to patients and offspring are not well known (such as ICSI), consideration could be given to retain this information should further analysis of assisted reproduction procedures and their effects on health be warranted. The Agency also has the authority under the AHR Act to collect, analyse and manage health reporting information relating to controlled activities.

While destruction of HRI could occur following an established minimal time period for retention, the actual HRI that could be destroyed will also need to be discussed. For example, if any HRI is retained for analytical purposes, the identity of a donor could be removed while the remaining HRI could be retained. When destruction occurs a record could also be required indicating the date of the destruction, the method of destruction, and the person supervising the destruction of the HRI.

While assisted reproduction practitioners have varying retention periods for the health information they collect, HRI regulations could set a minimum standard of time that the HRI should be retained. During the consultations, feedback will be solicited which will lead to options for retention of HRI and the circumstances and extent that HRI can be destroyed.

Topic 3: The disclosure of HRI by a licensee to the Agency.

Subsection 15(2) of AHR Act stipulates:

15(2) A licensee shall disclose health reporting information (a) to the Agency, to the extent required by the regulations [...]

Another issue which needs to be addressed is the extent to which the HRI collected by licensees should be disclosed to the Agency. A number of options will be discussed, namely:

- disclosure of all HRI collected by licensees to the Agency
- partial disclosure; or,
- disclosure only when required by the Agency

Topic 4: Financial and operational impacts (on licensees/IVF Clinics) of HRI collection, retention, destruction, and disclosure to the Agency.

It will be important to determine from participants, prior to the introduction of regulatory requirements concerning HRI, whether any additional financial and operational impacts may result from the proposed approaches to collecting, retaining, destroying and disclosing HRI.

Appendix A: Summary Table - Obligations and Authorities Respecting HRI Under the AHR Act

Obligations	Licensee	Agency
Collection	• s.14(1) HRI of donors of HRM and *in vitro* embryos • s.14(1) HRI of persons undergoing a controlled activity	• HRI is disclosed to the Agency by a licensee • s.24(1)(e) Agency may collect, analyse and manage HRI relating to controlled activities
Retention Period	• will be set out in the regulations	s.17 Personal Health Information Registry, containing HRI about: • donors of HRM and *in vitro* embryos • persons who undergo assisted reproduction procedures • persons conceived by means of those reproductive procedures
Use	To meet the licensees' obligations under the AHR Act	s.18 (1) Agency may use HRI for: • administration and enforcement of the Act • identification of health and safety risks, potential and actual abuses of human rights • ethical issues associated with AHR technologies and other matters to which this Act applies.

Obligations	Licensee	Agency
Disclosure	**a) Obligation to disclose (may include identity)** • s.15(2)(a) to the Agency, to the extent required by the regulations • s.15(2)(b) to the extent required for the administration of health care insurance plan under the *Canada Health Act* • s.15(2)(c) to comply with a subpoena, warrant or order by a court or person with jurisdiction, or to comply with rules of a court to produce information • s.15(2)(d) to the extent required by the provisions of federal or provincial law respecting health and safety specified in the regulations • s.15(3) to another licensee when HRM or *in vitro* embryo in its possession is transferred as specified in the regulations • s.15(4) the HRI in its possession respecting a donor, to the person undergoing the procedure, before performing an assisted reproduction procedure, however, the identity of the donor shall not be disclosed without the donor's written consent.	**a) Obligation to disclose (may include identity)** • s.18(3) a donor's HRI to a person undergoing an assisted reproduction procedure (identity is disclosed on request only with the donor's written consent) • s.18(3) a donor's HRI to persons conceived by means of assisted human reproduction and their descendants (identity is disclosed on request only with the donor's written consent) • s.18(5)(a) to comply with a subpoena, warrant or order, by a court or person with jurisdiction, or to comply with rules of a court to produce information • s.18(5)(a) per provisions of any federal or provincial law respecting health and safety that are specified in the regulations.
	b) Obligation to disclose • s.15(3.1) notify the Agency when an *in vitro* embryo is transferred between licensees in accordance with the regulations.	**b) Obligation to disclose (without identity)** • s.18(4) by written request of two individuals who have reason to believe that one or both were conceived by means of an assisted reproduction procedure, the Agency shall disclose to both whether is has information that they are genetically related, and if so, the nature of the relationship • s. 24(2)(b) on request by the Minister

Obligations	Licensee	Agency
Discretion to Disclose	**Discretion to disclose (without identity)** • s. 15(5) to an individual or organization for scientific research or statistical purposes.	**a) Discretion to disclose (may include identity)** • s.18(6)(a) for the purposes of the enforcement of the AHR Act • s.18(6)(b) for the administration of a health care insurance plan under the *Canada Health Act* • s.18(6)(c) for the purposes of disciplinary proceedings undertaken by a professional or disciplinary body under the laws of Canada or a province and specified in the regulations • s.18(7) the identity of a donor to a physician to address a risk to the health or safety of a person who has undergone a procedure, was conceived by means of such a procedure, or a descendant **b) Discretion to disclose without identity** • s.18(8) to an individual or organization for scientific research or statistical purposes, other than identity or identifying information

Access	• s.16(1) a person shall be given, on request, access to any HRI about the person that is under control of the licensee. This person may:
	  • request the correction of HRI,
	  • require a notation be attached if the requested correction was not made
	  • require that the correction/notation be communicated to any person or body to whom the information was disclosed during 2 years preceding the request.
		• Access to information and any modifications are subject to the *Privacy Act* and the *Access to Information Act*

Destruction	• s.16(2) the licensee shall destroy HRI at the request of donors of HRM or *in vitro* embryos, persons who have undergone procedures and persons conceived by means of such procedures to the extent provided by the regulations.	• Destruction of information is subject to the *Library and Archives of Canada Act*