Assisted Human Reproduction Canada | Procréation assistée Canada

Newsletter

Assisted Human Reproduction Canada

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Message from the President

Dr. Elinor Wilson, President

In our inaugural newsletter last November, we introduced readers to the Assisted Human Reproduction Canada (AHRC) Board of Directors and provided an overview of the principles and values that would guide their efforts to develop AHRC into a world-class regulatory agency in which all Canadians can take pride. We also noted the challenges of building an agency from the ground up, and our commitment to engaging Canadians in the process.

AHRC has now been in operation for over one year. From the beginning, our first priority has been to protect the health and safety of Canadians seeking access to, or born of, assisted human reproduction (AHR) technologies. At the same time as we have been building our core capacity, we have also been working with the AHR community to better understand what we need to do to promote awareness of and compliance with the *Assisted Human Reproduction Act* (AHR Act) and its regulations. For example, we recently developed a Guidance Document for clinics on the new Consent to Use regulations (section 8 of the Act). We intend to do the same for other upcoming regulations.

In this newsletter, we provide a thumbnail primer on certain sections of the AHR Act as well as an update on the implementation and enforcement of regulations. We also summarize the results of a national consultation we organized on AHR Oversight.

We are making steady progress!

Dr. Elinor Wilson
President

Inside:

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Protecting Health and Safety

While the AHR Act received Royal Assent on March 29, 2004, not all of its sections are yet in force. As described below in the ***Thumbnail Primer on the AHR Act*** and the ***Update on Regulations***, regulations giving effect to certain key provisions of the Act are being introduced in stages by the Government of Canada.

But even as Health Canada develops the remaining regulations, we are working hard to promote broad understanding of and adherence to the Act and the current regulations relating to Consent to Use. In the event that an alleged contravention of an activity prohibited under the Act is brought to our attention, or we learn that the Consent to Use regulations are not being followed, we will take action. Protecting the health, safety and dignity of Canadians is our paramount concern.

Our compliance strategy focuses on encouraging and facilitating compliance with the AHR Act through education and engagement. For example, we have developed a Guidance Document to help key AHR stakeholders understand and comply with the requirements of the Consent to Use regulations. We have also been working with Health Canada, the Canadian Fertility and Andrology Society, and the Society of Gynaecologists and Obstetricians of Canada to identify and resolve implementation issues associated with regulatory compliance. And we plan to use our interactive Web site to deliver timely and complete information on the regulations and their effects.

A Thumbnail Primer on the AHR Act

In 1978, the birth of the world's first baby conceived through *in vitro* fertilization—a process through which a woman's egg is fertilized outside her body—set in motion a series of deliberations on assisted human reproduction (AHR) that continue to evolve and are unlikely ever to be fully resolved. On one hand, the technique offered hope to couples and individuals having difficulties building a family. On the other hand, it gave rise to profound and sometimes heated debate as to the ethical, legal, philosophical, theological and scientific implications of both the technology itself and future research in this emerging field.

Like many other countries, Canada recognized the need for legislation and oversight in the field of AHR to protect the health and safety of Canadians using AHR technologies, and to provide a framework compatible with the values of Canadians. While professional colleges, accreditation boards and research ethics bodies moved quickly to establish guidelines for AHR research and practices, the need for a uniform policy and legislative framework for AHR that would apply equally across the country soon became apparent.

In order to engage Canadians and experts in a national dialogue on the issue, in 1989 the Government of Canada established a Royal Commission on New Reproductive Technologies. Although the release of the Royal Commission's final report and recommendations in 1993 was an important step forward in clarifying issues and options, consensus on the potential elements of a regulatory and oversight regime for AHR took time to finalize. In 2004, after further discussion and debate, Parliament passed the AHR Act.

The Act does not seek to restrict or prohibit Canadians from accessing the treatment they need to build their families. Rather, it aims to protect the health and safety, human rights, and human dignity of Canadians who choose to use AHR procedures or are born of AHR techniques. To that end, the Act also provides that AHR-related research is conducted in an ethical manner and in a controlled environment.

There are two main parts to the Act. One part deals with **prohibited activities** and the other with **controlled activities**, that is, activities that are permitted but, once the Act is fully implemented, will be subject to regulations and licensing.

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Prohibited activities, defined in sections 5 to 9 of the Act, are AHR activities that Parliament has determined to be ethically unacceptable or incompatible with Canadian values, or that pose significant human health and safety risks to Canadians. Prohibited activities under the Act include:

- Human cloning;
- Pre-selecting the sex of an embryo (except to prevent a sex-linked genetic condition);
- Transplanting non-human cells or tissues into a human being;
- Creating a hybrid (a mixture of human and non-human gametes) for the purpose of reproduction, or transplanting a hybrid into a human being or non-human life form;
- Creating a chimera (a mixture of human and non-human cells) for any purpose, or transplanting a chimera into a human being or non-human life form; and
- Paying, offering to pay, or advertising payment for the purchase of sperm, eggs or *in vitro* embryos from donors, or for surrogate mothers (including payment to a third party for arranging for the services of a surrogate mother).

This last prohibition is designed to prevent the "commercialization" of human reproduction. While the Act currently allows donors and surrogate mothers to be reimbursed for legitimate receipted expenditures they may incur, Health Canada is developing regulations to specify what types of expenditures are eligible.

Controlled activities, defined in sections 10 to 12 of the Act, are AHR activities that, once the Act is fully implemented and the regulations are in place, will be permitted if performed in accordance with regulations and by a licensed individual in licensed premises. They include many of the procedures already available, including:

- *In vitro* fertilization (IVF)
- Intra-cytoplasmic sperm injection (ICSI)
- Intrauterine insemination (IUI)
- Donor insemination
- Egg donation
- Transfer of an *in vitro* embryo
- Research on *in vitro* embryos

The Act also provides for:

- The licensing of persons authorized to conduct controlled activities and the licensing of premises at which the controlled activity is to be carried out;
- The creation of Assisted Human Reproduction Canada (AHRC) to oversee and implement the Act;
- Research on human *in vitro* embryos; and
- The development by AHRC of a confidential Personal Health Information Registry (PHIR) of information on donors, persons who undergo AHR procedures, and children born of AHR.

The PHIR, which will be developed in accordance with the AHR Act (s. 17) and Treasury Board's *Policy on Privacy Protection*, will be useful in monitoring and improving the safety and effectiveness of AHR procedures. For example, the PHIR will enable AHRC to issue yearly reports that compare the results of one type of AHR procedure over another.

The donor health information contained in the PHIR can be disclosed by AHRC upon request of persons undergoing an assisted reproduction procedure, their offspring and descendants. However, the donor's identity will not be disclosed without the donor's written consent. This provides for access to important health, social and family history information about the donor but preserves donor anonymity where it is desired.

Consultation on AHR Oversight

AHRC has the mandate to develop an inspection strategy for the AHR Act and its regulations. However, a variety of public sector agencies, professional associations and accreditation bodies already contribute in different ways to providing Canadians with access to safe, appropriate and timely health services. With the bulk of the regulations still in development, the time is right to explore a collaborative oversight approach that takes into account what is already in place in Canada.

With this objective in mind, on January 17 and 18, 2008, AHRC hosted a national invitational consultation of AHR stakeholders on AHR oversight. The meeting objectives included:

- Developing an inventory of potential partners interested in working together to build an effective, efficient and integrated pan-Canadian inspection and oversight system for AHR;
- Reviewing existing AHR legislative requirements and oversight mechanisms in different jurisdictions;
- Identifying ways to share information on best practices with a view to developing pan-Canadian guidelines and standards; and
- Establishing a framework for advancing pan-Canadian collaboration on AHR oversight.

The meeting generated thoughtful discussion on the benefits of an integrated, pan-Canadian approach to AHR oversight, the potential elements of such a regime, and opportunities for working towards its realization. Participants—including representatives from both levels of government—agreed that pursuant to the meeting, AHRC should liaise with provincial and territorial governments, colleges and accreditation bodies to build consensus on next steps. AHRC has already initiated discussion with several key stakeholders in this regard, and plans to host a workshop at the November 2008 annual meeting of the Canadian Fertility and Andrology Society to report on progress.

A summary report of the January 17-18, 2008 meeting will be posted to the AHRC Web site (www.ahrc-pac.gc.ca).

Update on the Implementation and Enforcement of Regulations

The *Update on the Implementation and Enforcement of Regulations* will be a regular feature of our newsletter for the foreseeable future. As we outlined in our inaugural newsletter, Health Canada is responsible for developing policy and regulations for assisted human reproduction under the Act, and will keep you informed in these areas. AHRC's responsibility is to ensure new regulatory requirements are widely understood and to implement and facilitate compliance. The past few months have witnessed significant progress on a number of aspects of the AHR regulatory framework.

The Consent to Use regulations (section 8 of the AHR Act) came into force on December 1, 2007. These regulations require that written consent be obtained before using a person's reproductive material (sperm or eggs) to create an embryo or before using an *in vitro* embryo for any purpose. To assist clinics, physicians and donors affected by these regulations to understand and comply with their requirements, AHRC developed an information package that was mailed out to various stakeholders and posted on our Web site. The package includes:

- A guidance document for clinics and physicians that includes a "plain language" interpretation of the regulations;
- Generic "consent to use" clauses that clinics and physicians can use as-is, or adapt as required, for their consent forms;
- Questions and answers about the Consent to Use regulations;
- An information sheet for providers of AHR services; and
- An information sheet for donors.