Health Canada Santé Canada

Questionnaire and Response Form

November, 2004

Canada

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maintain and improve their health.
Health Canada

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**Please use additional pages if necessary*

Consent to the use of human reproductive materials (HRM) for the purpose of creating an embryo

Question 1: Do you have any comments on the requirements for section 8 regulations (consent) 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;

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

- for third party reproductive use;

- for improving assisted human reproduction procedures; or

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

- 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?

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

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 the reproductive use of the donor's spouse/common law partner;

- for improving assisted human reproduction procedures; or

Question 3 ***(cont'd)*****:** 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 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?

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

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

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

- for posthumous reproductive use by the donor's partner; or

- for third party reproductive use; or

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

- 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?

Question 7 *(cont'd)*: Specifically, do you have any comments on the proposal that, in order to obtain informed consent, donors must be informed that:

- 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?

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?

Please submit your comments by December 10, 2004, using the form below.

Information about the regulatory development process and how to participate in future consultations will also be posted on Health Canada's website at

www.hc-sc.gc.ca/english/protection/reproduction/index.htm

www.hc-sc.gc.ca/francais/protection/procreation/index.htm

Response to the Document on "Regulations Concerning Section 8 (Consent) of the AHR Act (Consent) and the Definition of an *In vitro* Embryo Donor

Please send the following information with any comments you have pertaining to the questions or any other comments concerning the regulatory proposal in relation to section 8 and/or the proposed definition of an "*in vitro* embryo donor" to the address below. Please note that all information collected is subject to the *Access to Information Act* and the *Privacy Act* so respondents may not wish to provide identifying information.

The Assisted Human Reproduction Implementation Office (AHRIO)
Health Canada, AL 7002A
Ottawa, Ontario K1A 0K9
fax: (819) 934-1828
e-mail: ahr-pa@hc-sc.gc.ca

NAME (optional) _____

ADDRESS (optional) _____

_____

_____

EMAIL (optional) _____

IN WHICH STAKEHOLDER GROUP DO YOU BELONG (e.g. patient, individual born from an AHR procedure, AHR physician, AHR clinic employee)?

_____

WOULD YOU LIKE TO BE INCLUDED ON AHRIO'S MAILING LIST? _____

WOULD YOU LIKE TO BE ADVISED OF ANY FUTURE CONSULTATION EXERCISES CONCERNING THE AHR REGULATORY FRAMEWORK?

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