[Section 9]

RESEARCH INVOLVING HUMAN GAMETES, EMBRYOS OR FOETUSES

Because the topic of human reproduction invokes a discussion of fundamental values, research involving new reproductive technologies engenders acute ethical concerns for both the research community and the public at large. Respect for human dignity remains a paramount consideration in evolving ethical, policy and societal deliberations. Within this scenario, researchers and REBs have a continuing duty to remain abreast of the public interest in these issues, and to respect the developing policy, legal and regulatory frameworks.

The *Report of the Royal Commission on New Reproductive Technologies*[1] is an authoritative and thorough analysis of Canadian viewpoints, reflecting both the divisions and areas of consensus, within society, on these important matters. Statements of Government policy in effect at the time of drafting this Policy Statement have arisen from the Royal Commission Report. A moratorium on certain practices was announced by the Minister of Health in July 1995, and draft legislation (Bill C-47) was under consideration in the House of Commons at the time of the 1997 election.

Informed by such public and scholarly discussions, this Policy suggests to REBs a pragmatic position on research involving human reproduction. The position recognizes the following:

- That the present status of the law, ethics and health care in Canada regarding research in human reproduction is broadly consistent with a graduated approach that correlates permitted interventions with the developmental stages of the human embryo or foetus.

- That a careful, moderate and controlled approach to human reproductive research is preferred to the relatively uncontrolled introduction of new practices as therapy.

In addition to the considerations expressed elsewhere in this Policy, the following bear specifically on research involving the conception and development of human embryos and foetuses. REBs and researchers should be mindful of these guidelines in reviewing and conducting research:

- Research on human reproductive tissues or cells that are intended to result in an ongoing pregnancy is unacceptable—if the knowledge sought may be obtained by the use of other systems or models.

- Research involving the conception and development of human embryos and foetuses may prove beneficial due to the present lack of knowledge and its impact on the adequacy of care.

Such research raises many complex concerns, including possible physical harms to the embryo or foetus, the question of who may consent for the foetus, and an overall concern of respect for the embryo or foetus.

A. Research Involving Human Gametes

Article 9.1 **Researchers shall obtain free and informed consent from the individual whose gametes are to be used in research.**

Human reproductive cells (ova or sperm) may be obtained from a research subject as part of standard care, or may be requested solely for research. Sperm is relatively easy to obtain, while ova can only be obtained by a surgical procedure. As elaborated more generally in Section 2, researchers have a duty to seek the free and informed consent of prospective subjects for research involving their reproductive cells. Consistent with general requirements of full disclosure, subjects should be informed of the purpose of the proposed research, such as research involving infertility or birth control. The requirement for free and informed consent applies, of course, if the gametes were originally provided for a purpose other than research. Researchers and REBs should also pay close attention to the social sensitivity of such research.

The moratorium announced by the Minister of Health in July 1995 prohibits research involving gametes derived from cadavers. Respect for human dignity also means that it is unacceptable to obtain gametes from foetuses or individuals unable to consent for themselves.

Article 9.2 **In research, it is not ethical to use ova or sperm that have been obtained through commercial transactions, including exchange for service.**

Inspired by the fundamental ethical principle of respect for human dignity, Article 9.2 expresses the moral prohibition against the commercialization of human reproduction.

Article 9.3 **It is not ethically acceptable to create, or intend to create, hybrid individuals by such means as mixing human and animal gametes, or transferring somatic or germ cell nuclei between cells of humans and other species.**

Combining human genetic material with that of other species has the potential to create new life. The creation of hybrid individuals or species that may survive, or are intended to survive, violates our basic norm of respect for human life and dignity. Article 9.3 expresses this concern, while acknowledging that other related research may raise fewer ethical objections.

B. Research Involving Human Embryos

Research where fertilization occurs should be regarded as research on embryos.

Article 9.4 **It is not ethically acceptable to create human embryos specifically for research purposes. However, in those cases where human embryos are created for reproductive purposes, and subsequently are no longer required for such purposes, research involving human embryos may be considered to be ethically acceptable, but only if all of the following apply:**

(a) **The ova and sperm from which they were formed are obtained in accordance with Articles 9.1 and 9.2;**

(b) The research does not involve the genetic alteration of human gametes or embryos;

(c) Embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and

(d) Research involving human embryos takes place only during the first 14 days after their formation by combination of the gametes.

Research potentially altering the embryo by chemical or physical manipulation should be distinguished from research directed at ensuring normal development. For example, evaluation of potential teratogens and their effects on certain cell lineages may use early embryos, but those embryos must not be implanted for an ongoing pregnancy. On the other hand, pre-implantation diagnosis of a serious genetic disorder may involve testing of one cell of the early embryo, but not manipulation of the embryo itself ultimately destined for implantation (see Section 8).

The broad consensus restricting research on embryos to the first 14 days of development is based on the stages of biological development. Implantation usually begins at approximately the sixth or seventh day of development, and is usually completed around 14 days, beyond which time the embryo proper starts to develop the primitive streak, or the first indication of neural development.

Article 9.5 **It is not ethically acceptable to undertake research that involves ectogenesis, cloning human beings by any means including somatic cell nuclear transfer, formation of animal/human hybrids, or the transfer of embryos between humans and other species.**

Article 9.5 recognizes that while some research involving human reproduction is inherently objectionable to some schools of ethical and religious thought, it may not be so for others. Such techniques have provoked vigorous debates arising from conflicts in values, and such discussion and reflection need to continue. In the meantime, the intrinsic ills, potential harms, and the scientific and ethical uncertainty weigh in favour of not approving such research.

C. Research Involving Foetuses

Research may be undertaken on methods to treat, *in utero*, a foetus that is suffering from genetic or congenital disorders. Because the foetus and the woman cannot be treated separately, any intervention on one involves an intervention on the other. Accordingly, and consistent with the requirements of Section 2, research involving a human foetus requires the free and informed consent of the woman. Research methods on the treatment of foetuses *in utero* thus pose no issues that are not addressed elsewhere in this Policy.

D. Research Involving Foetal Tissue

Research involving the use of foetal tissue should be guided by respect for the woman's dignity and integrity. Researchers should thus obtain the free and informed consent of the woman whose foetal tissue is to be used for research. As a corollary of such respect, it is unacceptable to undertake research interventions that compromise the woman's decision on whether to continue her pregnancy. A former Minister of Health, responding to a question concerning the transplantation into patients of tissues obtained from elective abortions, stated that he would not approve federal funding for such a procedure.[2] The Royal Commission on New Reproductive Technologies has recommended that: "Research projects using foetal tissue (including those related to transplantation in human beings) be eligible for funding by the Medical Research Council of Canada and other public agencies, provided they meet applicable ethical and scientific research standards and tissue is obtained in accordance with the recommendations of the Royal Commission on New Reproductive Technologies." These recommendations include the establishment of a well-defined regulatory and licensing structure.[3]

There are few absolutes in areas such as these, where ethical deliberation and societal values continue to evolve rapidly. Hence, while a woman's autonomy to consent to the use of her foetal tissue shall be respected, countervailing ethical considerations hold that a woman should not direct the use of such tissue to particular individuals, such as choosing to have foetal tissue used for Parkinson's disease research in a relative. The objection is based on concerns that the foetus not be used simply as a source of tissue, but should be recognized as a potential person deserving of respect.

Endnotes

1 Royal Commission on New Reproductive Technologies, *Proceed with Care.* Ottawa, 1993.

2 Canada. Parliament. House of Commons, *Debates (Hansard)*, Question Period. July 15, 1988.

3 Royal Commission on New Reproductive Technologies, *Proceed with Care.* Ottawa, 1993, recommendations p. 289-293.