

# Assisted Human Reproduction Act (2004)

The Assisted Human Reproduction Act (AHR Act) is a piece of federal legislation passed by the Parliament of Canada. The Act came into force on 29 March 2004. Many sections of the Act were struck down following a 2010 Supreme Court of Canada ruling on its constitutionality. The AHR Act sets a legislative and regulatory framework for the use of reproductive technologies such as in vitro fertilization and related services including surrogacy and gamete donation. The Act also regulates research in Canada involving in vitro embryos. The AHR Act was the first law in Canada to regulate the use of reproductive technologies and related research. Most other Canadian policies on AHR rely on the Act and its provisions. By 2015, Canada was one of only a few countries worldwide to comprehensively address assisted human reproduction through policy.

In the 1980s, demand grew for assisted reproductive technologies (ARTs) such as in vitro fertilization (IVF). That development led to concerns among the Canadian government and Canadians, particularly women's health organizations, about AHR and the need for regulation. In that period, other countries established organizations, such as the Warnock Committee in the United Kingdom established in 1982, to develop principles for the regulation of IVF and embryology. The Warnock Committee published their recommendations in the "Report of the Committee of Inquiry into Human Fertilisation and Embryology" in 1984. In Australia, the New South Wales Law Reform Commission and Law Reform Commission of Victoria investigated the implications of ARTs beginning in 1982.

In the spring of 1987, a number of Canadian women's organizations, including the Canadian Women's Health Network, founded the Canadian Coalition for a Royal Commission on New Reproductive Technologies (NRTs). The Canadian Coalition for a Royal Commission on NRTs lobbied Canada's Parliament and federal government in Ottawa, Ontario, for a Royal Commission to create a forum for individuals and groups to educate themselves about reproductive technologies and to express their concerns to Parliament. In 1989, the Canadian Prime Minister, Brian Mulroney, founded the Royal Commission on New Reproductive Technologies also called the Baird Commission after its chair, Patricia Baird, a pediatrician and medical geneticist in Canada. The Commission included members from a variety of disciplines including law, medicine, religion, and sociology.

The Baird Commission researched the social, ethical, health, scientific, legal, and economic implications of NRTs, and the safeguards and policies that could be applied to NRTs. The opinions of approximately 40,000 Canadians were collected through a variety of methods including national surveys, personal interviews, and focus groups. The Baird Commission sought opinions about infertility, methods of assisted human reproduction, prenatal diagnosis techniques including gene therapies and sex selection, and research with human embryos and fetal tissues.

The investigation culminated in a publicly available two-volume final report in 1993 titled *Proceed with Care*, which made 293 policy recommendations. The Commission recommended that the legislation prohibit the sale of human body parts, payment for surrogacy services, and the use of embryos in research related to cloning. Additionally, it recommended the creation of a regulatory framework for NRTs, and the creation of an NRT Commission to develop and apply NRT policy.

Following the report, in 1995, the Minister of Health announced a voluntary moratorium for medical and research communities on nine practices specified in the Commission report. Those practices included buying and selling gametes and embryos, and cloning human embryos. Four attempts were made to pass national legislation on AHR. The first was Bill C-47, which was terminated at the dissolution of Parliament in 1997.

During the late 1990s, three of Canada's research funding agencies, the Canadian Institute of Health

Research (CIHR), the Natural Sciences & Engineering Research Council & the Social Research Sciences (NSERC) and Humanities Council, stated a need for guidelines to ensure ethical practice with NRTs and stem cell research. The three agencies developed a set of ethical standards in 1998, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. The document included guidelines for research involving human gametes, embryos, and fetuses. Additionally, in 2002, CIHR published guidelines for human pluripotent stem cell research describing how stem cells could be derived and used for research in Canada.

In May 2001, the Minister of Health invited the House of Commons Standing Committee on Health to be an advising agency for the drafting of AHR legislation. The Health Committee responded with thirty-three recommendations. Many of these recommendations were included in Bill C-56 and presented between 2001 and 2002 in the House of Commons located in Ottawa. Bill C-56 established a legislative and regulatory framework to address AHR and research involving in vitro embryos. The Bill was tabled two times, renamed Bill C-13, and then Bill C-6, and then passed in 2004, becoming the Assisted Human Reproduction Act.

The beginning sections of the AHR Act define several terms and list some principles that apply to the application and enforcement of the Act. The Act's section about principles emphasizes the health and well-being of women using reproductive technologies and of children born through AHR. The Act says that people seeking to undergo assisted reproduction procedures must not be discriminated against, and that the principle of free and informed consent must be applied for those engaging with ARTs. Additionally, the principles identify a number of ethical issues about the potential for exploitation, about the need to promote health, safety, dignity, and rights, and to protect human individuality and diversity. The Act legally defines terms such as donor, embryo, fetus, and human clone. The Act defines the concept of a human embryo as an organism during the first fifty-six days of development following fertilization or creation. The Act defines the concept of a fetus as a human organism during the period of its development beginning on the fifty-seventh day following fertilization or creation.

The AHR Act details prohibitions and controlled activities, the administration and enforcement of AHR in Canada, and penalties for engaging in those activities. The AHR Act prohibits human cloning and regulates the use of human embryos in research. The Act prohibits payment for surrogacy, and for gamete, gene, or cell donations. Additionally, the Act prohibits the use of human reproductive material to create embryos without written consent from the donor, and prohibits gamete donation from someone younger than eighteen years of age. The Act sets standards for the alteration and manipulation of reproductive material and embryos, and for reimbursement of expenses for donors and surrogates.

The Act creates a personal health information registry to contain health reporting information on donors and on everyone who undergoes AHR. The AHR Act also creates a regulatory agency. Located in Vancouver, Canada, the Assisted Human Reproduction Canada (AHRC) was created in 2006 to promote compliance with and to enforce the AHR Act. The Act details the structure, objectives, power, and responsibilities of the agency. The Act outlines the administration and enforcement of the Act, as the responsibility of the Agency. That responsibility includes licensing, and the steps to be taken if it is suspected that the Act has been contravened. The AHRC creates regulations required in the Act. For instance, the AHRC under section 12, may outline allowable expenses for the cost of transportation to and from a fertility clinic, and for which gamete donor and surrogates could be reimbursed. Finally, the Act describes the offenses and punishments for persons who contravene the Act. For instance, the state can prosecute a person who contravenes sections 5 through 7 and 9 of the Act on an indictable or summary offense. If charged by indictment, the more severe offense, a person faces a penalty of up to five hundred thousand Canadian dollars, or imprisonment not exceeding ten years.

Since the Act came into force, it has undergone a number of changes. In 2004, the province of Quebec submitted a challenge of the Act to the Quebec Court of Appeal in Quebec, Canada. The Attorney General of Quebec argued that many sections of the Act were unconstitutional as they infringed on the provincial government's jurisdiction in the area of health care. On 19 June 2008, the Quebec Court of Appeal held that the contested sections, sections 8 through 19, 40 through 53, 60, 61 and 68, were unconstitutional. In 2009, the government of Canada appealed that decision to

the Supreme Court of Canada, in Ottawa, in the appeal Reference re Assisted Human Reproduction Act.

The Supreme Court of Canada examined whether the pith and substance (purpose and legal effects) of the Act were to protect morality, safety, and public health, which were primarily federal responsibilities, or to regulate medical practice and research, which was a provincial responsibility. On 22 December 2010 the Supreme Court of Canada held that some, but not all, of the contested sections were unconstitutional, sections 10, 11, 13, 14 through 18, 40(2), (3), (3.1), (4), (5), 44(2), and (3). Some sections deemed unconstitutional included regulation around the alteration and manipulation of reproductive material and embryos (section 10), access to information, health reporting and the creation of a personal health information registry (sections 14 through 18), and licensing (section 40).

With the decision, the Supreme Court of Canada reduced the federal role of regulation of AHR. Consequently, the 2012 Canadian federal budget ordered that AHRC be dismantled in early 2013. In response to both the Supreme Court of Canada's decision and to the budget, the government tabled amendments to the AHR Act as part of Bill C-38, the "Jobs, Growth and Long-Term Prosperity Act." That Bill came into force on 29 June 2012. The amendments repealed all provisions of the Act that were found to be unconstitutional, as well as those around AHRC. Health Canada in Ottawa is responsible for enforcement of the remaining sections of the Act, and under section 12 for regulating permissible reimbursable expenses for gamete donors and surrogates that was never completed.

By 2014, Health Canada had not fulfilled its regulatory responsibilities provided in section 12 of the Act. The Act received criticism from scholars, such as bioethicist Françoise Baylis at Dalhousie University, in Halifax, Nova Scotia, previously a member of the board of directors for AHRC, and from Canadian AHR practitioners, all of whom criticized the act for its incomplete regulation. The provinces and territories now regulate any of the issues in AHR Act's sections that were repealed. Scholars, such as Baylis, have criticized what they call a fragmented approach to regulation, with different provinces and territories having differing regulations. By 2015, there had been little initiative on the part of provinces and territories to regulate AHR issues. While AHRC was critiqued for not enforcing the Act, with the shuttering of AHRC, Canada lacked an organization to enforce the Act.

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