

G12 COUNTRY REGULATIONS OF ASSISTED REPRODUCTIVE TECHNOLOGIES



The United States notably has little federal or state regulations pertaining to the assisted reproductive technology (ART) industry. This is in contrast to other developed nations, which provide more extensive regulations on the use of ART and in many cases restrict its use for certain ends, such as reproductive cloning. While some of these regulations may not be ideal, they are steps taken to ensure the health and safety of women utilizing ART and the children resulting from these technologies, as well as the ethical use of ART by all participants. The respective regulations of the Group of Twelve (G12) countries are summarized below, including key laws, prohibitions, and policies. The G12 consists of members of the Group of Ten (G10), the wealthiest members of the International Monetary Fund, with the addition of Spain and Australia. This group was chosen since the G12 is composed of industrially advanced countries suitable for comparison with the U.S.

Australia

Australia regulates ART at both the federal and state level, with the states providing the most regulation. The key federal law is the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006*. This law prohibits reproductive cloning and allows states to either permit or prohibit research cloning. Research cloning is permitted in Victoria, New South Wales, Tasmania, Queensland, South Australia and the Australian Capital Territory. Additionally, this law prohibits germline modification and the commercial trading of human eggs, sperm or embryos.

The National Health and Medical Research Council publishes *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research*. These general guidelines must be followed for ART centers to be accredited by the Reproductive Technology Accreditation Committee. These guidelines encourage limiting the number of embryos created to those needed during the course of treatment, strict recording of the outcomes of ART, and the prohibition of non-medical sex selection and commercial surrogacy. Non-commercial or altruistic surrogacy is permitted by some Australian states.

Belgium

Belgium's key laws pertaining to ART are the *Law on Research into Embryos In Vitro 2002* and the *Law on Medically Assisted Reproduction and the Disposition of Supernumerary Embryos and Gametes 2007*. These laws

prohibit reproductive cloning, the creation of embryos for research purposes, non-medical sex selection or treatment for eugenic purposes, and the creation of chimeras or hybrid embryos.

As of 2003, ART is completely covered by Belgium's national health plan. This insurance provides up to 6 cycles of ART for women under the age of 42. Women over 42 years are ineligible for coverage. This coverage comes with strict limits on the number of embryos transferred per cycle, limiting the number of embryos transferred to a maximum of 2 for women under the age of 36 and a maximum of three for women under the age of 40.

Canada

Canada's *Assisted Human Reproduction Act (2004)* created the Assisted Human Reproduction Agency of Canada (AHRA) responsible for administering and enforcing the AHR act and its regulations. This Act prohibits reproductive and research cloning, the creation of IVF embryos for purposes other than reproduction or reproduction research, non-medical sex selection, germline modification, the creation of a chimera or hybrid embryo, commercial surrogacy, and the commercial trading of human eggs, sperm and embryos. This Act also establishes a series of principles related to ART including the provision that "the health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions respecting their use" and that "the health and well-being of women must be protected in the application of these technologies." These principles also discourage discrimination against persons seeking to use ART on the basis of their sexual orientation or marital status and they discourage the use of ART for commercial ends due to its exploitative nature.

France

France's key laws include the *Bioethics Law No. 2004-800 (2004)* and the *Law on the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis, No. 94-654 (1994)*. The *Bioethics Law* created the French Biomedicine Agency, responsible for licensing and regulating ART centers. These laws prohibit reproductive and research cloning, the creation of embryos for research purposes, germline modification, and non-medical sex selection. Surrogacy is also prohibited. In France, preimplantation genetic diagnosis is allowed only when a parent or close relative has a serious genetic disease and also for HLA

tissue matching. France's national health plan provides complete coverage for ART to heterosexual couples who are of reproductive age and are married or have lived together for two years.

Germany

Germany's key laws and guidelines pertaining to ART include the *Federal Embryo Protection Law 1990*, the *Adoption Brokerage Law 2006*, and the *Guideline of the German Federal Medical Chamber 2006*. These laws prohibit research and reproductive cloning, gamete donation, the creation of hybrid embryos, the cryopreservation of fertilized eggs, sex-selection (with the exception of sperm sorting for the prevention of a few sex-linked genetic disorders), preimplantation genetic diagnosis, and all forms of surrogacy. Only three eggs can be fertilized and transferred in one reproductive cycle.

Italy

In Italy, ART is regulated under the *Medically Assisted Procreation Law (2004)*. This law prohibits research and reproductive cloning, the manipulation of embryos, the use of donated eggs or sperm for ART, and the cryopreservation of embryos (with the exception of severe injury/illness preventing embryo transfer). A maximum of three eggs can be fertilized and transferred per reproductive cycle. Sex-selection is only permitted through sperm sorting for sex-linked genetic diseases. All forms of surrogacy are prohibited. The use of preimplantation genetic diagnosis for the selection of embryos is generally prohibited, but has been allowed through the courts on a case-by case basis. Genetic testing for non-medical purposes is prohibited. The use of ART is restricted to stable heterosexual couples who live together, are of reproductive age, are over the age of 18, have documented infertility, and have been first provided the opportunity for adoption.

Japan

In Japan, the only law related to ART is the *Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques (June 2001)*. This law prohibits reproductive cloning, germline modification, and the transfer of human/animal hybrid embryos to either a human or animal. Research cloning is permitted in Japan. Other ART activities are regulated by voluntary guidelines produced by the Japan Society of Obstetrics and Gynecology.

Netherlands

The Netherlands's key laws on ART are the *Act Containing*

Rules Relating to the Use of Gamete and Embryos (Embryos Act) (July 1, 2002) and the *Commercial Surrogacy Act* (November 1, 1993). The *Embryos Act* prohibits the creation of embryos for research purposes, allowing an embryo to develop outside the human body for longer than 14 days, reproductive cloning, germline modification, the creation of human/animal hybrid embryos, non-medical sex selection, and commercial donation of gametes or embryos for reproductive or research purposes. The *Commercial Surrogacy Act* prohibits commercial and professionally arranged surrogacy. In the Netherlands, preimplantation genetic diagnosis is permitted only for serious genetic disease at one facility, although the government has recently allowed testing for certain hereditary cancers and is considering offering testing for a wider range of conditions in the future.

Spain

In Spain, key laws pertaining to ART are the *Law on Assisted Human Reproduction Techniques, No. 14/2006* (May 27, 2006) and the *Biomedicine Law 14/2007* (July 3, 2007). The National Commission on Human Reproductive Assistance is Spain's ART advisory committee. The above laws prohibit reproductive cloning, the transfer of more than three embryos per reproductive cycle, the creation of embryos for purposes other than reproduction, germline modification, non-medical sex selection, and the use of preimplantation genetic diagnosis for non-medical purposes. Surrogacy is not recognized in Spain. The commercial donation of gametes is allowed for assisted reproduction and research, although only 6 children can be born from the same donor.

Sweden

In Sweden, key laws regulating ART are the *Act on Ethics Review of Research Involving Humans, Law No. 460* (2003), and the *Genetic Integrity Act, Law No. 351* (2006). Sweden provides financial coverage for ART to couples who are married or are in a stable relationship. Reproductive cloning, surrogacy, germline modification, and the use of preimplantation genetic diagnosis for social purposes are prohibited. Preimplantation genetic diagnosis is permitted for disease and for HLA matching (only after approval by the Board of Health and Welfare). Sweden allows only one embryo (two in older women) to be transferred per reproductive cycle. Embryos can be cryopreserved for up to five years.

Switzerland

Switzerland's key laws regulating ART include the *Federal Law on Medically Assisted Reproduction* (1998), the *Federal Act on Research Involving Embryonic Stem Cells* (2003), and the *Federal Law on Medically Assisted Reproduction* (2004). Prohibited practices include reproductive and research cloning, egg and embryo donation for ART, creating an embryo for research purposes, creating a hybrid embryo, germline modification, preimplantation genetic diagnosis, non-medical sex-selection, and surrogacy. Switzerland limits the number of embryos transferred per reproductive cycle to three and requires cryopreserved gametes and embryos to be destroyed after five years.

United Kingdom

The United Kingdom's laws on ART include the *Surrogacy Arrangement Act* (1985), the *Human Embryology &*

Fertilisation Act (1990), and the *Human Reproductive Cloning Act*. These laws prohibit reproductive cloning, the transfer of a non-human embryo to a woman or a human embryo into an animal, allowing embryos to develop outside of the human body for fourteen days, germline modification, non-medical sex selection, and commercial surrogacy arrangements. The *Human Embryology and Fertilisation Act* established the Human Fertilisation and Embryology Authority (HFEA) responsible for licensing fertility clinics and regulating the use of donor gametes, assisted fertilization, preimplantation genetic diagnosis, the storage of gametes and reproductive tissue, and research using human embryos. The HFEA limits the number of embryos transferred per reproductive cycle to 1-2 embryos for women under the age of 40. A maximum of three embryos can be transferred to women over 40. The HFEA also prohibits commercial egg and sperm donation.

United States

The only federal legislation passed pertaining to ART is the *Fertility Clinic Success Rate and Certification Act of 1992* establishing the reporting of pregnancy success rates to the Centers for Disease Control and Prevention for publication. Regulation of ART varies at the state level. Seven states have legislation that prohibit human cloning for both reproductive and research purposes, while eight states ban reproductive cloning. Other states prohibit commercial surrogacy or regulate surrogacy agreements. Several states require private insurance coverage of ART and regulate the donation of sperm, eggs, and embryos. Only Pennsylvania extensively regulates and monitors ART clinics and activities.

(Compiled from the following resources and in direct consultation with the following international laws)

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*Google Translate was used to verify the content of these laws discussed in secondary sources.