

Human Germline Modification

Summary of National and International Policies

International Law

According to a number of international declarations, human germline modification may be considered unethical human experimentation or an abuse of human rights:

- The United Nations Education, Scientific and Cultural Organization's (UNESCO) [Universal Declaration on the Human Genome and Human Rights](#) indicates in Article 24 that "germ-line interventions" could be "contrary to human dignity."
- The Council of Europe's [Convention on Human Rights and Biomedicine](#) indicates in Article 13 that "an intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants."
- According to the 2001 [European Union Directive on clinical trials](#), "No gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity."
- [The International Covenant on Civil and Political Rights](#) indicates in Article 7 that "No one shall be subjected without his free consent to medical or scientific experimentation."

See also: "[Is there an emerging international consensus on the proper uses of the new human genetic technologies?](#)" Testimony of Richard Hayes before the US House Subcommittee on Terrorism, Nonproliferation and Trade, June 19th, 2008.

National Law

More than 40 countries around the world have laws on their books prohibiting the inheritable genetic modification of humans. See a full list [here](#).

In the United States there is no such law, but clinical trial proposals for germline alterations will not be accepted by the Recombinant DNA Advisory Committee (RAC) of the National Institutes of Health (NIH), as [reiterated](#) recently by Francis Collins. The Food and Drug Administration has also asserted authority in this area. Furthermore, the Dickey-Wicker Amendment prevents federal funding of research involving the creation or destruction of human embryos.

Here are a majority of the national laws in place that prohibit human germline genetic modification:

- Belgium's Act on Research on Embryos in Vitro (2003)
- Bulgarian Health Act (SG No. 70/10 2004)
- China's Guidelines on Human Assisted Reproductive Technologies (2003)
- Denmark's Act on Assisted Fertilisation in Connection with Medical Treatment, Diagnosis and Research (1997, amended 2003)
- Finland's Medical Research Act (488/1999, 295/2004, 794/2010)

- France’s Bioethics Law (2004, amended 2009)
- Indian Council of Medical Research, Ethical Guidelines for Biomedical Research on Human Participants (2006)
- Israel’s Law on the Prohibition of Genetic Intervention Act (Human Cloning and Genetic Manipulation of Reproductive Cells), (1999, renewed 2004, 2009, and valid until May 23, 2016)
- New Zealand’s Human Assisted Reproductive Technology Act (2004)
- Spain’s Law 14/2006 on Assisted Human Reproduction Techniques
- The Netherlands’ Act containing rules relating to the use of gametes and embryos (2002)
- The UK’s Human Fertilisation and Embryology Act (1990, amended 2008) and the Human Fertilisation and Embryology (Research Purposes) Regulations (2001)
- Australia’s Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act (2006)
- Austria’s Law on Medically Assisted Human Reproduction (1992, 2004)
- Brazil’s Biosafety Law (2005)
- Canada’s Assisted Human Reproduction Act (2004)
- Costa Rica’s Decree No. 24029-S - A Regulation on Assisted Reproduction (1995)
- Germany’s Embryo Protection Act (1990)
- Ireland’s Guide to Professional Conduct and Ethics for Medical Practitioners, Seventh Edition, 2009, Medical Council.
- Italy’s Assisted Medical Procreation Law (2004)
- Japan’s Guidelines of Clinical Research Regarding Gene Therapy (2002, amended 2004, 2008)
- Lithuania’s Law on Ethics of Biomedical Research (VIII-1679/2000, amended 2007)
- Mexico’s General Health Law (1997)
- Portugal’s Law on medically assisted procreation (32/2006)
- Singapore’s Human Cloning and Other Prohibited Practices Act (2004)
- South Korea’s Bioethics and Safety Act (2008)
- Sweden’s Genetic Integrity Act (2006)
- Switzerland’s The Federal Constitution (1999)
- The Czech Republic’s Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine / Convention on Human Rights and Biomedicine (96/2001) /Act on research on human embryonic stem cells and related activities and on amendment to some related acts (2006)

This data was drawn from a spreadsheet created by Tetsuya Ishii and Motoko Araki for the paper [“International regulatory landscape and integration of corrective genome editing into in vitro fertilization.”](#) Their spreadsheet is available [here](#). Countries with ambiguous laws regarding these technologies have been left out of this document.