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:

- Bulgarian Health Act (SG No. 70/10 2004)
- Denmark’s Act on Assisted Fertilisation in Connection with Medical Treatment, Diagnosis and Research (1997, amended 2003)
• France’s Bioethics Law (2004, amended 2009)
• Indian Council of Medical Research, Ethical Guidelines for Biomedical Research on Human Participants (2006)
• 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)
• Brazil’s Biosafety Law (2005)
• Germany’s Embryo Protection Act (1990)
• Italy’s Assisted Medical Procreation Law (2004)
• 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)

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.