Global Regulation of Human Embryonic Stem Cell Research

	Prohibition of derivation of hESCs	Allowing importation of hESC lines or use of existing hESC lines	Allowing derivation of hESCs from excess IVF embryos	Prohibition of creation of human embryos for research including SCNT	Allowing creation of human embryos for research through SCNT	No specific legislation regarding hESC research	Policies and further information	Stem cell network, society or foundation
Australia							Since 2002, Australian scientists have been permitted to use donated in vitro fertilisation (IVF) embryos in research. Under the Commonwealth legislation - *Research Involving Human Embryos Act 2002* – scientists can apply for a licence from the National Health and Medical Research Council (NHMRC) to use donated human IVF embryos for stem cell research or research to improve infertility treatments and IVF, provided that the embryos are no longer required for infertility treatment. Additional legislation was also introduced in 2002, the *Prohibition of Human Cloning Act 2002* which made it illegal to create, or even attempt to create, a human using cloning technology. In 2005 the Australian legislation was reviewed by an independent committee which became known as the *Lockhart Review* after the late Hon John Lockhart AO QC who chaired the committee. The committee's recommendations were incorporated into legislation in 2006 following a conscience vote in both Houses of Parliament. The amending legislation - *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* - specifically allowed Australian researchers to apply for a licence to use somatic cell nuclear transfer technology (SCNT, also known as therapeutic cloning) for stem cell research within a strict set of criteria. The amending legislation also increased the penalties associated with any attempts to abuse this technology to clone humans, with reproductive cloning remaining specifically prohibited. The legislation is currently being reviewed by an independent committee who are due to table a report on 27 May 2011. Full details can be found at https://legislationreview.nhmrc.gov.au/	Australian Stem Cell Centre Australasian Society for Stem Cell Research New South Wales Stem Cell Network Stem Cell Network Asia Pacific
Brazil							In March 2005, Brazil's Congress voted to permit research using embryos left over from IVF that had been frozen for at least three years. It upheld a ban on cloning embryos. In May 2008 six of Brazil's Supreme Court's 11 justices upheld the 2005 law allowing embryonic stem cell research and turned down a petition filed that same year by then Attorney General Claudio Fontelles, who argued the law was unconstitutional because it violates the right to life. Further information: Nature, Biosafety law brings stem-cell research to Brazil, doi:10.1038/434128b and Cell Stem Cell, Stem Cell Research in Brazil: A Difficult Launch, doi:10.1016/j.cell.2006.03.003.	
Canada							hESC research has been permitted in Canada since 2002 under national guidelines. In March 2004, Bill C-6: an *Act Respecting Assisted Human Reproduction and Related Research* became law. The Act applies to the derivation of stem cells from human embryos, but does not apply to research using hESC lines that have already been derived. Updated Guidelines for Human Pluripotent Stem Cell Research were released in June 30, 2010.	Stem Cell Network Canada
China							Ministry of Science of Technology and Ministry of Health, Ethical Guidelines for Research on Human Embryonic Stem Cells (2003) (authorised translation). The guidelines prohibit human reproductive cloning and allow for the derivation of hESCs from excess IVF embryos and SCNT.	Stem Cell Network Asia Pacific

	Prohibition of derivation of hESCs	Allowing importation of hESC lines or use of existing hESC lines	Allowing derivation of hESCs from excess IVF embryos	Prohibition of creation of human embryos for research including SCNT	Allowing creation of human embryos for research through SCNT	No specific legislation regarding hESC research	Policies and further information	Stem cell network, society or foundation
France							France's current *Bioethics Law* received final approval on 6 February 2006. The law allows for five year licences to be issued to create new hESC lines from excess IVF embryos, to import hESC lines and to develop research programs. The law prohibits the creation of embryos for research including SCNT. See www.agence-biomedecine.fr The French government is currently reviewing the laws and in October 2010, a draft of the revised Bioethics Law was released which proposed maintaining the current system. The French Parliament began debating the revised bill on 8 February 2011 with the final law expected to be passed by the end of 2011. Read more at Nature, France mulls embryo research reform, doi:10.1038/469277a.	Institute for Stem Cell Therapy and Exploration of Monogenic Diseases French National Alliance for Life Sciences and Health
Germany							The *German Stem Cell Act* of 2002 which was last amended in 2008 prohibits the derivation of hESCs from excess IVF embryos and bans SCNT. However research is allowed on imported hESCs that have been created before 1 May 2007. For more information visit EuroStemCell	German Society for Stem Cell Research Stem Cell Network North Rhine Westphalia Network in Regenerative Medicine
India							The Indian Council of Medical Research *National Guidelines for Stem Cell Research and Therapy, 2007* allow for the creation of hESCs from excess IVF embryos and SCNT is allowed with restrictions. Reproductive cloning is specifically banned. The guidelines can be found at the Indian Council of Medical Research.	The Stem Cell Research Forum of India Stem Cell Network Asia Pacific
Ireland							The legal situation regarding embryonic stem cell research in Ireland is not well defined. Ireland does not have specific legislation dealing with stem cell research or research on embryos produced, but not used, during IVF treatment. The Medical Council which regulates doctors, produced guidelines in 2009 that forbid the creation of embryos specifically for use in research and prohibit doctors from engaging in human reproductive cloning. However, these guidelines do not apply to scientists. Article 40.3.3 of the Constitution of Ireland protects the right to life of the unborn "with due regard to the equal right to life of the mother". Some people have interpreted the wording of Article 40.3.3 to mean that embryonic stem cell research was forbidden under the Constitution. However, a recent Supreme Court judgment (December 2009) found that three frozen embryos produced during IVF treatment were not considered 'unborn' as outlined in the Constitution. The Court ruled that the provisions of Article 40.3.3 only applied following the implantation of an embryo in the womb. Therefore, this Article is not applicable to embryonic stem cell research. The Department of Health and Children has stated its intention to regulate this area and is currently reviewing the situation. Read more at the Irish Council for Bioethics www.bioethics.ie	Irish Stem Cell Foundation
Israel							Israel's *Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law, 5759-1999* allows for the creation of hESCs from excess IVF embryos. SCNT is allowed with restrictions. Human reproductive cloning is specifically prohibited. Read more at the Israel Society for Sciences and Humanities.	The Israel Stem Cell Society

	Prohibition of derivation of hESCs	Allowing importation of hESC lines or use of existing hESC lines	Allowing derivation of hESCs from excess IVF embryos	Prohibition of creation of human embryos for research including SCNT	Allowing creation of human embryos for research through SCNT	No specific legislation regarding hESC research	Policies and further information	Stem cell network, society or foundation
Italy							hESC research is prohibited in Italy under *Law 40* which was issued in 2004 and limited the use of IVF procedures and banned research on human embryos. According to this law, each IVF procedure is allowed to create only three embryos, all of which must be implanted into the recipient mother. Read more at EMBO Reports: Science Under Politics, an Italian Nightmare, doi:10.1038/embor2010.198; Journal of Medical Ethics: The new Italian law on assisted reproduction technology (Law 40/2004), doi:10.1136/jme.2004.010231; and European Science Foundation, Science Policy Briefing, May 2010, Human Stem Cell Research and Regenerative Medicine. A European Perspective on Scientific, Ethical and Legal Issues	
Japan							hESC research, including the creation of new hESC lines has been allowed in Japan since 2001 under *The Guidelines for Derivation and Utilization of Human Embryonic Stem Cells* and *The Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques* (Law No. 146, 2000). However the bureaucratic approval process for hESC research is onerous and restrictive. In 2009 some of the restrictions were loosened to make it easier for researchers. Read more at Nature, Japan relaxes human stem-cell rules, doi:10.1038/4601068a	Stem Cell Network Asia Pacific
Singapore							Singapore has not enacted any specific legislation pertaining to the generation and use of hESCs. Instead researchers in Singapore adhere strictly to guidelines drafted in 2002 by the Bioethics Advisory Committee (http://www.bioethics-singapore.org/) and subsequently endorsed by the Government, which was modelled on UK legislation. The creation of hESC lines from excess IVF embryos and SCNT is allowed in Singapore as is the creation of hybrid (human–animal) embryos for SCNT.	Singapore Stem Cell Consortium Stem Cell Network Asia Pacific
South Korea							The Ministry of Science, Education and Technology coordinates research policy and oversight. The *Bioethics and Biosafety Act* became effective on December 6, 2008 and allows for the derivation of excess IVF embryos and for SCNT. Reproductive cloning and interspecies SCNT are specifically banned. An unofficial English translation of the Act can be read at: http://www.mbbnet.umn.edu/scmap/KoreanBioethics.pdf	Stem Cell Network Asia Pacific
Spain							Since 2003 Spain has allowed the derivation of hESCs from excess IVF embryos and in June 2007 Spain's parliament passed a law to allow SCNT. Law 14/2007, of 3 July, on Biomedical Research [available only in Spanish] http://noticias.juridicas.com/base_datos/Admin/l14-2007.html Read more about Spain's stem cell laws in Cell Stem Cell, Stem Cell Research in Spain: If Only They Were Windmills …, doi: 10.1016/j.stem.2009.05.016	Barcelona Centre of Regenerative Medicine
Sweden							Sweden allows the derivation of hESCs from excess IVF embryos and SCNT and prohibits human reproductive cloning. Read more, European Science Foundation, Science Policy Briefing, May 2010, Human Stem Cell Research and Regenerative Medicine. A European Perspective on Scientific, Ethical and Legal Issues	
United Kingdom							The Human Fertilisation and Embryology Authority is responsible for the implementation of the *Human Fertilisation and Embryology Act* which governs the use of human embryos in research in the UK. The Act allows for the creation of hESCs from excess IVF embryos and SCNT including interspecies SCNT. Human reproductive cloning is specifically banned. The Act was first enacted in 2001 and reviewed and revised in 2008.	UK National Stem Cell Network Scottish Stem Cell Network North East England Stem Cell Institute London Regenerative Medicine Network

	Prohibition of derivation of hESCs	Allowing importation of hESC lines or use of existing hESC lines	Allowing derivation of hESCs from excess IVF embryos	Prohibition of creation of human embryos for research including SCNT	Allowing creation of human embryos for research through SCNT	No specific legislation regarding hESC research	Policies and further information	Stem cell network, society or foundation
USA **(refer below for some State by State examples)**							The USA has no federal legislation regarding human cloning and the creation and research of human embryonic stem cells. However there are guidelines around the federal funding of stem cell research. President Obama changed federal policy pertaining to hESC research when he signed Executive Order (EO) 13505, Removing Barriers to Responsible Scientific Research Involving Human Stem Cells on 9 March 2009, changing the way the National Institutes of Health (NIH) could fund hESC research. The EO revoked the 2001 President Bush ban on the use of federal funds for research using hESCs created after 2001. Following the EO on 7 July 2009, new NIH Guidelines for funding hESC research became effective. However researchers are still unable to use existing federal funds, to derive or create lines (just research on existing approved lines created using other funding means). This is because of the so-called Dickey-Wicker amendment, which specifically bans the use of tax dollars to create human embryos, or for research in which embryos are destroyed, discarded or knowingly subjected to risk of injury. It first became law in 1996, and has been renewed by Congress every year since. Within the individual US States there is a huge variation of laws between the individual states. See the National Conference of State Legislators for more information.	Interstate Alliance for Stem Cell Research (IASCR) is a voluntary body whose mission is to advance stem cell research (human embryonic, adult, and other) by fostering effective interstate collaboration.
California							California permits research on adult and embryonic stem cells including the derivation of hESCs from excess IVF embryos and SCNT. See the National Conference of State Legislators or the California Department of Public Health Guidelines for Human Stem Cell Research for more information.	California Institute for Regenerative Medicine (CIRM)
Massachusetts							Massachusetts prohibits reproductive cloning but permits derivation of hESCs from excess IVF embryos and SCNT. See the National Conference of State Legislators or the Massachusetts Courts for more information.	Harvard Stem Cell Institute Massachusetts Life Sciences Center International Stem Cell Registry at UMASS
Michigan							4 November 2008 - Michigan voters approved Proposal 2 which amended the state constitution, overturning a 1978 Michigan law that prohibited the use of human embryos for research, even if those embryos were to be discarded. The change allows Michigan researchers to derive new embryonic stem lines from excess IVF embryos. Michigan's ban on human reproductive cloning was not altered by Proposal 2 and remains in full effect. See the National Conference of State Legislators for more information.	Michigan Center for hESC Research University of Michigan Center for Stem Cell Biology Stem Cell Institute of New Jersey
New Jersey							New Jersey permits SCNT for hESC research but prohibits reproductive cloning. New Jersey allows the derivation of hESCs from excess IVF embryos. See the National Conference of State Legislators for more information.	Stem Cell Institute of New Jersey
New York							New York permits the derivation of new hESC lines and the creation of hESCs using SCNT. See the National Conference of State Legislators for more information.	The New York Stem Cell Foundation

LEGEND:

Prohibition of derivation of hESCs	Allowing importation of hESC lines or use of existing hESC lines	Allowing derivation of hESCs from excess IVF embryos	Prohibition of creation of human embryos for research including SCNT	Allowing creation of human embryos for research through SCNT	No specific legislation regarding hESC research

REFERENCES & SOURCES

A. Rayaand and J.C. Izpisúa Belmonte (2009), *Cell Stem Cell*, Stem Cell Research in Spain: If Only They Were Windmills …, doi: 10.1016/j.stem.2009.05.016

D. Butler (2011), *Nature*, France mulls embryo research reform, doi:10.1038/469277a.

D. Cyranoski (2009), *Nature*, Japan relaxes human stem-cell rules, doi:10.1038/4601068a

E. Cattaneo and G. Corbellini (2011), *EMBO Reports*, Science Under Politics, an Italian Nightmare, doi:10.1038/embor2010.198

European Science Foundation, Science Policy Briefing, May 2010, Human Stem Cell Research and Regenerative Medicine. A European Perspective on Scientific, Ethical and Legal Issues

EuroStemCell Regulations in European Union member states, at: http://www.eurostemcell.org/Documents/Outreach/stemcell_hesc_regulations_2007FEB.pdf

Global Biopolitics Research Group, The global politics of human embryonic stem cell science, at: http://www.ioh.uea.ac.uk/biopolitics/workingpapers_pdf/wp2.pdf

ISSCR International Legislation on Human Embryonic Stem Cell Research, at: http://www.isscr.org/public/regions/index.cfm

L. Nelson (2005), *Nature*, Biosafety law brings stem-cell research to Brazil, doi:10.1038/434128b

M. Leite (2006), *Cell Stem Cell*, Stem Cell Research in Brazil: A Difficult Launch, doi:10.1016/j.cell.2006.03.003
R Isasi and B Knoppers (2006), *European Journal of Health Law*, Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries, doi:10.1163/157180906777036328

Stem Cells World Map, at: http://www.mbbnet.umn.edu/scmap.html

StemGen WorldMap, at: http://www.stemgen.org/mapworld.cfm

The European Group on Ethics in Science and New Technologies to the European Commission, *Recommendations on the ethical review of hESC FP7 research projects, Opinion No 22*

The Hinxton Group, World Stem Cell Policies http://www.hinxtongroup.org/wp.html

The status of hESC research legislation throughout Europe, at: www.hescreg.eu

V Fineschi, M Neri and E Turillazzi, (2005), *Journal of Medical Ethics*, The new Italian law on assisted reproduction technology (Law 40/2004), doi:10.1136/jme.2004.010231

GLOSSARY / ACRONYMS

ART Assisted Reproductive Technology. Includes a range of methods used to circumvent human infertility such as in vitro fertilisation

CIRM California Institute for Regenerative Medicine (USA)

EO Executive Order (USA)

hESC Human Embryonic Stem Cell. hESCs are derived from a four to seven day old blastocyst (early embryo). They have the ability to form virtually any type of cell found in the human body, but are not capable of developing into a whole new organism.

IVF In vitro fertilisation. Is a procedure whereby an egg (or more than one egg) is retrieved from the body of a woman and combined with sperm outside the body to achieve fertilisation. If fertilisation is successful the newly formed embryo is subsequently transferred back into the woman with the aim of achieving a pregnancy. If many embryos develop some of the surplus embryos may be frozen and used later.

NHMRC National Health and Medical Research Council (Australia)

NIH National Institutes of Health (USA)

SCNT Somatic cell nuclear transfer (also known as therapeutic cloning). Refers to the removal of a nucleus, which contains the genetic material or DNA, from virtually any cell of the body and its transfer by injection into an unfertilised egg (oocyte) from which the nucleus has also been removed. The newly reconstituted entity is then stimulated to start dividing. After 5-7 days in culture, embryonic stem cells can then be removed from the resulting blastocyst. These embryonic stem cell lines are genetically identical to the cell from which the DNA was originally removed.