

## **Global Regulation of Human Embryonic Stem Cell Research and Oocyte Donation**

	Prohibition of derivation of HESCs	Prohibition of derivation but allowing importation of 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 including SCNT	No specific legislation regarding HESC Research	Regulations for Oocyte Donation	Policies and Further Information	Stem Cell Network, Society or Foundation
Australia			X		X		The National Health and Medical Research Council (NHMRC) has released revised Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (ART guidelines). The revised ART guidelines provide ethical advice in areas such as: human egg donation; research on embryos that are unsuitable for implantation; research on embryos created by somatic cell nuclear transfer; and 'proper consent' in relation to the donation of human eggs and embryos.  The guidelines also provide ethical advice for the clinical practice of ART, including: guidelines for the use of donated embryos; information giving, counseling and consent; and innovations, training and quality assurance.	In late 2006 the Australian parliament voted to amend the legislation surrounding hESC regulation to allow SCNT and the derivation of hESC lines from embryos deemed unsuitable for implantation through PGD.  The amended act, the "Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006" came into force in June 2007 and can be found on the NHMRC Website at: http://www.nhmrc.gov.au/publications/synopses/ files/prohibit.pdf	Australian Stem Cell Centre www.stemcellcentre.edu.au  Australasian Society for Stem Cell Research www.asscr.org  New South Wales Stem Cell Network  http://www.diabetes.unsw.edu.au/S TEM/
Austria	X			X				HESC research is not allowed, it is covered by the legislation applying to reproductive medicine: www.ris.bka.gv.at/bundesrecht  Austria voted against HESC research during the European Council decision for FP7.	
Belgium			Х		Х			Belgium – Law on research on human embryos in vitro, (April 2003).	
Brazil			X	X				In March 2005, the Congress voted to permit research using embryos left over from in-vitro fertilization 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 a 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.	
Bulgaria	Х								
Canada			Х	х				Updated Guidelines for Human Pluripotent Stem Cell Research, June 28, 2006 http://www.cihr-irsc.gc.ca/e/31488.html	Stem Cell Network Canada www.stemcellnetwork.ca

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China			Х		X			Ministry of Science of Technology and Ministry of Health, "Guidelines for Research on Human Embryonic Stem Cells," January 2004. Authorized translation	
Cyprus				Х		X			
Czech Rep			X					http://www.msmt.cz/Files/PDF/JJHumanstemcells.pdf	
Denmark			X	X					Danish Stem Cell Research Center http://www.dasc.dk/  The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion.
									http://www.scanbalt.org/sw222.asp
Estonia			X	X					The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion.  http://www.scanbalt.org/sw222.asp
Finland			X					Finland has no law neither prohibiting nor allowing SCNT.	The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion. http://www.scanbalt.org/sw222.asp
France			X	X			"Bioethics Law" (6 Aug 2004, amended Law No. 94-653 of July 29 1994, on Respect for the Human Body and Law No. 94-654 of July 29 1994, on the Donation and Use of Elements and Products of the Human Body, Medically Assisted Procreation, and Prenatal Diagnosis.)	The new <i>Bioethics Law</i> received final approval of the government on 6 Feb 2006. The new law allows for 5 year licences to be issued to import HESC lines, to create new HESC lines from excess IVF embryos and to develop research programs. The law prohibits the creation of embryos for research including SCNT.  www.agence-biomedecine.fr	

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Germany	X	X		X				Research using hESC is permitted under criteria established by the German Stem Cell Act of 2002 which was amended in 2008. Under these guidelines, only stem cell lines created before 1st May 2007 may be used in research.	Stem Cell Network North Rhine Westphalia  www.stammzellen.nrw.de  Network in Regenerative Medicine  www.cellnet.org  www.rmig.org  The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion.  http://www.scanbalt.org/sw222.asp
Greece			Х	Х					
Georgia				Х					
Hungary			Х	Х					
Iceland				X					Icelandic Stem Cell Research Centre  http://www.stemcell.no/index.htm  The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion.  http://www.scanbalt.org/sw222.asp
India			X		X		There should be no commodification of human oocyte, human sperm or human embryo by way of payment or services, except for reimbursement of reasonable expenses incurred by the person (amount to be decided by IC-SCRT/ IEC. Similarly, no payments should be made for donation of somatic cells for use in SCNT except for reimbursement for attending the clinic.  For full details on Oocyte donation seen new guidelines at: http://www.icmr.nic.in/stem_cell/stem_cell_guidelines.pdf	Indian Council of Medical Research (ICMR), newly released National Guidelines for Stem Cell Research and Therapy.  http://www.icmr.nic.in/stem_cell/stem_cell_guidelines.pdf	The Stem Cell Research Forum of India  www.scrfi.org
Ireland	Х			Х					

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Israel			X		X		While SCNT for the derivation of cell lines is allowed, donation of oocytes is not permitted for research purposes, currently restricting this technology.  From 9 May 07 the Knesset (Israeli Parliament) has started the process of approving egg donation for various purposes including research. The legal procedure is comprises of three following votes, the first of which has been accomplished	"Law 5759-1999 - Prohibition of Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells)" (1999, amended March 2004).	The Israel Stem Cell Society  http://www.weizmann.ac.il/ISCS/  The Israeli Consortium Bereshith (Genesis) for Cell Therapy
Italy	X	Х		X					
Japan			х					An English translation of the amended guidelines on hESC research is not yet available. The original guidelines are at: <a href="http://www.mext.go.jp/a_menu/shinkou/seimei/2001/es/020101.pdf">http://www.mext.go.jp/a_menu/shinkou/seimei/2001/es/020101.pdf</a>	RIKEN Centre for Developmental Biology http://www.cdb.riken.jp/en/index.ht ml
Lithuania	х			Х					The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion. http://www.scanbalt.org/sw222.asp
Luxembourg						X			inp.// www.coamban.org/cwzzz.acp
Latvia				Х					The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion.  http://www.scanbalt.org/sw222.asp
Malta						X			
Mexico			х		Х			Mexico reversed a previous ban on stem cell research in June 2004, creating the National Institute of Genomic Research ( <a href="www.inmegen.org.mx">www.inmegen.org.mx</a> ) and permitting research on supernumerary embryos and allowing SCNT.	
Netherlands			Х	Х					
Norway				X		X			Norwegian Center for Stem Cell Research  http://www.stemcell.no/ncs.htm  The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion.  http://www.scanbalt.org/sw222.asp

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Poland						X			The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion.
						X			http://www.scanbalt.org/sw222.asp
Portugal				Х		^			
Russia			X		х				The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion.  http://www.scanbalt.org/sw222.asp
Singapore			X		х		The Prohibition of Cloning and Other Prohibited Practices Act contains the following clause:  Prohibition of commercial trading in egg, sperm and embryo This prevents the giving of valuable consideration such as money or gifts in exchange for a supply of egg, sperm or embryo, but does not refer to the reasonable reimbursement of expenses incurred or services provided in the collection, storage of transport of the tissue.	Human Cloning and Other Prohibited Practices Act came into effect on 1 October 2004	Singapore Stem Cell Consortium  http://www.sscc.a-star.edu.sg/
South Africa			X		х			South Africa passed the National Health Bill (http://www.doh.gov.za/docs/bills/b32b.pdf) in late 2003 permitting HESC research on supernumerary embryos and embryos created specifically for stem cell research. SCNT is permitted and reproductive cloning is banned.	
South Korea			X		х			The Ministry of Science and Technology (http://www.most.go.kr/) coordinates research, both private and public. The Bioethics and Biosafety Act implemented in January 2005 prohibits reproductive cloning and the creation of embryos for non-reproductive purposes, but allows the use of supernumerary IVF embryos for research purposes, and SCNT	
Spain			X		X			Spain's parliament passed a law to allow SCNT in June 2007. Law 14/2007, of 3 July, on Biomedical Research [available only in Spanish]  http://noticias.juridicas.com/base_datos/Admin/l14-2007.html  15 June 2007, MADRID - The lower house of the Spanish Parliament voted in favor of a bill on biomedical research that authorizes therapeutic cloning. The measure, which expressly prohibits reproductive cloning, was supported by all the parties in that chamber with the exception of the main opposition conservative Popular Party.	The Spanish Ministry of Health (MSC), together with the Autonomous Communities, approved the creation of three research centres (July 2004): Catalonia (CMRB), Andalusia (CABIMER) ,Valencia (Centro de Investigación Príncipe Felipe)  www.cmrb.eu  http://www.ochoa.fib.es

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Sweden			X		X		This statute and the <i>in vitro</i> Fertilization law of 1988 govern embryo research. Any research, which seeks to genetically modify the embryo, is prohibited. The statute implicitly prohibits embryo and oocyte cloning with criminal sanction.  In December 2001, the Swedish Research Council declared that creating embryos through somatic cell nuclear transfer for therapeutic purposes "can be ethically defensible" which would require formulation or a legal framework by the Swedish government.  http://www.vr.se/fileserver/index.asp?fil =LCK7HDEK3U6H		The ScanBalt Stem Cell Research Network has been established with representatives from all the 11 countries in the ScanBalt BioRegion.  http://www.scanbalt.org/sw222.asp
Switzerland			Х	Х					Swiss Stem Cell Networks  http://www.unige.ch/sciences/biologie/biani/sscn/
Slovenia			Х	Х					
Slovakia				Х		X			
Taiwan			Х	x				Department of Health, "Ethical Regulations for Embryonic Stem Cell Research," 2002. – New legislation pending.	Taiwan Society for Stem Cell Research http://www.tsscr.org.tw/
Thailand						X		Medical Council of Thailand, "Regulations on Human Cloning No. 21/2544," June 2002. The regulations ban human reproductive cloning.	
United Kingdom			X		X		In Feb 2007 HFEA changed the regulations so that women are now allowed to donate eggs for research. Compensation is set at £250  Source: www.hfea.gov.uk	The Human Fertilisation and Embryology Authority (http://www.hfea.gov.uk) is responsible for the implementation of the HFE Act.  "Human Reproductive Cloning Act 2001," UK Stat. 2001 c23 &1, (in force 4 December 2001).  http://www.legislation.hmso.gov.uk/acts/acts2001/20010023.htm  The current HFE Amendment Bill is being debated by the UK Parliament.  At 18 Sep 08 it had passed the second reading, bill tracker: http://services.parliament.uk/bills/2007-08/humanfertilisationandembryology.html	UK National Stem Cell Network  www.uknscn.org Scottish Stem Cell Network  www.sscn.co.uk North East England Stem Cell Institute  www.nesci.ac.uk East of England Stem Cell Network  www.eescn.org.uk London Regenerative Medicine Network  www.regenmednetwork.com

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USA						X	existing federal policy in this area is the research on, or the creation of, new ster ban on 9 Aug 2001. For full details see thttp://stemcells.nih.gov/research/registry  Within the individual US States there is a California which has permissive laws for HESC research to other states with no la Legislators for more information: http://w  The Stem Cell Blog has produced a use Your State? It can be found at http://thes  The US has the most developed and lea oocytes for reproductive purposes comprocedures used oocytes purchased for are paid to vendors with additional desir cycle.  Whilst the US has a large number of ste research, as the states step in to fund restrictions on paying for oocytes for ste	A huge variation of laws between the states. From HESC research to states with an outright ban on aws at all. See the National Conference of State aww.ncsl.org/programs/health/Genetics/rt-shcl.htm ful guide to state legislation called What Color is stemcellblog.com  1. St regulated internal market for oocytes. Trading of non practice. For example, in 2002 11.4% of or ART fees of around \$5000 per cycle. Moreover premiums able characteristics of sums up to \$100,000 per  1. Moreover premiums and privately funded stem cell is earch not funded federally many are imposing m cell research. For example, California which has h through Proposition 71 prohibits the paying for	Interstate Alliance on 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.  http://www.iascr.org/ California Institute for Regenerative Medicine www.cirm.ca.gov  New York Stem Cell Foundation www.nyscf.org  Harvard Stem Cell Institute http://www.hsci.harvard.edu/



Sources:

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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: <a href="http://www.ioh.uea.ac.uk/biopolitics/workingpapers\_pdf/wp2.pdf">http://www.ioh.uea.ac.uk/biopolitics/workingpapers\_pdf/wp2.pdf</a>

The status of hESC research legislation throughout Europe, at: <a href="www.hescreg.eu">www.hescreg.eu</a>

Isasi, R and Knoppers, B (2006). Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries', European Journal of Health Law, Vol 13, 9-26.

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

StemGen WorldMap, at: <a href="http://www.stemgen.org/mapworld.cfm">http://www.stemgen.org/mapworld.cfm</a>
Stem Cells World Map, at: <a href="http://www.mbbnet.umn.edu/scmap.html">http://www.mbbnet.umn.edu/scmap.html</a>

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*, at: <a href="http://ec.europa.eu/european\_group\_ethics/activities/docs/opinion\_22\_final\_follow\_up\_en.pdf">http://ec.europa.eu/european\_group\_ethics/activities/docs/opinion\_22\_final\_follow\_up\_en.pdf</a>