



Public Sector Infrastructure Surrounding Human Stem Cell (hSC) Research

Research and Infrastructure	UNITED STATES (Federal)	UNITED KINGDOM
Planning Committee	Human Embryonic Stem Cell (hESC) Research Advisory Committee of the National Academy of Sciences (NAS) ¹	U.K. Stem Cell Initiative (UKSCI) Panel of the Department of Health (DOH) ²
Ethics Committee	President's Council on Bioethics (with hESC meetings) ³	DOH's Gene Therapy Advisory Committee ⁴
Regulatory Agency	National Institutes of Health (NIH), under the Department of Health and Human Services ⁵	Human Fertilisation and Embryology Authority (HFEA), reports to the Secretary of State ⁶
Public Sector Funding Agency	NIH	Cross Council Coordination Committee ⁷ [led by Medical Research Council (MRC) and Biotechnology and Biological Sciences Research Council (BBSRC)]
Public Opinion	72% of polled public supported hESC research (2006) ⁸	70% of polled public supported hESC research (2003) ⁹
All SC Funds/Annual Budget (%)	\$609 million ¹⁰ /\$2.57 trillion ¹¹ (0.0237%)	\$85 million ¹² /\$938.4 billion ¹³ (0.0091%)
All SC Funds/All Health Research Funds (%)	\$609 million/\$28.5 billion ¹⁴ (2.14%)	\$85 million/\$2.7 billion ¹² (3.15%)
# hESC Publications in 2004 ¹⁵	19	7
Stem Cell Bank	National Stem Cell Bank established in 2005 by NIH ¹⁶	U.K. Stem Cell Bank established in 2002 by MRC and BBSRC ¹⁷
Storage of Embryo or Gametes	Guidelines vary by the institution storing the materials	Maximum: 5 years (embryo), 10 years (gametes) ¹⁸
Public-Private Coordination of Research and Funding	No organized federal effort to engage private companies in research cooperation or funding investments	Suggested by UKSCI ² for partnership in clinical research and drug development
Remaining Issues to Address	Increase and expand funding of hESC research and create consistent regulations	Increase hESC production, distribution and engineering (already have more structured regulation and funding)

¹ <http://dels.nas.edu/bls/stemcells/>; The NAS is a non-governmental advisory committee that publishes reports in the USA on several scientific areas (Accessed October 11, 2006)

² <http://www.advisorybodies.doh.gov.uk/uksci/uksci-reportnov05.pdf>; The UKSCI is the UK DOH's advisory committee to the embryo research regulatory agency (the HFEA) (Accessed October 11, 2006)

³ http://www.bioethics.gov/topics/stemcells_index.html; USA President's Bioethics Committee (Accessed October 11, 2006)

⁴ <http://www.advisorybodies.doh.gov.uk/genetics/gtac/>; UK Department of Health's Bioethics Committee (Accessed October 11, 2006)

⁵ <http://stemcells.nih.gov/index.asp>; "Stem Cell Information," official USA NIH SC communication (Accessed October 11, 2006)

⁶ <http://www.hfea.gov.uk>; The UK's HFEA is an independent statutory body overseeing fertility treatment & embryo research; it publishes annual "Code of Practice" guidelines (Accessed October 11, 2006)

⁷ http://www.bbsrc.ac.uk/science/initiatives/stem_cell.html; Overview of the UK's multi-organization funding for SC research (Accessed October 11, 2006)

⁸ http://www.camradvocacy.org/resources/POLL_5_2006.pdf; USA public opinion poll about SC research (Accessed October 11, 2006)

⁹ <http://www.ipsos-mori.com/polls/2003/amrc.shtml>; UK public opinion poll about SC research (Accessed October 11, 2006)

¹⁰ <http://www.nih.gov/news/fundingresearchareas.htm>; USA NIH yearly spending organized by topic (Accessed October 11, 2006)

¹¹ <http://www.washingtonpost.com/wp-srv/politics/interactives/budget06/budget06Agencies.html> USA Federal spending (Accessed October 11, 2006)

¹² Personal communication with Frances Rawle, Head of Research Career Awards at the UK's MRC; numbers are approximate.

¹³ http://budget2006.treasury.gov.uk/index_files/bud06_leaflet_225.pdf#search=%22uk%20total%20government%20spending%202006%20budget%22; UK Treasury's budget (Accessed October 11, 2006)

¹⁴ <http://www.nih.gov/about/almanac/appropriations/part2.htm>; USA NIH yearly budget (Accessed October 11, 2006)

¹⁵ From personal communication with Jen McCormick, author of 2006's "An International Gap in Human ES Research," J. Owen-Smith & J. McCormick, *Nature Biotechnology* (24: 391-392).

¹⁶ <http://www.nih.gov/news/pr/oct2005/od-03.htm>; Press research announcing funding for the USA National SC Bank (Accessed October 11, 2006)

¹⁷ <http://www.ukstemcellbank.org.uk/>; Statement of funding for the UK SC Bank (Accessed October 11, 2006)

¹⁸ http://www.hfea.gov.uk/cps/rde/xbcr/SID-3F57D79B-FAAAF985/hfea/Code_of_Practice_Sixth_Edition_-_final.pdf; 2006 UK HFEA "Code of Practice:" official guidelines for hESC and IVF (Accessed October 11, 2006)



Public Sector Regulation of hSC Research

Regulations	U.S. Current: Bush policy ¹⁹	U.S. Suggested: NAS guidelines ²⁰	UNITED KINGDOM
Regulatory Guidelines	Official White House Communication (2001): → bans federal funding of research on hESC lines created after 8/9/01 ²¹ → no additional restrictions on private hESC research	“Guidelines for hESC Research” (2005): → allow federal funding for development of, and research on, new hESC lines (includes creation and use of embryos); → form a national oversight panel to regulate all hESC research (publicly funded or privately funded)	Human Fertilisation & Embryology Act(1990 ²² ,2001 ²³) → allows the creation of embryos (SCNT) and the use of existing embryos (IVF derived) for hESC research → establishes HFEA to license and regulate research → requires an HFEA license from to conduct any hESC research (publicly funded or privately funded) → tight IVF rules: eligibility, embryo storage, donation
Illegal	Using NIH funds for hESC lines created after 8/9/01	1) research on any embryo >14 days old ²⁴ 2) conducting hESC research without an oversight committee 3) sale of gametes 4) human-non-human chimeric blastocyst 5) human embryo into non-human uterus 6) human-non-human chimera breeding	1) research on any embryo >14 days old ²³ 2) conducting hESC research without an HFEA-granted hESC research license 3) sale of gametes 4) human-non-human gamete or embryo-uterus combo. 5) reproductive cloning ²⁵ 6) genetic manipulation of cell while it is in the embryo 7) nuclear transfer into a pre-existing embryonic SC
Donating Reproductive Tissue	No guidelines	Different physicians for the decision to donate and any clinical decisions	Nurse discusses the decision for donation with the patient, and is independent from all clinical decisions
Reimbursement for Egg Donation	Illegal to sell, but legal to provide high compensation	Maximum: repay direct expenses	Maximum: repay direct expenses at a pre-specified rate, and compensate financial loss <£50 per day
Origin of hESC ²⁶ : IVF Embryo and SCNT	Legal, but not federally funded or substantially regulated for new lines	Legal and funded upon review by local oversight committee	Legal with proper license and federally funded
Human-nonhuman Chimera Production	Legal, but not federally funded or regulated	Requires review by oversight and animal welfare committees (esp. if brain tissue)	Legal with proper licenses from HFEA and animal welfare committees ²⁷ and federally funded
Compliance Review	NIH will not fund proposals with non-approved hESC	Require evidence of compliance for journal submission, funding renewals, and inclusion in professional societies	Formal complaint review process available to all patients in reproductive clinics, and all clinics must give the HFEA an annual review of complaints

¹⁹ <http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html>; USA President G.W. Bush’s White House Fact Sheet on Embryonic Stem Cell Research set the guidelines for NIH funding (Accessed October 24, 2006)

²⁰ <http://newton.nap.edu/books/0309096537/html/>; USA NAS suggested hESC research guidelines (Accessed October 11, 2006)

²¹ All hESC lines created before 08/09/01 in the USA are on a list of “federally approved lines” that are eligible for research funding by the NIH.

²² http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm; UK HFEA establishment and statement of purpose (Accessed October 11, 2006)

²³ Expansions of the UK’s HFEA 1990 Act as follow: 2001 HFE Research Purposes Regulation to allow SCNT, and the 2001 Human Reproductive Cloning Act prohibiting reproductive cloning.

²⁴ Appearance of the primitive streak (indicative of germ layer formation).

²⁵ Reproductive cloning: placing an in-vitro derived embryo (i.e.: from SCNT as described below) into a woman’s uterus to undergo gestation.

²⁶ 1) IVF embryo: embryos made in excess of those required by a patient seeking In Vitro Fertilization (IVF) fertility treatment. hESCs can be extracted from these donated embryos; 2) SCNT: Developmental biology technique of Somatic Cell Nuclear Transfer, wherein an egg’s nucleus is replaced with a nucleus transplanted from a somatic cell (e.g.: a skin cell). Once the egg is stimulated to divide, hESCs can be extracted from it.

²⁷ As of 2004’s Animal Procedure Committee, a UK chimera research license may also be reviewed by the Home Office’s Animals in Scientific Procedures Division

(http://www.apc.gov.uk/reference/Home%20Office_Animal%20Procedure%20HC%20466.pdf) (Accessed October 16, 2006)