

# The Business of Regulating Stem Cell Research:

Investment of time, finances and  
political will

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# Policy concerns about HESC research

- Permissibility of derivation of hES cells - requiring embryo research
- Derivation from surplus IVF embryos or from embryos created for research
- Research on hESC lines

# Policy options

- Prohibit embryo research (and HESC research)
- Prohibit derivation but permit importation of stem cell lines
- Permit use of certain cell lines (up to certain date)
- Permit HESC research with surplus IVF embryos
- Permit HESC research with surplus embryos and with cloned embryos (SCNT) (research cloning)



# Policy Trend

- Increasing trend toward comprehensive national ART or embryo research legislation
- UK HFEA as model
- Canada, France, Australia, NZ
- Investment of political will, time and resources

# Investment of Time

- UK – 1984 Warnock Report
  - 1990 legislation passed
- Canada Royal Commission on New Reproductive Technologies 1992
  - Voluntary moratorium 1996, failed Genetic and Reproductive Technologies Act 1998, passage of Assisted Human Reproductive Technologies Act 2004
- France 1994 bioethics laws
  - implementation of new law in late 2005

# Considerations for US Regulators: Elements of a regulatory system

- 1. Licensing Schemes
- 2. Consent of donors of human biological materials
- (b) Confidentiality systems for donors/information registries
- 3. Legislative Review
- 4. Ancillary development of infrastructure
- 5. Methods for public consultation or facilitated public discussion

# Elements of a regulatory system

- Licensing Schemes
  - inspections; audits; power of revocation/suspension
  - limits that keep research protocols of high scientific and ethical quality:
    - Previous protocol review, scientific and ethical
    - No animal model possible for the proposed research
    - Means of research are scientifically valid
    - Ends of research are desirable and necessary (benefits to humanity)
    - 14 day limit
    - # of embryos/oocytes requested in protocol are necessary

# Elements of a regulatory system

- 2. Consent of donors of human biological material
  - Informed, written and specific
  - E.g. human research cloning – oocyte donation (need for regulation of supply of oocytes)
  - No coercion at point of supply
  - Conflicts of interest management
  - Restrictions on commercialization
- (b) Confidentiality systems for donors; information registries

# Elements of a regulatory system

- Legislative Review
  - Sunset clauses (Aust); moratoria for limited periods
    - In light of scientific/medical developments
    - Changing social views
  - Review of research protocol outcomes after period of time
  - Review of surplus embryo supply

# Ancillary development of infrastructure

- Reproductive cloning bills/Acts
- Aust revisiting IP issues
- Changes in embryo donation/oocyte donation laws
- Regulatory structure for what is done with stem cells once removed from embryos e.g. secondary ES cell research outside HFEA remit
- MRC bank for stem cell lines
- Regulations for international exchange human biological materials
- Access/benefit issues wrt potentially medical beneficial research

# Beyond embryo research

- Canada:
- CIHR
  - Guidelines for funding stem cell research
  - SCOC (funding decisions)
  - One hESC derivation funded to date
- AHRA
  - Agency (licensing decisions)
  - Anticipated start 2007
  - Secondary uses of stem cells not covered
  - Interaction between two agencies?

# Beyond embryo research

- UK:
  - Secondary uses of stem cells (not covered in HFEA)
- MRC stem cell bank
  - Code of Practice
  - Procedural and administrative organization and resources

# Code of Practice for the use of Human Stem Cell Lines

## CODE OF PRACTICE FOR THE USE OF HUMAN STEM CELL LINES

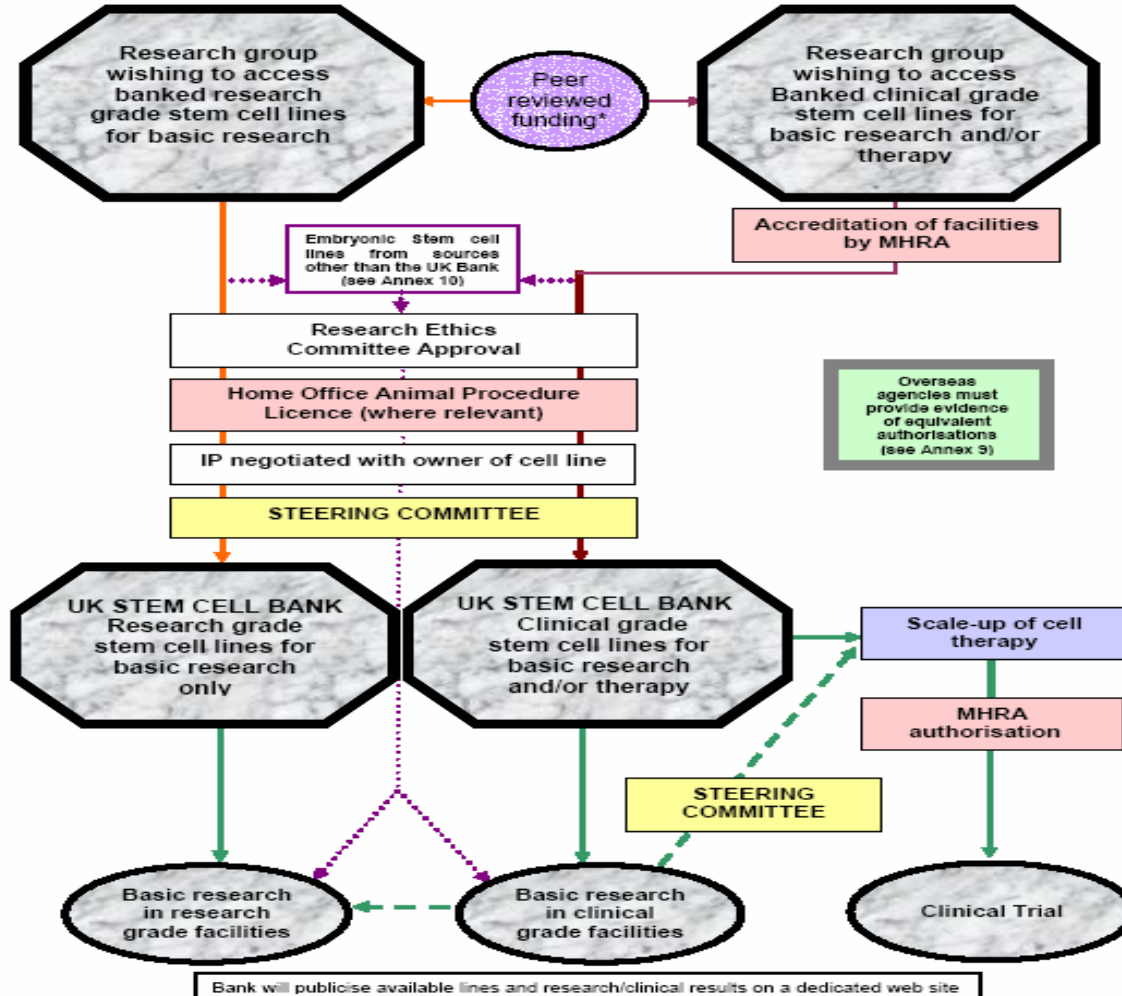
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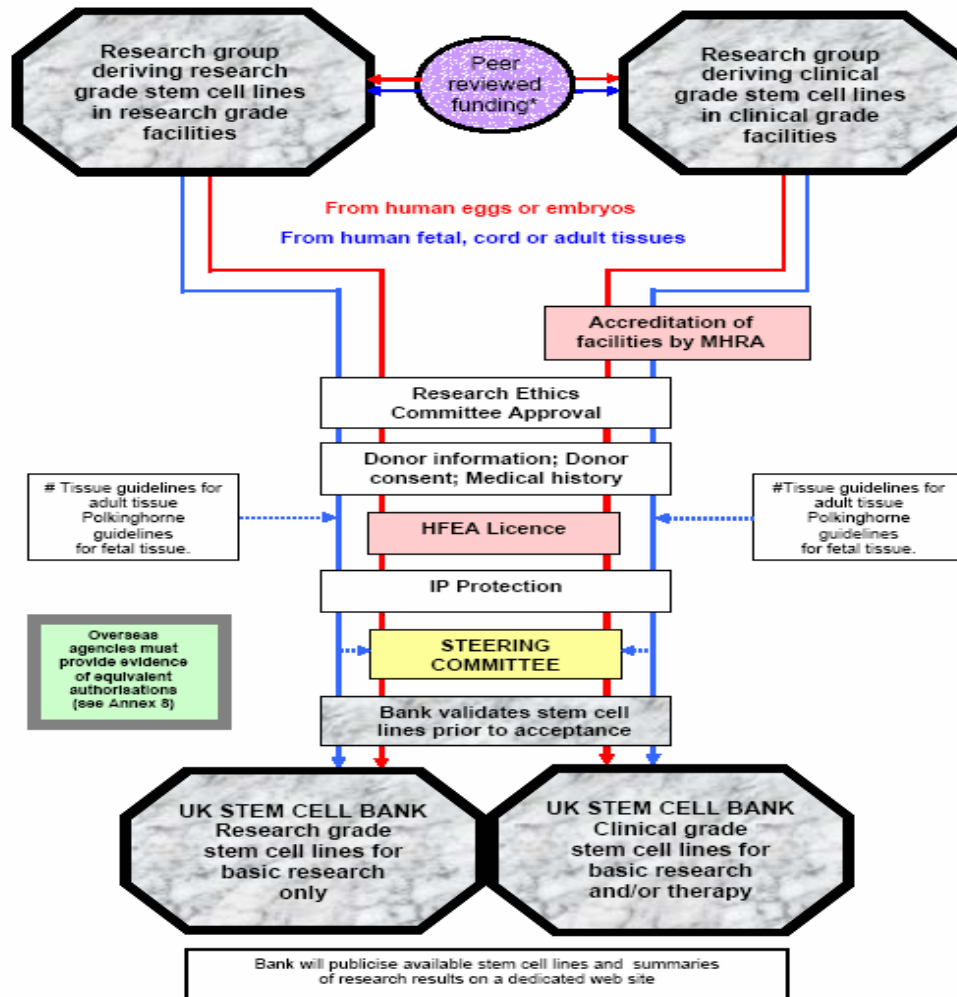
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ROUTE MAP FOR UK GROUPS WISHING TO ACCESS RESEARCH GRADE OR CLINICAL GRADE BANKED STEM CELL LINES FOR BASIC RESEARCH AND/OR THERAPY



\* Companies, and academics funded by companies, must secure equivalent Independent approval  
 HFEA = Human Fertilisation and Embryology Authority; IP = Intellectual Property; MHRA = Medicines and Healthcare products Regulatory Agency; Steering Committee = Steering Committee for the UK Stem Cell Bank and for the use of Stem Cell Lines  
 NB. There may be very exceptional cases where research grade lines are the only route to therapy; such lines would have to be re-processed and banked in MHRA-accredited facilities prior to clinical use

ROUTE MAP FOR UK GROUPS WISHING TO DERIVE AND BANK RESEARCH GRADE AND CLINICAL GRADE STEM CELL LINES



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 HFEA = Human Fertilisation and Embryology Authority; MHRA = Medicines and Healthcare products Regulatory Agency; IP = Intellectual Property. Steering Committee = Steering Committee for the UK Stem Cell Bank and for the use of Stem Cell Lines  
 # = There are ongoing reviews and consultations by the DH (England) and the Scottish Executive on the use of human organs and tissues. Any ensuing legislation may also require some revision of the current Polkinghorne guidelines.

# Elements of a regulatory system

- Methods for public consultation or facilitated public discussion
- “It should be recalled that the purpose of bioethics is not to ban upfront scientific advances particularly in the field of medicine, but to define the limits of the socially desirable and ethically permissible”
  - Bioethics Advisory Committee of Israel National Academies of Science and Humanities