

Human Embryo Research – informing regulatory policy

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History of UK approach to regulating Embryo Research

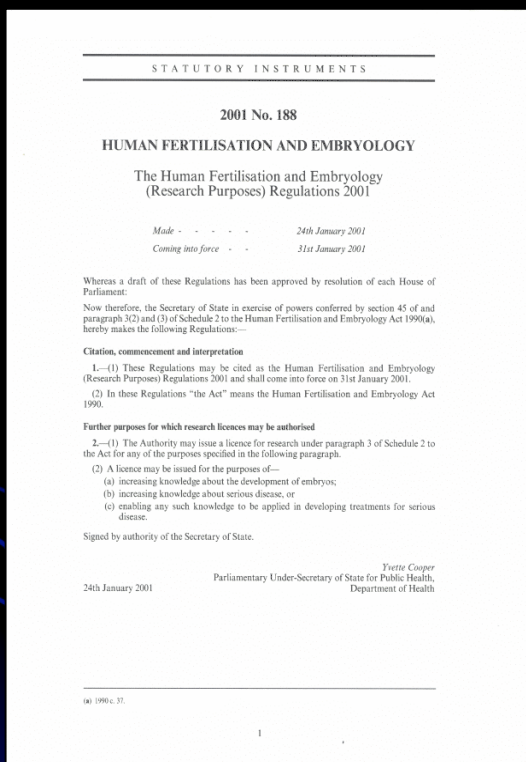
- λ 1st IVF baby – UK 1978
- λ Warnock enquiry into Human Fertilisation and Embryology reports 1984
- λ HFEA established 1991
- λ Dolly the sheep cloned 1997
- λ CMO report into stem cell research 2000
- λ Legislation amended to allow use of embryos for stem cell research 2001
- λ UK ban on reproductive cloning 2001
- λ UK stem cell bank launched 2004

Purposes for which a human embryo research licence may be granted

- ♣ Promoting advances in the treatment of infertility,
- ♣ Increasing knowledge about the causes of congenital disease,
- ♣ Increasing knowledge about the causes of miscarriages,
- ♣ Developing more effective techniques of contraception, or
- ♣ Developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.....

Sched. 2, para. 3(2)

Additional HF&E (Research Purposes) Regulations 2001



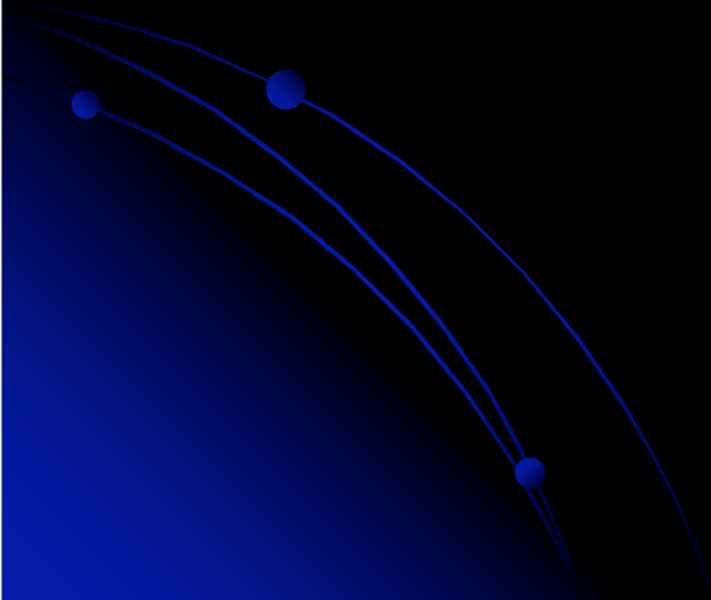
- ♣ increasing knowledge about the development of embryos;
- ♣ increasing knowledge about serious disease, or
- ♣ enabling any such knowledge to be applied in developing treatments for serious disease

s.2(2)

Preventing: prohibitions of the HFE Act

- λ No person can use/store a human embryo after the appearance of the primitive streak and/or fourteen days after fertilisation
- λ No person can introduce a human embryo into an animal
- λ No person can introduce animal eggs, sperm or embryos into a woman's body
- λ Alter the genetic structure of an embryo

New Developments

- λ Sex selection
 - λ PGD with HLA typing
 - λ Stem cell derivation
 - λ Hybrid embryos
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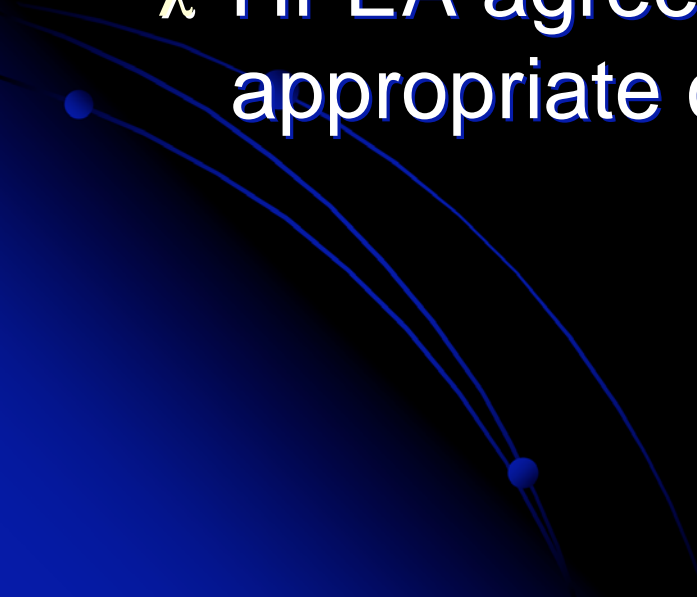
Sex Selection

- λ Technically possible to select male and female sperm and hence choose sex of embryo apparently safely using laser sorting
- λ HFEA decision informed British Government decision to prohibit sex selection from non-medical reasons

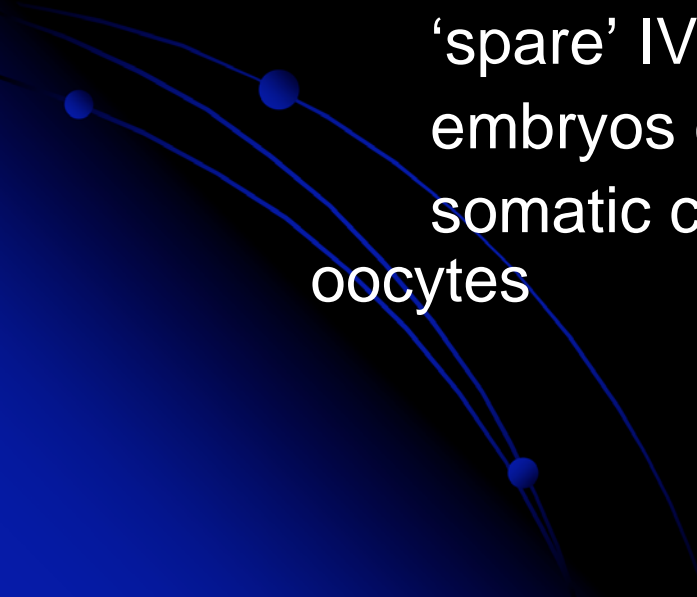
Sex Selection

- λ Betrays the commonly held presumption in favour of liberty
- λ Should be available in a strictly regulated fashion in order to gather empirical evidence
- λ Overlooks the legitimate interests of some families
- λ Further research needed

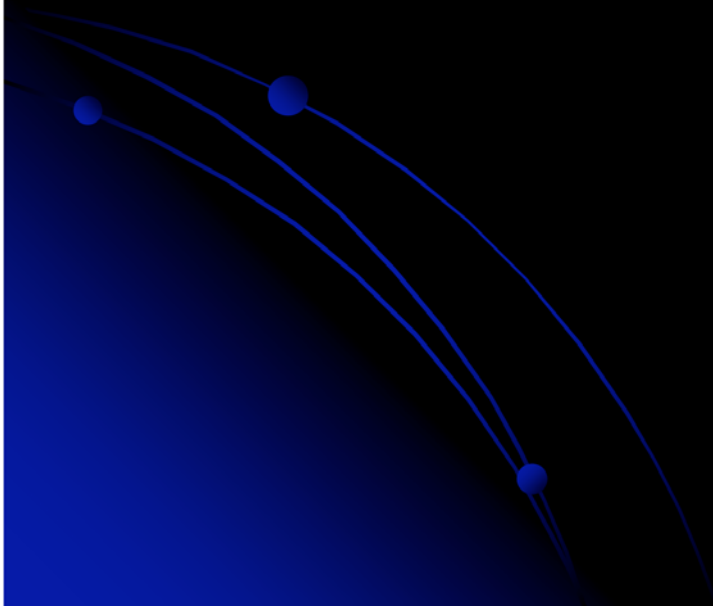
PGD and HLA Typing

- λ Saviour sibling possibilities
 - λ Testing of embryos for unaffected and HLA matched with living affected child
 - λ HFEA agreed to licence under appropriate clinical circumstances
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Stem cell sources: what is permitted in UK

- Adult stem cells (e.g. bone marrow)
 - Foetal cells (foetal tissue or cord blood)
 - Embryonic stem cells (pre-implantation embryos)
 - ‘spare’ IVF embryos
 - embryos created from donated gametes
 - somatic cell nucleus transfer from donated oocytes
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Human Hybrid Embryo Consultation



Joint Committee on the Draft Human Tissue and Embryos Bill - 2007

- λ Who decides what the Government should enact in the new Bill?
- λ Will there be a consistent world opinion? – and does it matter?
- λ How do religious and non-religious views differ and how can this be taken into account in a multicultural society?

Hybrid Embryos

λ Cytoplasmic Hybrids

λ Hybrids

λ Chimeras

λ Transgenic Human Hybrids

Decision Tree

Does the HFEA have the legal remit to license research involving the creation of human-animal embryos?

∫

Is the research desirable?

Are there important benefits to be gained by this research?

Do the scientific community and the public recognise the potential benefits of the research?

∫

Is the research necessary?

From the scientific information presented, are you convinced that the research is necessary?

Does the balance of ethical concerns support the need for this research?

Are there alternatives to pursuing research of this kind, which have the potential to achieve the same benefits?

What are the foreseeable consequences if this research did not take place?

Hybrid Embryos Consultation

- λ The scientific community felt confident that the creation of cytoplasmic hybrids is an avenue of research worth exploring and in particular could be a viable technique, and an alternative to using human eggs, to investigate the mechanisms of creating patient matched embryonic stem cells.
- λ Sufficient evidence is available to the Authority to enable it to form a view on cytoplasmic hybrid embryos. HFEA worked through the decision tree as part of the decision making process. This clarified for them that cytoplasmic hybrids fall within its jurisdiction.

Hybrid Embryos

- λ HFEA – following a full consultation decision that a hybrid embryo containing significant amounts of a human genome falls within its remit to regulate
- λ HFEA licence committees therefore able to consider individual applications for research licences to create human/animal hybrid embryos

**'Frankenstein' researchers plan
embryo with three parents**

**'MOUSE MAN'
ARRIVING SOON**

*Public Poll says 'No'
to more embryo research*