

HUMAN FERTILISATION AND EMBRYOLOGY ACT 2008

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 1: Amendments of Human Fertilisation and Embryology Act 1990

Section 13: Consent to use or storage of gametes, embryos and human admixed embryos etc.

Exceptions to the requirement for consent

Existing cells or cell lines

105. The Act inserts new paragraphs 20 and 21 into Schedule 3 to the 1990 Act, which provide an exception to the general requirement for an effective consent, found in paragraph 6 of Schedule 3, for the use of a person's cells to bring about the creation of an embryo or human admixed embryo and for the subsequent storage and use of any resulting embryo. This exception to the requirement for consent only applies to cells stored *before* the commencement of the consent provisions in the Act. In addition, the exception will only apply if the Authority are satisfied that either:
- i. the licence holder could not reasonably identify the donor;
 - ii. the donor had died, or was reasonably believed to be dead and consent from a family member or close friend has been obtained working on the basis of a hierarchy established by the Human Tissue Act 2004 (person in a qualifying relationship); or
 - iii. the donor was not reasonably traceable and if there was reason to believe the donor was dead a person in a qualifying relationship was not reasonably traceable.
106. In each case, there must not be any information available to the person responsible under the licence to suggest that the donor would have objected to the research. In addition, the Authority have to be satisfied there were reasonable grounds for believing that scientific research would be adversely affected to a significant extent if the only cells that could be used were those for which consent had been obtained, (or which fall within the exception to consent for adults lacking capacity, detailed below at paragraph 109).
107. New section 15(5) to the 1990 Act, as inserted by paragraph 7 of Schedule 7 to the Act, makes it a condition of any research licence, which relies on the exception to consent under new paragraph 20 of Schedule 3 to the 1990 Act, that any embryos or human admixed embryos created must be anonymised so that they cannot be linked back to the donor.