These notes refer to the Human Fertilisation and Embryology Act 2008 (c.22) which received Royal Assent on 13 November 2008

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.

Consent to use of human cells

- 81. In Schedule 3 to the 1990 Act as it stands, paragraph 6 requires the consent of any person before their gametes can be used to create an embryo *in vitro* for one of the purposes listed in paragraph 2(1). Under paragraph 8 of the Schedule as it stands, consent must also be obtained from a gamete donor to storage of their gametes, or of any embryo created using their gametes.
- 82. New scientific procedures have enabled embryos to be created or altered using human cells. It is also possible to create embryos using other embryos or human admixed embryos.
- 83. Paragraph 6 of Schedule 3 to the 1990 Act is amended by paragraph 9 of Schedule 3 to the Act to require an effective consent from a person whose gametes or human cells are used to create an embryo *in vitro* for use in treatment services (not including implantation) or for a project of research. ("Human cells" are defined by new paragraph 22 to exclude reproductive cells).
- 84. Consent is also required from each "relevant person" in relation to an embryo for its use for any purpose (see paragraph 6(3)). In addition consent from each "relevant person" must be in place before an embryo is received by any person.
- 85. New sub-paragraph (3A) is inserted into paragraph 6 to provide that a "relevant person" means -:
 - each person whose gametes or human cells were used to bring about the creation of the embryo (embryo A);
 - each person whose gametes or human cells were used to create *in vitro* an embryo which was then used to create embryo A; and
 - each person whose gametes or human cells were used to create *in vitro* a human admixed embryo, which was then used to create embryo A.
- 86. Paragraph 15 of Schedule 3 to the Act inserts paragraph 22 into Schedule 3 to the Act and provides that references to an embryo or human admixed embryo used to create an embryo include all predecessor embryos or human admixed embryos. This creates a chain of consent, so that a person must consent to their gametes or human cells

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(as defined) being used to create an embryo and their consent is then required to the subsequent use of that embryo to create other embryos or human admixed embryos.

- 87. Paragraph 8 of Schedule 3 to the 1990 Act is amended by paragraph 11 of Schedule 3 to the Act to require consent from each "relevant person" to the storage of any embryo. Consent to storage of human cells continues to be regulated under the Human Tissue Act 2004.
- 88. Paragraph 2(4) of Schedule 3 to the 1990 Act is substituted to enable consent to relate to the use or storage of a particular embryo or to the use or storage of any embryo created using human cells or gametes (or using any embryo or human admixed embryo created using a person's cells or gametes). Consent can be withdrawn or varied either in relation to a specific embryo or generally.
- 89. Paragraph 4 of Schedule 3 to the 1990 Act is also amended by paragraph 6 of Schedule 3 to the Act to require notice to be given to the person keeping the human cells if the donor wishes to withdraw or vary their consent. This mirrors the existing provision for gametes and embryos. However if the person has consented to any embryo created from their cells or gametes being used to create subsequent embryos or human admixed embryos they will not be able to withdraw their consent once the initial embryo has been used for treatment services (not including implantation in a woman) or research.
- 90. Paragraph 7 of Schedule 3 to the 1990 Act is amended by paragraph 10 of Schedule 3 to the Act to prohibit the use of an embryo taken from a woman to create an embryo *in vitro* or to create a human admixed embryo *in vitro*.
- 91. New paragraph 22 of Schedule 3 to the 1990 Act applies the consent provisions contained in Schedule 3 to the use of human cells to *alter* embryos or human admixed embryos, in the same way that they apply to human cells or gametes used to *create* embryos or human admixed embryos. This ensures consent is in place for example before human cells could be used to alter a human embryo to create a human chimera. New paragraph 22 of Schedule 3 also defines human cells as excluding cells of the female or male germ line or cells of an embryo.
- 92. Paragraphs 22 to 24 of Schedule 7 to the Act make related amendments of the Human Tissue Act 2004 to ensure that, where consent is required under the 1990 Act (as amended) for the use of human cells to create or alter an embryo or a human admixed embryo, consent under the Human Tissue Act is not also required.