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.

73. Section 13 introduces Schedule 3 to the Act which amends Schedule 3 to the 1990 Act, relating to consent to store or use embryos or gametes to create an embryo *in vitro*.

Formalities of consent

74. Schedule 3 to the 1990 Act states that consent for the storage and use of gametes and embryos is required in writing. This requirement for written consent is retained, there is now an express requirement that the consent must be signed.

Physical incapacity

75. People who have suffered an injury resulting in a condition such as quadriplegia or a similar condition may lack the physical ability to sign the consent form although they have the capacity to consent. New paragraph 1(2) of Schedule 3 to the 1990 Act will allow a physically incapacitated person, who is unable to write and therefore give consent in writing, to direct another to sign on their behalf, in the presence of a witness.

Purpose of consent

76. Under the 1990 Act, a consent must specify the purposes for which any gamete or embryos are to be used. The Act amends paragraph 2(1) of Schedule 3 so that, in addition to being able to consent to the use of embryos for treatment or research, a person may now also specify that an embryo can be used in the training of embryologists.

Variation and withdrawal of consent

77. Paragraph 4 of Schedule 3 to the 1990 Act requires that a person withdrawing their consent to the storage and/or use of gametes or embryos gives notice of this to the establishment holding the gametes or embryos. New paragraph 1(1) of Schedule 3 requires this notice to be provided in writing and signed by the person withdrawing consent.

78. Paragraph 7 of Schedule 3 to the Act inserts new paragraph 4A to Schedule 3 into the 1990 Act and introduces a "cooling off period" where one person in a couple seeking fertility treatment withdraws their consent to the storage of an embryo or, where donated gametes are used, where the gamete donor withdraws consent. This provision does not alter the requirement that the consent of both parties is required to store the embryos

but it is intended to provide a year-long "cooling off" period during which the embryos will not be destroyed unless all interested persons (see paragraph 4A(3)) consent. There is also to be a "cooling off" period where a single woman seeks fertility treatment and the gamete donor or donors withdraw consent.

79. This provision allows embryos to remain lawfully stored while the parties, if they wish, attempt to reach a private resolution on the future of the embryos. If the interested persons do not agree to the embryos being removed from storage or simply do not respond to the notification, the embryos will remain in storage until the one year period expires after which they would be allowed to perish.

Non-medical fertility services

80. Paragraph 5 of Schedule 3 to the 1990 Act provides that a person's gametes must not be used for the purpose of treatment services unless there is an effective consent. The Act makes provision to also apply this condition where a person's gametes are used for the purpose of non-medical fertility services.

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 (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.

Cases where consent not required for storage

93. Patients who undergo chemotherapy or radiotherapy can be left infertile. Prior to treatment, if time allows, fertility could be preserved by placing gametes in storage. However, in some cases, the patient might not have the capacity to give consent to storage. In the case of childhood cancer, a child may be too young to be considered competent to consent to storage of their gametes.

94. Similarly, people who suffer a serious physical injury, the treatment of which could again result in infertility, would also be able to preserve their fertility by this means. For example, a severe injury may have rendered an adult unable, perhaps because of a coma, to give consent or direct another person to do so on his or her behalf.

95. New paragraphs 9 and 10 of Schedule 3 to the 1990 Act will allow the storage of gametes, without written consent, providing a medical practitioner certifies that the conditions set out in those paragraphs have been met. The gametes cannot be used for any purpose unless the gamete provider becomes competent and consents to such use.

Creation, use and storage of human admixed embryos

96. New paragraphs 12 to 14 are inserted into Schedule 3 to the 1990 Act by paragraph 13 of Schedule 3 to the Act and introduce consent requirements for the creation, use and storage of human admixed embryos (as defined by new section 4A (5) of the 1990 Act, inserted by section 4 of the Act). Human admixed embryos can be created using embryos, human cells, gametes and other human admixed embryos.

97. Paragraph 12 makes provision equivalent to paragraph 6 of Schedule 3 to the 1990 Act (as amended by the Act) and requires an effective consent before a person's gametes or human cells can be used to create a human admixed embryo *in vitro* for the purpose of a research project.

98. Consent is also required from each "relevant person" in relation to a human admixed embryo for its use in a research project (see paragraph 12(3)). In addition consent from each "relevant person" must be in place before a human admixed embryo is received by any person.

99. New paragraph 13 of Schedule 3 to the 1990 Act achieves equivalent provision to paragraph 8 of Schedule 3 of the 1990 Act (as amended) and requires consent from each "relevant person" to storage of a human admixed embryo.

100. New paragraph 14 defines "relevant person", for the purposes of new paragraphs 12 and 13, to mean any of the following:

- each person whose gametes or human cells were used to bring about the creation of the human admixed embryo (human admixed embryo A);
- each person whose gametes or human cells were used to create an embryo *in vitro*, which was then used to create human admixed embryo A; and
- each person whose gametes or human cells were used to create a human admixed embryo *in vitro*, which was then used to create human admixed embryo A.

101. As for the creation of embryos, new paragraph 22 of Schedule 3 to the 1990 Act, as inserted by paragraph 15 of Schedule 3 to the Act, provides that references to an embryo or human admixed embryo used to create a human admixed 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 being used to create a human admixed embryo and their consent is then required to the subsequent use of that human admixed embryo to create other embryos or human admixed embryos.

102. Paragraph 2 of Schedule 3 to the 1990 Act is amended to make equivalent provision to embryos used to create human admixed embryos. These amendments ensure that the consent to use of any human admixed embryo must relate to a research project and enables conditions to be attached to such use. In addition the consent must specify a maximum storage period and state what will happen to the human admixed embryo if the person who has consented dies or loses capacity. Conditions can also be attached to storage of the human admixed embryo.

103. Provision is made under the new paragraph 2(4) of Schedule 3 to the 1990 Act to allow a person to consent to the use or storage of a particular human admixed embryo or to the use and storage of any human admixed embryo created using a person's cells or gametes (or using an embryo or human admixed embryo created using their cells or gametes). Consent can be withdrawn or varied in relation to a specific human admixed embryo or generally.

104. Paragraph 4 of Schedule 3 to the 1990 Act is also amended to enable consent to be withdrawn or varied by notice to the person keeping the human admixed embryo. This ability to withdraw or vary consent in relation to a human admixed embryo is subject to the same limitation as for embryos set out at paragraph 89 above. This means once the initial human admixed embryo has been used for research purposes consent cannot be withdrawn or varied in relation to any further embryos or human admixed embryo created from it.

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.

Adults who lack capacity

108. The Act inserts new paragraph 16 to 19 of Schedule 3 to the 1990 Act. Paragraph 16 provides an exception to the requirement for an effective consent, found in paragraph 6 of Schedule 3, for the use of cells from a person who has attained 18 years of age, to bring about the creation of an embryo or human admixed embryo and for the subsequent storage and use of any resulting embryo. Reliance on this exception is subject to the conditions set out in new paragraphs 17 and 18. The Authority must be satisfied that:

i. the adult lacks capacity and is unlikely to have capacity again;

ii. the adult suffers from, or is likely to develop a serious disease, serious disability or other serious medical condition;

iii. the proposed embryonic research is intended to increase knowledge about that disease/ disability/ condition or its treatment and care (or similar conditions);

iv. there is no evidence that the adult would have refused to participate at any time they may have had capacity in the past;

v. there are reasonable grounds for believing research of comparable effectiveness could not be carried out using the cells of a person who could consent themselves;

vi. the licence holder has taken steps to identify a carer for the adult who could be consulted or has nominated someone if a carer could not be found;

vii. the carer or nominee has been consulted as to their opinion of what the adult who lacks capacity's wishes or feelings would be about the proposed use of their cells – if they indicated they did not think that they would want them to be used then the researcher could not use their cells.

109. New paragraph 19 of Schedule 3 to the 1990 Act provides that if the adult donor acquired capacity they can give notice that their cells are not to be used to create any further embryos, or that any existing embryos may not be used in research.

Cells from children

110. Paragraphs 6 and 8 of Schedule 3 to the 1990 Act are amended by paragraph 9(5) and 11(3) of Schedule 3 to the Act, to allow the use of cells from a child under the age of 18 years (or, in Scotland, 16 years) to create an embryo, and the subsequent use and storage of such embryos, without the child's consent, if consent is given by a person with parental responsibility *and* a number of other safeguards are in place (see below). The Act inserts new paragraphs 12(4) and (6) and 13(2) and (3) of Schedule 3 to the 1990 Act to make equivalent provision for the use of a child's cells to create human admixed embryos and for the use and storage of such embryos. These provisions also ensure that if a child attained the age of 18 or became competent before that time, they would be able to vary or withdraw any consent given by a person with parental responsibility (subject to the usual limits on varying and withdrawing consent set out in paragraph 4 of Schedule 3 to the 1990 Act). These provisions cannot be relied on unless the Authority are satisfied that the "parental consent conditions" set out in new paragraph 15 of the 1990 Act are met. The Authority need to be satisfied that:

i. The child suffers from or is likely to develop a serious disease, serious disability or any other serious medical condition;

ii. The proposed research is intended to increase knowledge about the disease/ disability/ condition, or its treatment and care (or similar conditions);

iii. There are reasonable grounds for believing research of comparable effectiveness could not be carried out using the cells of a person who could consent themselves.

111. Paragraph 2(2) of Schedule 3 ensures that where consent was given to the use of a child's cells to create an embryo or human admixed embryo and for the storage of that embryo the consent would have to state what should happen to the embryo if the child dies. In addition any consent by a person to the use of their cells to create an embryo or human admixed embryo is to endure their death, unless otherwise stated.

112. New paragraphs 22(5) to (7) of Schedule 3 to the 1990 Act set out the meaning of the terms "parental responsibility" and "capacity" in relation to England, Wales, Scotland and Northern Ireland. They also provide for the provisions relating to children to apply, in Scotland, to those under 16 years rather than those under 18.