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 11: Activities that may be licensed

46. This section introduces Schedule 2 to the Act which amends Schedule 2 to the 1990 Act. These amendments relate to licensable activities, specifically embryo testing and amending the purposes for which research licenses can be granted including the creation, keeping and use of human admixed embryos.

Licences for treatment

47. Paragraph 2 of Schedule 2 to the Act amends paragraph 1 of Schedule 2 to the 1990 Act to enable treatment licences to be granted for the use of embryos for training persons in embryo biopsy, embryo storage and other embryological techniques, but only where the HFEA is satisfied that such use is necessary for that purpose. Paragraph 1 is also amended to ensure that only "permitted embryos" within the meaning of new section 3ZA can be placed in a woman. The Act substitutes a new provision for paragraph 1(4) of Schedule 2 to prevent a treatment licence authorising the alteration of the nuclear or mitochondrial DNA of a cell while it forms part of an embryo. This is subject to any regulations under new section 3ZA(5) as inserted by section 3.

Embryo testing

48. Paragraph 3 of Schedule 2 to the Act adds to Schedule 2 to the 1990 Act new paragraphs 1ZA to 1ZC which relate to embryo testing and practices designed to secure that a resulting child will be of one sex rather than the other.

49. Embryo testing can involve invasive procedures such as embryo biopsy, involving removal of a cell or cells from the embryo for subsequent analysis. The effect of the new provisions is that testing of an embryo can only be authorised for the purposes in new paragraph 1ZA(1)(a) to (e). For example, sub-paragraph (1)(a) could authorise testing to establish whether an embryo contained an abnormal number of chromosomes likely to result in miscarriage, sometimes referred to as pre-implantation genetic screening. Sub-paragraph (1)(b) could, for example, authorise testing to establish the presence or absence of a genetic disorder in a case where there was a particular risk of such an abnormality being present, sometimes referred to as preimplantation genetic diagnosis. A particular risk might be evidenced, for example, by a family history of the disease.

50. Sub-paragraph (1)(c) could authorise establishing the sex of an embryo where there is a particular risk that any resulting child will have or develop a gender-related serious physical or mental disability, serious illness or other serious medical condition. This provision enables sex selection not only for conditions which are clearly linked to sex

chromosomes, for example Duchenne Muscular Dystrophy but also where there is a particular risk of gender-related conditions for example a strong family history of breast cancer where the mother has also been affected (and therefore is probably a carrier of the faulty gene), and wishes to avoid passing this condition on to a daughter.

51. Paragraph 1ZA(1)(b) is subject to the further provisions set out in sub-paragraph (2). Sub-paragraph (2) provides that in order for testing to be authorised under sub-paragraph (1)(b), the HFEA must be satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

52. A provision of section 14 is closely related to the provisions on embryo testing discussed above. Section 14 amends the 1990 Act to make it a condition of a treatment licence that, in the circumstances described, embryos that are known to have an abnormality as described are not to be preferred to embryos not known to have such an abnormality. The same restriction is also applied to the selection of persons as gamete or embryo donors. Similarly for sex selection, embryos of a particular sex that are at a particular risk, compared to embryos of that sex in general, of a gender-related disability, illness or medical condition, should not be preferred to those that are not known to be at risk (see note on section 14).

Tissue typing

53. Paragraph 1ZA(1)(d) is concerned with "tissue typing" – establishing whether the embryo would result in a child whose tissue was compatible with that of an existing child (the sibling). Embryo testing for this purpose could be licensed where the sibling suffers from a serious medical condition that could be treated with matched tissue from the child to be born including stem cells found in umbilical cord blood and bone marrow or "other tissue". Paragraph 1ZA(4) provides that the reference to "other tissue" in paragraph 1ZA(1)(d) does not include a whole organ. This provision ensures that tissue typing cannot be licensed if the match was to be carried out because the older sibling required a whole organ.

Testing in the event of uncertainty

54. Paragraph 1ZA(1)(e) is intended to ensure that embryos can be tested in order to resolve any uncertainty that has arisen as to the identity of the persons who provided the gametes used to create the embryo.

Sex selection

55. Previously, as a matter of policy, the HFEA has not allowed sex selection except for medical reasons. This position is maintained in the Act. Paragraph 1ZB deals more generally with practices of sex selection, for example sperm sorting, and precludes them from being authorised by a licence other than where there is a particular risk that a woman will give birth to a child who will have or will develop a gender-related serious physical or mental disability, serious illness or other serious medical condition (see paragraph 52 of these notes). Paragraph 1ZB does not prevent any embryo testing practices that may be permitted under paragraph 1ZA.

56. Paragraph 1ZC provides regulation-making powers to amend new paragraph 1ZA (embryo testing), and to make consequential amendments of the new paragraph 1ZB (sex selection). However, regulations may not authorise testing embryos to establish their sex or other practices of sex selection, except on grounds relating to the health of any resulting child.

57. Paragraph 4 of Schedule 2 to the Act makes an amendment that is intended to prevent sex selection, in the context of the provision of non-medical fertility services. A licence cannot authorise the procurement or distribution of sperm to which any process has been applied which is designed to result in a child of a specific sex.

Licences for research

58. Under paragraph 3 of Schedule 2 to the 1990 Act, a research licence may authorise the creation, keeping and/or use of human embryos for the purposes of a project of research. Paragraph 6 of Schedule 2 to the Act substitutes new paragraphs 3 and 3A for the existing provision.

Purposes for which embryo research may be undertaken

59. A research licence may not authorise any activity unless the HFEA considers it to be necessary or desirable for one of the specified research purposes.

60. The list of permitted research purposes was extended by the Human Fertilisation and Embryology (Research Purposes) Regulations (SI 2001/188) ("the 2001 Regulations"), which allowed embryos to be created and used for research into stem cell therapies and the treatment of serious disease. New paragraph 3A brings together all the research purposes listed in the 1990 Act and the 2001 Regulations. It also makes three significant changes to the previous position on licensable research using embryos.

61. The list of purposes for which research may be licensed has been expanded in new paragraph 3A(2)(a) to include research which is undertaken to increase knowledge, not only about serious diseases, but also about other serious medical conditions. This includes conditions such as neural trauma or other tissue damage, which would not be considered to be diseases and therefore would not previously have been permitted.

62. New paragraph 3A(2)(b) allows for research into the development of treatments for other serious medical conditions, as well as for serious disease. Research may lead to an understanding of how to change stem cells into particular tissues, which may have the potential to regenerate or repair tissue damage caused by disease or trauma.

63. New paragraph 3A(1)(b) extends an existing provision, to give the HFEA power to not only issue licences where it is necessary or desirable for one of the principal purposes, but also where the research will increase knowledge about serious disease or other serious medical conditions, or develop treatments for them.

64. The 2001 Regulations have been superseded and are therefore revoked by Part 2 of Schedule 8 to the Act.

Genetic modification of cells

65. Previously paragraph 3(4) of Schedule 2 to the 1990 Act prohibited alteration of the genetic structure of the cell of an embryo, except in such circumstances as may be specified in regulations. No such regulations were in fact made. This prohibition is not included in the re-enacted paragraph 3. Therefore research involving the genetic modification of embryos may now be authorised under a research licence.

Human admixed embryos

66. Paragraph 3(2) of Schedule 2 to the 1990 Act, as inserted by paragraph 6 of Schedule 2 to the Act, continues to allow the mixing of sperm with the egg of a hamster, or other animal specified in directions, for the purposes of research into the normality or fertility of sperm. Any resulting human admixed embryo must be destroyed as soon as the research is complete and no later than the two-cell stage.

67. New paragraph 3(3) enables licences to be issued to create, keep and use human admixed embryos (as defined by new section 4A(5)(a) to (e) inserted by section 4 of the Act) for the purposes of a project of research specified in the licence.

68. New paragraph 3(5) provides that no research licence can be granted unless the proposed use of embryos or human admixed embryos is necessary for the purposes of the research.

69. New paragraphs 3(6), (8) and (9) of Schedule 2 to the 1990 Act deal with time limits and conditions applying to research licences.

Licences for storage (of human admixed embryos)

70. Under paragraph 2 of Schedule 2 to the 1990 Act, a storage licence may authorise the storage of gametes or embryos, or both. Paragraph 5 of Schedule 2 to the Act inserts new sub-paragraph (1A) into paragraph 2 of Schedule 2 to the 1990 Act allowing the storage of human admixed embryos (regardless of whether the licence holder is already licensed to store embryos or gametes). Any such licence would be subject to the same conditions and time limits under paragraph 2(2) and (3) of Schedule 2 to the 1990 Act as licences to store embryos and gametes.