

HUMAN FERTILISATION AND EMBRYOLOGY ACT 2008

EXPLANATORY NOTES

COMMENTARY ON SECTIONS

Part 1: Amendments of Human Fertilisation and Embryology Act 1990

Section 1: Meaning of “embryo” and “gamete”

22. This section amends section 1 of the 1990 Act so as to ensure that the Act applies to all live human embryos regardless of the manner of their creation, and to all live human gametes (eggs and sperm).
23. An embryo will continue to be defined under the new section 1(1) in broad terms as a “live human embryo” but the definition no longer assumes that an embryo can only be created by fertilisation. This brings the term “embryo” up to date with technologies that have been developed since the time of enactment of the 1990 Act.
24. The definition of an “embryo” in the new section 1(1)(a) of the 1990 Act excludes certain types of embryos created by combining together human and animal gametes, or human embryos altered using animal DNA or animal cells. Such entities are defined as “human admixed embryos” by new section 4A of the 1990 Act as inserted by section 4.
25. The term “gametes” under section 1(4) of the 1990 Act has been amended to expressly encompass not only mature eggs and sperm, but also immature gametogenic cells such as primary oocytes, and spermatocytes.
26. A regulation-making power has been taken to expand the definitions of “embryo”, “eggs”, “sperm” or “gametes”, where this is considered by the Secretary of State to be necessary or desirable in light of developments in science or medicine (see new section 1(6)).

Section 2: Meaning of “nuclear DNA”

27. This section inserts a new definition into section 2 of the 1990 Act to clarify that any reference to “nuclear DNA” includes DNA in both the nucleus and pronucleus of an embryo.

Section 3: Prohibitions in connection with embryos

28. **Section 3** amends section 3 of the 1990 Act, which covers prohibitions connected with embryos. Section 3(2) prohibits the placing in any woman of any embryo other than a permitted embryo or any gametes other than permitted eggs or permitted sperm.
29. A permitted embryo is defined as an embryo which has been formed by the fertilisation of a permitted egg by a permitted sperm, whose nuclear or mitochondrial DNA has not been altered and which has not had cells added (except by division of the embryo’s own cells). Permitted eggs are defined as eggs produced by or extracted from the ovaries

of a woman and permitted sperm as sperm produced by or extracted from the testes of a man. These eggs and sperm must also not have been subject to any alterations to their nuclear or mitochondrial DNA. This section ensures embryos created by artificial gametes or genetically modified gametes could not be placed in a woman. Similarly, genetically modified embryos or embryos created by cloning cannot be placed in a woman. This prevents reproductive cloning and supersedes the Human Reproductive Cloning Act 2001.

30. A regulation-making power has been provided under new section 3ZA(5) of the 1990 Act to allow the meaning of permitted eggs and permitted embryos to be extended to include eggs or embryos that have been treated in such a way as specified in regulations to prevent the transmission of serious mitochondrial disease¹. In the future, it may be possible to create embryos using an affected woman's egg, her partner's sperm and healthy donated mitochondria. This regulation-making power will enable such embryos and eggs to be implanted in a woman if the technology became available and was proven safe. Further provision regarding mitochondrial donation is made in section 26, which inserts new section 35A into the 1990 Act.

Section 4: Prohibitions in connection with genetic material not of human origin

31. This section inserts new section 4A into the 1990 Act to provide that certain types of embryo, which contain both human and animal DNA, are subject to regulation under the 1990 Act. These are defined as "human admixed embryos" and include:
- Cytoplasmic hybrids (Cybrids): embryos created by techniques used in cloning, using human gametes or cells and animal eggs. The embryos would be mostly human except for the presence of animal mitochondria (see the notes on section 3 for more information on mitochondria) (section 4A(6)(a));
 - Human-animal hybrid embryos: any other embryo created using a human egg and the sperm of an animal, or an animal egg and a human sperm or by combining a pro-nucleus of an animal with a human pro-nucleus (section 4A(6)(b));
 - Human transgenic embryos: embryos created by the introduction of animal DNA into one or more cells of the embryo (section 4A(6)(c));
 - Human-animal chimeras: human embryos, altered by the addition of one or more cells from an animal (section 4A(6)(d))
 - Any embryo which does not fall within any of the categories already mentioned and which contains both human nuclear or mitochondrial DNA and nuclear or mitochondrial DNA of an animal, but where the animal DNA is not predominant (section 4A(6)(e)).
32. Section 4A(2) prohibits mixing human gametes with the gametes of an animal and creating, keeping or using a human admixed embryo without a licence.
33. Section 4A(3) provides that any human admixed embryo created under licence cannot be kept after the earliest of either:
- the appearance of the primitive streak (an indicator for the start of a process by which the cells of the embryo begin to separate into three distinct cells types which will go on to form different types of tissue); or
 - 14 days from the day on which the process of creating the human admixed embryo began.

¹ Mitochondria are found outside the nucleus of the cell and contain a small amount of DNA. They are involved in energy production and are present in most cells in the body. If a woman's egg is fertilised by sperm the mitochondria from her egg will become the mitochondria for every cell of the embryo formed. Therefore, if a woman has a genetic medical condition associated with her mitochondria, these will be inherited via her eggs.

This is consistent with the time limits for keeping human embryos *in vitro* for research purposes.

34. New section 4A(5) contains a regulation-making power that enables the circumstances in which a human admixed embryo can be kept or used to be restricted. This power could be used, for example, if it became necessary to shorten the 14-day time limit, for which human admixed embryos may be kept in some circumstances. This mirrors an existing power in relation to human embryos in section 3(3)(c) of the 1990 Act. This regulation-making power is subject to the affirmative procedures.
35. Further provisions about the licensing of activities involving human admixed embryos are made in sections 11, 12, 13, and 15, paragraphs 5 and 6 of Schedule 2 and paragraph 13 of Schedule 3.
36. New section 4A(11)(a) provides a regulation-making power to amend (but not repeal) the definitions of a human admixed embryo under paragraphs (a) to (e) of subsection (6). Section 4A(11)(b) provides a regulation-making power to amend the definition of the terms “embryo”, “eggs” or “gametes” for the purpose of section 4A. Both these powers can only be exercised if it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine. Both powers are subject to the affirmative resolution procedure.

Section 5: Membership of the Authority: disqualification and tenure

37. **Section 5** introduces Schedule 1 which contains amendments to Schedule 1 to the 1990 Act. These relate to the conditions for disqualification for appointment to the chair, deputy chair and membership of the HFEA. In particular, those who have been the subject of bankruptcy orders or certain criminal convictions cannot be appointed to the HFEA.

Section 6: Additional general functions of the Authority

38. **Section 6** amends section 8 of the 1990 Act relating to general functions of the Authority. It adds to the list of the HFEA’s general functions in (i) requiring the Authority to maintain a statement of general principles and (ii) requiring the HFEA to promote compliance with the requirements imposed by the 1990 Act and with the Code of Practice under section 25 of the 1990 Act.
39. New section 8(2) gives the Authority power to charge for advice given under section 8(1)(c). It is intended that the charge would recover all or part of the costs of providing the advice.

Section 7: Duties in relation to carrying out its functions

40. This section requires the HFEA to carry out its functions effectively, efficiently and economically and to have regard to the principles of best regulatory practice in doing so.

Section 8: Power to contract out functions etc.

41. **Section 8** inserts into the 1990 Act new sections 8B and 8C which give the HFEA power to make arrangements with a government department, a public authority or the holder of a public office for the carrying out of any function of the Authority. However, the HFEA will retain responsibility for carrying out its functions. This new flexibility will, for example, permit the Authority to arrange with another public body for that body to conduct inspections on behalf of the HFEA.
42. Similarly, the HFEA will have power to contract-out certain of its functions to a body that is not a public authority. The functions that may be contracted out do not include licensing, the right of entry and power of search and seizure; or the power to make subordinate legislation. New section 8C(1)(a) prevents the contracting out of any

function which, by virtue of any enactment, may be exercised only by members of the Authority. The Secretary of State can by order prevent any function of the HFEA from being contracted out (section 8C(1)(c)).

43. **Section 8** also inserts new section 8D which provides the necessary authority for those exercising HFEA functions under an agency arrangement or contract, to receive and disclose information, such as that contained on the HFEA register, where this is necessary or expedient for the purpose of exercising the relevant function.

Section 9: Power to assist other public authorities

44. **Section 9** inserts in the 1990 Act a new section 8E which allows the HFEA to provide assistance to any other public authority in the UK. The HFEA may charge a fee for these services. It is intended that the fee would recover the costs of providing the assistance. This allows the HFEA to carry out functions on behalf of another organisation.

Section 10: Power to delegate and establish committees

45. **Section 10** inserts new section 9A into the 1990 Act. Subsection (1) of section 9A provides that the HFEA may delegate its functions to a committee or a member of the Authority, or to the Authority's staff. Subsection (2) provides that the HFEA may establish committees and sub-committees which may, in accordance with subsection (3), include people who are not members of the Authority. This provision replaces that in section 9 of the 1990 Act requiring licence committees to be comprised only of members of the Authority. These new provisions enable the HFEA to delegate any function, apart from those which can only be exercised by members, to its staff or to a committee. These functions can include licence decisions and development of the Code of Practice.

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.

Section 12: General conditions of licences

- 71. **Section 12** sets out general conditions that apply to every licence granted under the 1990 Act. The 2007 Regulations amended section 12 to except non-medical fertility services from the ambit of Schedule 3 to the 1990 Act. Neither the remit of the EU Directive or the powers under which it was implemented allowed for the consent provisions in Schedule 3 to the 1990 Act about the use and storage of gametes and embryos to be applied in the case of persons providing gametes for the purpose of the provision of non-medical fertility services. This section amends section 12 of the 1990 Act to rectify that situation.
- 72. **Section 12** also amends section 12 of the 1990 Act to ensure that no money or other benefit can be given or received for the supply of human admixed embryos (unless authorised by directions) and that if human admixed embryos are supplied to a person to whom another licence applies they must be provided with any information that the HFEA may specify in conditions. These amendments ensure that any research licence granted in connection with human admixed embryos will be subject to the same relevant licence conditions as for embryos or gametes.

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.

Section 14: Conditions of licences for treatment

113. This section amends section 13 of the 1990 Act which relates to conditions of licences for treatment.

Embryo testing

114. [Section 14\(4\)](#) contains a provision that relates to the provisions on embryo testing (see note on section 11). New sections 13(8) to (11) amend the 1990 Act to make it a condition of a treatment licence that embryos that are known to have an abnormality (including a gender-related abnormality) 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. This would prevent assisted reproduction technology being used to select an embryo with a view to increasing the chance of giving birth to a child that had or would develop a serious medical condition, or to select a donor to increase the chance of a child having a serious medical condition.

Welfare of the Child

115. Section 13(5) of the 1990 Act requires that:
- “A woman shall not be provided with treatment services, other than basic partner treatment services, unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth.
116. The HFEA is required by section 25(2) of the 1990 Act to provide guidance on this duty, and does so in its Code of Practice to licence holders.
117. Section 14(2)(b) of the Act amends the reference to a child’s need for a father so that the licence condition to be imposed under section 13(5) of the 1990 Act will refer instead to the child’s need for “supportive parenting”. Section 23 makes the same amendment to section 25(2) which concerns the guidance to be given about that licence condition. Section 13(5) as amended will therefore require licence holders, before providing treatment services, to consider the welfare of a child who may be born as a result of the treatment (including the need of that child for supportive parenting) and the welfare of any other child who may be affected by the birth. This will continue to be a matter on which the HFEA must provide guidance.
118. [Section 14\(6\)](#) makes transitional arrangements so that licences which are in force at the date of commencement of the amendment made by section 14(2)(b) will have effect as if they include the condition relating to consideration of welfare.

Welfare of the child where basic partner treatment services are provided

119. Basic partner treatment services are treatment services that are provided for a woman and a man together, without using donated gametes, gametes that have been stored, or embryos created outside the woman’s body. These include artificial insemination (intrauterine insemination, IUI) using sperm that has been processed but not donated or frozen. These services were brought within the HFEA’s remit by the 2007 Regulations.
120. [Section 14\(2\)\(a\)](#) applies the requirement to take account of the welfare of the child where basic partner treatment services are provided in the same way that the requirement applies to other treatment services regulated under the 1990 Act.

Requirement to offer counselling

121. [Section 14\(3\)](#) and Schedule 4 to the Act extend the existing requirements under the 1990 Act as to the provision of counselling by fertility clinics. Under section 13(6) of the 1990 Act, it is a requirement of all licences for treatment issued by the HFEA that a woman may not be provided with any treatment services involving donated gametes or embryos, or the use of an embryo which has been created *in vitro*, unless she and any man with whom she is being treated have been provided with relevant information and offered counselling. The new provision will extend this requirement to same sex couples. In addition, it will ensure that, before proceeding with embryo transfer or DI, clinics are required to offer counselling and provide relevant information to couples who have given notice that they consent to the intended mother's partner being treated as the parent of a child who is conceived using donor sperm. Where such notices have been given, but if one of the partners subsequently withdraws their consent, clinics will be required to notify the other partner of this.
122. The substituted section 13(6) requires that any woman receiving treatment of certain kinds, and any partner of that woman who is receiving treatment with her, must be given a suitable opportunity to receive counselling and must be provided with relevant information *before* treatment is provided. The new section 13(6A) requires a suitable offer of counselling to be given and relevant information to be provided before treatment is provided in a case where two people consent to the parenthood of any child that may be born as a result of that treatment.
123. New section 13(6B) applies the new concepts of "agreed fatherhood conditions" and "agreed female parenthood conditions" to subsection (6A) as provided for under sections 35 and 42 of the Act.
124. New section 13(6C) provides that where the treatment services provided involve the use of donated gametes, or embryos taken from a woman not receiving services, the information provided under subsection (6) and (6A) must include such information as is proper about –
- the importance of informing any resulting child at an early age that the child was donor conceived; and
 - suitable methods of informing the child about their conception.
125. The new sections 13(6D) and (6E) provide that where either partner withdraws consent to agreed fatherhood or parenthood, the person responsible (as defined by section 17(1) of the 1990 Act) must notify the other partner. This also applies where the woman being treated withdraws her consent for the other partner to be the parent of any resulting child. Where the male or female partner of the woman receiving treatment withdraws his or her consent, the person responsible must not place any embryo, sperm or eggs in the woman until she has been notified of the withdrawal of consent.
126. [Schedule 4](#) to the Act inserts a new Schedule 3ZA into the 1990 Act. Part 1 specifies treatment involving the use of donated gametes or embryos taken from a woman not receiving services and the use of embryos created *in vitro* as the kinds of treatment in relation to which clinics must offer counselling in accordance with licence conditions imposed under section 13(6). Part 2 defines the events in connection with which counselling must be offered in accordance with licence conditions imposed under section 13(6A) – that is, the giving of notices of consent to parenthood. These provisions take account of the new provisions about parenthood in Part 2 of the Act.

[Section 15: Conditions of storage licences](#)

127. [Section 15](#) amends section 14 of the 1990 Act. Section 14, as amended, continues to provide for various conditions to apply to storage licences. Section 15 amends the statutory conditions attached to storage licences and amends the maximum statutory

storage limit for embryos to bring it into line with the ten-year limit applicable to the storage of gametes.

128. Under the 1990 Act as it had effect before the amendments made by this section, embryos could be put into storage for five years. This has been amended to remove the five-year break point and allow couples to opt for a full ten-year storage period at the outset.
129. [Section 14](#) is also amended to apply a ten-year statutory storage period to human admixed embryos.

Section 16: Grant of licence

130. This section amends section 16 of the 1990 Act. It removes from section 16 of the 1990 Act the requirement for a licence application to be in a particular form and for an initial and an additional fee to be paid. Fees will be set in accordance with a scheme made by the HFEA under new section 35B of the 1990 Act set out at section 27.

Section 17: The person responsible

131. [Section 17](#) repeals the definition of “nominal licensee” from the 1990 Act. The term “nominal licensee” is no longer used because it does not adequately reflect the responsibilities of a licence holder.

Section 18: Revocation and variation of licence

132. [Section 18](#) provides that the HFEA may revoke or vary any licence on application by the person responsible or the licence holder (if different). The HFEA may also revoke or vary a licence of its own volition where certain conditions are satisfied. The power to vary a licence does not include the power to vary the mandatory conditions that are, by virtue of sections 12 to 15 of the 1990 Act, included in every licence.

Section 19: Procedure for refusal, variation or revocation of licence

133. [Section 19](#) makes a number of small amendments to the procedures in the 1990 Act for notifying licensing decisions to interested parties. The HFEA will provide the applicant with notice of its proposed decision and the reasons for the decision. Once a person has been given notice they will then have the right to make representations about the proposed decision. If the HFEA proceeds with the decision, then section 20 (inserted by section 21 of the Act) provides that the applicant may apply for reconsideration of the decision.

Section 20: Power to suspend licence

134. This section inserts new section 19C which replaces the previous section 22 of the 1990 Act and relates to the Authority’s powers to suspend a licence. Any period of suspension is restricted to a maximum of 3 months although this may be renewed. Appeals against a decision to suspend may be made to an appeals committee constituted under regulations made by the Secretary of State in the same way as appeals against other licensing decisions (see new section 20A of the 1990 Act).

Section 21: Reconsideration and appeals

135. [Section 21](#) substitutes sections 20 and 21, and inserts new section 20A and 20B into, the 1990 Act.
136. Substituted section 20 sets out the rights of appeal against licensing decisions of the HFEA.
137. New section 20A provides that the HFEA must maintain one or more appeals committees. The constitution of appeals committees will be set out in regulations made

by the Secretary of State, that are subject to the affirmative procedure. The regulations may also provide for the appeals committee to appoint advisors to give specialist scientific, legal and other advice.

138. New section 20B provides that reconsideration of licensing decisions and suspension notices will be by way of a fresh decision. It provides for regulations to make provision about the procedure to be followed. Those regulations may in particular make provision about the right of the appellant and the HFEA to appear before the committee; the consideration of written representations by the committee; the giving and admissibility of evidence and the production of documents; the taking of decisions by the committee and the notification of those decisions.
139. New section 21 provides that a further appeal may be made to the High Court (or, in Scotland, the Court of Session) by a person aggrieved by the appeals committee's decision, but only on a point of law.

Section 22: Directions

140. Section 24 of the 1990 Act provides for directions to be given in respect of various matters. Section 22 makes several amendments to this section, some of which concern the directions which may be given in respect of human admixed embryos and others which make updated provision concerning what is to happen when a licence is varied or ceases to have effect.

Section 23: Code of Practice

141. Section 25 of the 1990 Act requires the HFEA to maintain a Code of Practice giving guidance about the conduct of licensable activities. In particular the Code must provide guidance to clinics about the account to be taken of the welfare of children who may be born as a result of treatment services (including a child's need for a father) and of other children who may be affected by such births.
142. **Section 23(2)** amends section 25(2) of the 1990 Act to replace the reference to "a child's need for a father" with a reference to "a child's need for supportive parenting".
143. **Section 23** also inserts new section 25(2A) into the 1990 Act to require the HFEA to provide guidance in the Code of Practice about the giving of a suitable opportunity to receive proper counselling and the provision of such relevant information as is proper, as required by the licence conditions for clinics under new section 13(6) and (6A) of the 1990 Act.

Section 24: Register of information

144. Section 31 of the 1990 Act requires the HFEA to keep a register of information obtained by it which relates to the provision of treatment services, or the keeping or use of any gametes or an embryo taken from a woman, or the procurement or distribution of sperm for certain purposes. It also requires the HFEA to keep a register of information obtained by it about people born as a result of treatment services.
145. **Section 31** makes provision for people conceived as a result of donated gametes since the 1990 Act came into effect to require the HFEA to provide them with certain information.
146. Donor-conceived people are able to find out whether, but for the provisions of the Act which determine parenthood in relation to people born as a result of certain treatment services (sections 27 to 29 of the Act), they would be related to the person they intend to marry and at age 18 they are able to find out whether the register shows that they were, or may have been, conceived using donor gametes. If so, they are able to obtain such information which is held on the register as is specified in regulations made under section 31(4).

147. [Section 24](#) of the Act replaces section 31 with new sections 31 to 31ZG. New section 31 re-enacts the parts of the amended section 31 which deal with the register so that the HFEA must continue to keep a register of the information referred to above and must also record such information which it obtains after the Act comes into effect.
148. New section 31ZA re-enacts the existing provisions of section 31 of the 1990 Act which enable a donor-conceived person (“the applicant”) to obtain information about their donor. However, the donor-conceived person will now be able to request this information from age 16. Only non-identifying information can be disclosed whilst the donor-conceived person is under 18.
149. New section 31ZA(2)(b) enables a donor-conceived person to obtain information, at age 16, and on request, about the number, sex and year of birth of their donor-conceived half siblings who were conceived using gametes of the same donor but are not the donor’s legal children.
150. The HFEA has a discretion not to comply with a request for information about the genetic half-siblings if it is aware of special circumstances which increase the likelihood that the applicant would be able to identify the donor (in a case where the applicant does not have a right to obtain information about the donor’s identity) or any such genetic half-sibling.
151. New section 31ZB enables a donor-conceived person to find out whether they are related to someone they propose to marry, enter a civil partnership or intimate physical relationship with or with whom they are having an intimate physical relationship. The consent of the person with whom they are having or intend to have, a relationship will need to be given to the HFEA. The consent of the person they are in or intend to enter into the relevant relationship with will need to be given to the HFEA. There is no age limit in relation to applications under this section by donor-conceived people who are intending to marry or enter a civil partnership. This is in line with the current provision in section 31. In order to make an application as a person who is in or is intending to enter into an intimate physical relationship, the donor-conceived person must be aged 16 or over.
152. New section 31ZC gives the HFEA the power to inform a donor of the fact that a donor-conceived person has requested information about him. Donor-conceived people will be able to request identifying information about their donor from 2023 onwards, in relation to donors who donated identifiably from April 2005. This could happen sooner if someone who donated before April 2005 elected to re-register as identifiable, and a person conceived from his or her donation requested identifying information from the HFEA. In practice, the HFEA would try to forewarn the donor before identifying information is given to the donor-conceived applicant. This might not be possible in all cases, for example if the donor has moved and has not updated their address. The HFEA may not disclose identifying information about the donor-conceived person to the donor.
153. New section 31ZD enables donors (including past donors) to be provided with information on request about the number, sex and year of birth of children born as a result of their donations. They may ask the clinic where they donated or the HFEA (if the clinic has closed or the clinic is not able to, or fails to, provide the information). The information can be withheld from the donor if the HFEA is aware that circumstances exist which would mean that releasing the information would increase the likelihood that the donor would be able to identify a child born as a result of their donation.
154. New section 31ZE enables donor-conceived people to request and obtain identifying information about their genetic half-siblings who were conceived using gametes from the same donor, where neither is the donor’s legal offspring. The half-sibling whose information is being released must consent to the disclosure and both siblings must have had a suitable opportunity to receive counselling. There is also a proviso that the disclosure would not lead to the identification of a donor without the donor’s consent

unless regulations provide that his or her identity could be released to either of the donor-conceived people on request.

155. New section 31ZF introduces a power for the HFEA to set up, or keep, a voluntary contact register of people who would like to receive information about any person to whom they are genetically related as a consequence of the provision to any person of assisted conception treatment services in the United Kingdom involving donors before the HFEA's register began on 1 August 1991. New section 31ZG enables the HFEA to fund, on such terms and conditions as the HFEA considers appropriate, another person or body to set up and keep a voluntary register.
156. If the HFEA keeps a register under new section 31ZF, it may charge a fee to people wishing to join it, arrange for DNA samples of people who join to be analysed, with their consent, and matched with those of others on the register, and make arrangements for information to be disclosed between people who are genetically related. It is intended that the fee charged would recover all or part of the costs of keeping the register. Such a voluntary contact register, UK DonorLink, has been run as a national pilot project since 2004 by After Adoption Yorkshire, a voluntary organisation.

Section 25: Restrictions on disclosure of information

157. This section inserts into the 1990 Act new section 33A which will replace the current section 33. New section 33A retains the prohibition on the disclosure of the information falling within section 31(2) of the 1990 Act.
158. Section 33 of the 1990 Act distinguishes between information which can be disclosed by the HFEA and information which can be disclosed by licence holders and persons to whom directions have been given. New section 33A places all persons who might hold information which is on the HFEA's register on a similar footing when it comes to lifting the prohibitions on disclosure. Information which has been obtained by any person as a member or an employee of the HFEA, a person to whom a licence applies, including those covered by third party agreements, those to whom directions from the HFEA have been given, and authorised people who are carrying out functions which have been contracted out to them by the HFEA (and their members of staff or employees), may not be disclosed except to the categories of person or in the circumstances specified in new section 33A(2).
159. Section 33A(2) lifts the prohibition on disclosure which section 33A(1) imposes in certain circumstances. Previously the exceptions to the prohibitions have been listed in section 33 of the 1990 Act, as amended by the Human Fertilisation and Embryology (Disclosure of Information) Act 1992 and the 2007 Regulations. Most of the current section 33 exceptions are being retained. Some are however being replaced, and additional exceptions have been included in new section 33A(2). For example, now section 33A(2) lifts the prohibition on disclosure where disclosure is to other persons or bodies discharging a regulatory function and or is to a person who is performing functions contracted out to them by the HFEA, or under third party agreements, or with the consent of those to whom the information relates (in certain circumstances). Anyone considering whether it is lawful to disclose the relevant information will still need to satisfy themselves that the disclosure would not breach the Data Protection Act 1998 or any confidentiality rights. New section 33C provides a regulation-making power to make further exceptions to 33A(1).
160. New section 33D enables the Secretary of State to make provision, in regulations, requiring or regulating the disclosure of information falling within section 31(2) for research purposes. Information can be disclosed for the purposes of medical research where the Secretary of State considers it necessary or expedient in the public interest or in the interests of improving patient care. Information can be disclosed for other research purposes if the Secretary of State considers it necessary or expedient in the public interest. Fees may be charged in accordance with regulations made by the Secretary of State for these purposes. The regulations may make provision requiring

fees of a prescribed amount to be paid to the HFEA by persons in relation to the disclosure of protected information to them under the regulations. It is intended that the fees charged would recover all or part of the costs of providing the information. Such research could include follow-up studies on the safety of IVF. The regulations may make provision for disclosure to be lawful despite any duty of confidentiality owed in relation to the information. It is expected that this power would only be used in such circumstances where it would not be possible to obtain consent to the disclosure.

161. Before making the regulations, the Secretary of State must consult, to the extent that he considers appropriate, such bodies who appear to represent the interests of those who are likely to be affected by the regulations. The regulations may make provision for the establishment of a body which will have the function of considering whether disclosure should be authorised, should the Secretary of State consider this to be appropriate.

Section 26: Mitochondrial donation

162. **Section 3** of the Act inserts new section 3ZA(5) into the 1990 Act to provide a regulation-making power to enable eggs and/or embryos with altered mitochondrial DNA to be classified as “permitted” eggs or embryos, and thus to be implanted in a woman (see note on section 3 above).
163. The provisions of the 1990 Act assume that only one woman’s egg has been used to produce a child. New section 35A (inserted by section 26) provides a further regulation-making power to amend specified sections of the 1990 Act if the power under new section 3ZA(5) is exercised. This enables provision to be made about cases where permitted embryos and/or eggs have been created using material from more than one woman. The relevant provisions are set out in section 35A(2).

Section 27: Fees

164. This section inserts in the 1990 Act a new section 35B setting out the circumstances where the HFEA may charge a fee under the 1990 Act. Fees are to be determined by the HFEA under a scheme determined by the Authority, subject to the approval of the Secretary of State and the Treasury. Different fees may be fixed for different circumstances and, in fixing the fee, the HFEA may have regard to the costs incurred in exercising its functions under the 1990 Act.
165. The inserted section 35B also provides a new power for the HFEA to charge fees to recoup the cost of meeting various statutory requests for information from donor-conceived people. In these cases, it is intended that the amount of the fee should only reflect the cost of dealing with applications under the provision concerned.

Section 28: Inspection, entry, search and seizure

166. This section introduces Schedule 5 to the Act which inserts new Schedule 3B into the 1990 Act. New Schedule 3B replaces the existing sections 39 and 40, which relate to the power to enter, inspect and search premises and to seize items found on premises. Schedule 3B also deals with the obtaining and execution of warrants where an offence is suspected. It also provides that failure to comply with certain requirements under the Schedule, or obstruction of the exercise of any rights under it, is an offence. Section 28 also provides that it is not unlawful for a member or employee of the HFEA to be in possession of embryos, gametes or human admixed embryos in the course of their employment.

Section 29: Offences under 1990 Act

167. **Section 29** relates to offences and penalties described in the 1990 Act, as extended by the Act. It amends section 41 of the 1990 to take account of the prohibitions introduced by the Act including those relating to the creation or use of human admixed embryos without a licence; and sets out the circumstances where a defence can be raised under the

1990 Act. The requirement for consent of the Director of Public Prosecutions remains unchanged.

Section 31: Power to make consequential provision

168. New sections 1(6) and 4A(11) of the 1990 Act confer powers to amend the definitions of “embryo”, “gametes” and “human admixed embryo” in the 1990 Act by regulations. Section 31 inserts new section 45A into the 1990 Act to enable consequential changes to other legislation as a result of amending any of these definitions. The power enables amendments to be made to Acts of Parliament, Acts of the Scottish Parliament, Measures or Acts of the Welsh Assembly and Northern Ireland legislation and any secondary legislation made under them (after consultation with the devolved administrations where appropriate). The power under section 45A is exercisable by order.

Section 32: Orders under the 1990 Act

169. [Section 32](#) inserts new section 45B into the 1990 Act. This states that the power to make an order under new section 45A and section 8C(1)(c) (see section 8) of the 1990 Act is exercisable by statutory instrument. The negative resolution procedure applies to section 8C(1)(c) but the affirmative procedure is applicable to new section 45A.