Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

VALID FROM 06/04/2009

SCHEDULES

VALID FROM 01/10/2009

SCHEDULE 1

Section 5

AMENDMENTS TO SCHEDULE 1 TO THE 1990 ACT RELATING TO MEMBERSHIP OF THE AUTHORITY

1 Schedule 1 to the 1990 Act (supplementary provision about Authority) is amended as follows.

2 After paragraph 4 (appointment of members) insert—

"4A (1) A person ("P") is disqualified for being appointed as chairman, deputy chairman, or as any other member of the Authority if—

(a) P is the subject of a bankruptcy restrictions order or interim order,

(b) a bankruptcy order has been made against P by a court in Northern Ireland, P's estate has been sequestered by a court in Scotland, or under the law of Northern Ireland or Scotland, P has made a composition or arrangement with, or granted a trust deed for, P's creditors, or

(c) in the last five years P has been convicted in the United Kingdom, the Channel Islands or the Isle of Man of an offence and has had a qualifying sentence passed on P.

(2) Where P is disqualified under sub-paragraph (1)(b) because a bankruptcy order has been made against P or P's estate has been sequestered, the disqualification ceases—

(a) on P obtaining a discharge, or

(b) if the bankruptcy order is annulled or the sequestration of P's estate is recalled or reduced, on the date of that event.

(3) Where P is disqualified under sub-paragraph (1)(b) because of P having made a composition or arrangement with, or granted a trust deed for, P's creditors, the disqualification ceases—

(a) at the end of the period of five years beginning with the date on which the terms of the deed of composition or arrangement or trust deed are fulfilled, or

(b) if, before then, P pays P's debts in full, on the date on which the payment is completed.

(4) For the purposes of sub-paragraph (1)(c), the date of conviction is to be taken to be the ordinary date on which the period allowed for making an appeal or application expires or, if an appeal or application is made,

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

the date on which the appeal or application is finally disposed of or abandoned or fails by reason of its non-prosecution.

(5) In sub-paragraph (1)(c), the reference to a qualifying sentence is to a sentence of imprisonment for a period of not less than three months (whether suspended or not) without the option of a fine."

3 In paragraph 5—

(a) after sub-paragraph (4), insert—

"(4A) A person holding office as chairman, deputy chairman or other member of the Authority is to cease to hold that office if the person becomes disqualified for appointment to it.", and

(b) in sub-paragraph (5)—

(i) omit paragraph (b) and the word "or" immediately after it,

(ii) in paragraph (c) for "functions of a member" substitute " person's functions as chairman, deputy chairman or other member ", and

(iii) in the full-out words, for the words from "declare" to the end substitute " remove the member from office as chairman, deputy chairman or other member ".

VALID FROM 01/10/2009

SCHEDULE 2

Section 11

ACTIVITIES THAT MAY BE LICENSED UNDER THE 1990 ACT

Introductory

1 Schedule 2 to the 1990 Act (activities for which licences may be granted) is amended as follows.

Licences for treatment

2 (1) Paragraph 1 (licences for treatment) is amended as follows.

(2) In sub-paragraph (1)—

(a) after paragraph (c) insert—

"(ca) using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques,",

(b) in paragraph (d), omit the words from "or" onwards,

(c) in paragraph (e), for "embryo" substitute " permitted embryo ", and

(d) in paragraph (g), after "practices" insert " , apart from practices falling within section 4A(2), ".

(3) For sub-paragraph (4) substitute—

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

"(4) A licence under this paragraph cannot authorise altering the nuclear or mitochondrial DNA of a cell while it forms part of an embryo, except for the purpose of creating something that will by virtue of regulations under section 3ZA(5) be a permitted embryo."

(4) After sub-paragraph (4) insert—

"(4A) A licence under this paragraph cannot authorise the use of embryos for the purpose mentioned in sub-paragraph (1)(ca) unless the Authority is satisfied that the proposed use of embryos is necessary for that purpose."

(5) At the end insert—

"(6) In this paragraph, references to a permitted embryo are to be read in accordance with section 3ZA."

Embryo testing and sex selection

3 After paragraph 1 insert—

"Embryo testing

1ZA(1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes—

(a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

(c) in a case where there is a particular risk that any resulting child will have or develop—

(i) a gender-related serious physical or mental disability,

(ii) a gender-related serious illness, or

(iii) any other gender-related serious medical condition,

establishing the sex of the embryo,

(d) in a case where a person ("the sibling") who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling, and

(e) in a case where uncertainty has arisen as to whether the embryo is one of those whose creation was brought about by using the gametes of particular persons, establishing whether it is.

(2) A licence under paragraph 1 cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied—

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(a) in relation to the abnormality of which there is a particular risk, and

(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b),

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.

(3) For the purposes of sub-paragraph (1)(c), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that—

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

(4) In sub-paragraph (1)(d) the reference to "other tissue" of the resulting child does not include a reference to any whole organ of the child.

Sex selection

1ZB(1) A licence under paragraph 1 cannot authorise any practice designed to secure that any resulting child will be of one sex rather than the other.

(2) Sub-paragraph (1) does not prevent the authorisation of any testing of embryos that is capable of being authorised under paragraph 1ZA.

(3) Sub-paragraph (1) does not prevent the authorisation of any other practices designed to secure that any resulting child will be of one sex rather than the other in a case where there is a particular risk that a woman will give birth to a child who will have or develop—

(a) a gender-related serious physical or mental disability,

(b) a gender-related serious illness, or

(c) any other gender-related serious medical condition.

(4) For the purposes of sub-paragraph (3), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that—

(a) it affects only one sex, or

(b) it affects one sex significantly more than the other.

Power to amend paragraphs 1ZA and 1ZB

1ZC(1) Regulations may make any amendment of paragraph 1ZA (embryo testing).

(2) Regulations under this paragraph which amend paragraph 1ZA may make any amendment of sub-paragraphs (2) to (4) of paragraph 1ZB (sex selection) which appears to the Secretary of State to be necessary or expedient in consequence of the amendment of paragraph 1ZA.

(3) Regulations under this paragraph may not enable the authorisation of—

(a) the testing of embryos for the purpose of establishing their sex, or

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(b) other practices falling within paragraph 1ZB(1),

except on grounds relating to the health of any resulting child.

(4) For the purposes of this paragraph, "amend" includes add to and repeal, and references to "amendment" are to be read accordingly."

Licences for non-medical fertility services

4 In paragraph 1A (licences for non-medical fertility services) after sub-paragraph (1) insert—

"(1A) A licence under this paragraph cannot authorise the procurement or distribution of sperm to which there has been applied any process designed to secure that any resulting child will be of one sex rather than the other."

Licences for storage

5 In paragraph 2 (licences for storage)—

(a) after sub-paragraph (1) insert—

"(1A) A licence under this paragraph or paragraph 3 may authorise the storage of human admixed embryos (whether or not the licence also authorises the storage of gametes or embryos or both).", and

(b) in sub-paragraph (2), after "such storage" insert " as is mentioned in sub-paragraph (1) or (1A) ".

Licences for research

6 For paragraph 3 substitute—

"Licences for research

3 (1) A licence under this paragraph may authorise any of the following—

(a) bringing about the creation of embryos *in vitro*, and

(b) keeping or using embryos,

for the purposes of a project of research specified in the licence.

(2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.

(3) A licence under this paragraph may authorise any of the following—

(a) bringing about the creation of human admixed embryos *in vitro*, and

(b) keeping or using human admixed embryos,

for the purposes of a project of research specified in the licence.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).

(5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.

(6) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence.

(7) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.

(8) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.

(9) This paragraph has effect subject to paragraph 3A.

Purposes for which activities may be licensed under paragraph 3

3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority—

(a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) ("the principal purposes"),

(b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or

(c) to be necessary or desirable for such other purposes as may be specified in regulations.

(2) The principal purposes are—

(a) increasing knowledge about serious disease or other serious medical conditions,

(b) developing treatments for serious disease or other serious medical conditions,

(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

(d) promoting advances in the treatment of infertility,

(e) increasing knowledge about the causes of miscarriage,

(f) developing more effective techniques of contraception,

(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or

(h) increasing knowledge about the development of embryos."

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

VALID FROM 01/10/2009

SCHEDULE 3

Section 13

CONSENT TO USE OR STORAGE OF GAMETES, EMBRYOS OR HUMAN ADMIXED EMBRYOS ETC.

Introductory

1 Schedule 3 to the 1990 Act (giving of consent to use or storage of gametes or embryos) is amended as follows.

2 In the title to that Schedule, for "OF GAMETES OR EMBRYOS", substitute " OR STORAGE OF GAMETES, EMBRYOS OR HUMAN ADMIXED EMBRYOS ETC ".

General requirements as to consent

3 For paragraph 1 substitute—

"1 (1) A consent under this Schedule, and any notice under paragraph 4 varying or withdrawing a consent under this Schedule, must be in writing and, subject to sub-paragraph (2), must be signed by the person giving it.

(2) A consent under this Schedule by a person who is unable to sign because of illness, injury or physical disability (a "person unable to sign"), and any notice under paragraph 4 by a person unable to sign varying or withdrawing a consent under this Schedule, is to be taken to comply with the requirement of sub-paragraph (1) as to signature if it is signed at the direction of the person unable to sign, in the presence of the person unable to sign and in the presence of at least one witness who attests the signature.

(3) In this Schedule "effective consent" means a consent under this Schedule which has not been withdrawn."

Terms of consent

4 (1) Paragraph 2 (terms etc. of consent) is amended as follows.

(2) In sub-paragraph (1), for the "or" at the end of paragraph (b) substitute—

"(ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or".

(3) After sub-paragraph (1) insert—

"(1A) A consent to the use of any human admixed embryo must specify use for the purposes of any project of research and may specify conditions subject to which the human admixed embryo may be so used."

(4) For sub-paragraph (2) substitute—

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

"(2) A consent to the storage of any gametes, any embryo or any human admixed embryo must—

(a) specify the maximum period of storage (if less than the statutory storage period),

(b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it, and

(c) where the consent is given by virtue of paragraph 8(2A) or 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies,

and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.

(2A) A consent to the use of a person's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person's death.

(2B) In relation to Scotland, the reference in sub-paragraph (2)(b) to the person lacking capacity is to be read as a reference to the person—

(a) lacking capacity within the meaning of the Age of Legal Capacity (Scotland) Act 1991, or

(b) being incapable within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000."

(5) For sub-paragraph (4) substitute—

"(4) A consent under this Schedule may apply—

(a) to the use or storage of a particular embryo or human admixed embryo, or

(b) in the case of a person providing gametes or human cells, to the use or storage of—

(i) any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and

(ii) any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.

(5) In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to—

(a) a particular embryo or particular embryos, or

(b) a particular human admixed embryo or particular human admixed embryos."

Information to be given to a person giving consent

5 In paragraph 3 (procedure for giving consent), in sub-paragraph (2), after "paragraph 4" insert " and, if relevant, paragraph 4A ".

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

Variation and withdrawal of consent

6 (1) Paragraph 4 (variation and withdrawal of consent) is amended as follows.

(2) In sub-paragraph (1), for "or embryo" substitute " , human cells, embryo or human admixed embryo ".

(3) In sub-paragraph (2)—

(a) for "The" substitute " Subject to sub-paragraph (3), the ", and

(b) for the "or" at the end of paragraph (a) substitute—

"(aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or".

(4) After sub-paragraph (2) insert—

"(3) Where the terms of any consent to the use of an embryo ("embryo A") include consent to the use of an embryo or human admixed embryo whose creation may be brought about *in vitro* using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).

(4) Subject to sub-paragraph (5), the terms of any consent to the use of any human admixed embryo cannot be varied, and such consent cannot be withdrawn, once the human admixed embryo has been used for the purposes of any project of research.

(5) Where the terms of any consent to the use of a human admixed embryo ("human admixed embryo A") include consent to the use of a human admixed embryo or embryo whose creation may be brought about *in vitro* using human admixed embryo A, that consent to the use of that subsequent human admixed embryo or embryo cannot be varied or withdrawn once human admixed embryo A has been used for the purposes of any project of research."

Withdrawal of consent to storage: notification of interested persons

7 After paragraph 4 insert—

"4A (1) This paragraph applies where—

(a) a permitted embryo, the creation of which was brought about *in vitro*, is in storage,

(b) it was created for use in providing treatment services,

(c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation ("P") gives the person keeping the embryo notice withdrawing P's consent to the storage of the embryo, and

(d) the embryo was not to be used in providing treatment services to P alone.

(2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P's withdrawal of consent.

Status: *Point in time view as at 13/11/2008.*
***Changes to legislation:** Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.

(4) Storage of the embryo remains lawful until—

(a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or

(b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P's withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.

(5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA."

Application of consent provisions to non-medical fertility services

8 In paragraph 5 (use of gametes for treatment of others), in sub-paragraph (1), after "treatment services" insert " or non-medical fertility services ".

In vitro fertilisation and subsequent use of embryo

9 (1) Paragraph 6 (*in vitro* fertilisation and subsequent use of embryo) is amended as follows.

(2) In sub-paragraph (1)—

(a) after "person's gametes" insert " or human cells ",

(b) after "to any embryo" insert a comma,

(c) after "those gametes" insert " or human cells, ", and

(d) for "paragraph 2(1)" substitute " paragraph 2(1)(a), (b) and (c) ".

(3) In sub-paragraph (2)—

(a) for the words from "each person" to "creation of" substitute " each relevant person in relation to ", and

(b) for "paragraph 2(1)" substitute " paragraph 2(1)(a), (b), (ba) and (c) ".

(4) In sub-paragraph (3), for the words from "person" to "creation of" substitute " relevant person in relation to ".

(5) After sub-paragraph (3) insert—

"(3A) If the Authority is satisfied that the parental consent conditions in paragraph 15 are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years ("C"), the Authority may in the licence authorise the application of sub-paragraph (3B) in relation to C.

(3B) Where the licence authorises the application of this sub-paragraph, the effective consent of a person having parental responsibility for C—

(a) to the use of C's human cells to bring about the creation of an embryo *in vitro* for use for the purposes of a project of research, or

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(b) to the use for those purposes of an embryo in relation to which C is a relevant person by reason only of the use of C's human cells,

is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.

(3C) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (3B) ceases to apply in relation to C.

(3D) Sub-paragraphs (1) to (3) have effect subject to paragraphs 16 and 20.

(3E) For the purposes of sub-paragraphs (2), (3) and (3B), each of the following is a relevant person in relation to an embryo the creation of which was brought about *in vitro* ("embryo A")—

(a) each person whose gametes or human cells were used to bring about the creation of embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A."

Use of embryos obtained by lavage etc.

10 (1) Paragraph 7 (embryos obtained by lavage etc.) is amended as follows.

(2) In sub-paragraph (3), for "This paragraph does" substitute " Sub-paragraphs (1) and (2) do ".

(3) After sub-paragraph (3) insert—

"(4) An embryo taken from a woman must not be used to bring about the creation of any embryo *in vitro* or any human admixed embryo *in vitro*."

Consents in relation to storage

11 (1) Paragraph 8 (storage of gametes and embryos) is amended as follows.

(2) In sub-paragraph (2), for the words from "person" to "creation of" substitute " relevant person in relation to ".

(3) After sub-paragraph (2) insert—

"(2A) Where a licence authorises the application of paragraph 6(3B) in relation to a person who has not attained the age of 18 years ("C"), the effective consent of a person having parental responsibility for C to the storage of an embryo in relation to which C is a relevant person by reason only of the use of C's human cells is to be treated for the purposes of sub-paragraph (2) as the effective consent of C.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(2B) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraph (2) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2A) ceases to apply in relation to C.

(2C) For the purposes of sub-paragraphs (2) and (2A), each of the following is a relevant person in relation to an embryo the creation of which was brought about *in vitro* ("embryo A")—

(a) each person whose gametes or human cells were used to bring about the creation of embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A."

(4) After sub-paragraph (3) insert—

"(4) Sub-paragraph (1) has effect subject to paragraphs 9 and 10; and sub-paragraph (2) has effect subject to paragraphs 4A(4), 16 and 20."

12 After paragraph 8 insert—

"Cases where consent not required for storage

9 (1) The gametes of a person ("C") may be kept in storage without C's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner—

(a) the treatment is likely to cause a significant impairment of C's fertility, and

(b) the storage of the gametes is in C's best interests.

(4) Condition C is that, at the time when the gametes are first stored, either—

(a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or

(b) C has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.

(5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes—

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(a) given consent under this Schedule to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications—

(a) for sub-paragraph (4), substitute—

"(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.", and

(b) in sub-paragraph (5), for "becoming competent to deal with the issue of consent to the storage of the gametes" substitute " acquiring such capacity ".

10 (1) The gametes of a person ("P") may be kept in storage without P's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner—

(a) the treatment is likely to cause a significant impairment of P's fertility,

(b) P lacks capacity to consent to the storage of the gametes,

(c) P is likely at some time to have that capacity, and

(d) the storage of the gametes is in P's best interests.

(4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.

(5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule—

(a) given consent to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.

(6) In relation to Scotland—

(a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,

(b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and

(c) that Act applies to the storage of gametes under this paragraph to the extent specified in section 84A of that Act.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

11 A person's gametes must not be kept in storage by virtue of paragraph 9 or 10 after the person's death."

Creation, use and storage of human admixed embryos

13 After paragraph 11 (as inserted by paragraph 12 above) insert—

"Creation, use and storage of human admixed embryos

12 (1) A person's gametes or human cells must not be used to bring about the creation of any human admixed embryo *in vitro* unless there is an effective consent by that person to any human admixed embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for the purposes of any project of research.

(2) A human admixed embryo the creation of which was brought about *in vitro* must not be received by any person unless there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for the purposes of any project of research.

(3) A human admixed embryo the creation of which was brought about *in vitro* must not be used for the purposes of a project of research unless—

(a) there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for that purpose, and

(b) the human admixed embryo is used in accordance with those consents.

(4) If the Authority is satisfied that the parental consent conditions in paragraph 15 are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years ("C"), the Authority may in the licence authorise the application of sub-paragraph (5) in relation to C.

(5) Where the licence authorises the application of this sub-paragraph, the effective consent of a person having parental responsibility for C—

(a) to the use of C's human cells to bring about the creation of a human admixed embryo *in vitro* for use for the purposes of a project of research, or

(b) to the use for those purposes of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C's human cells,

is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.

(6) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (5) ceases to apply in relation to C.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(7) Sub-paragraphs (1) to (3) have effect subject to paragraphs 16 and 20.

13 (1) A human admixed embryo the creation of which was brought about *in vitro* must not be kept in storage unless—

(a) there is an effective consent by each relevant person in relation to the human admixed embryo to the storage of the human admixed embryo, and

(b) the human admixed embryo is stored in accordance with those consents.

(2) Where a licence authorises the application of paragraph 12(5) in relation to a person who has not attained the age of 18 years ("C"), the effective consent of a person having parental responsibility for C to the storage of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C's human cells is to be treated for the purposes of sub-paragraph (1) as the effective consent of C.

(3) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraph (1) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2) ceases to apply in relation to C.

(4) Sub-paragraph (1) has effect subject to paragraphs 16 and 20.

14 For the purposes of paragraphs 12 and 13, each of the following is a relevant person in relation to a human admixed embryo the creation of which was brought about *in vitro* ("human admixed embryo A")—

(a) each person whose gametes or human cells were used to bring about the creation of human admixed embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of human admixed embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any other human admixed embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of human admixed embryo A."

Cases where human cells etc. can be used without consent of person providing them

14 After paragraph 14 (as inserted by paragraph 13 above) insert—

"Parental consent conditions

15 (1) In relation to a person who has not attained the age of 18 years ("C"), the parental consent conditions referred to in paragraphs 6(3A) and 12(4) are as follows.

(2) Condition A is that C suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(3) Condition B is that either—

(a) C is not competent to deal with the issue of consent to the use of C's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research, or

(b) C has attained the age of 16 years but lacks capacity to consent to such use of C's human cells.

(4) Condition C is that any embryo or human admixed embryo to be created *in vitro* is to be used for the purposes of a project of research which is intended to increase knowledge about—

(a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or

(b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.

(5) Condition D is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation *in vitro* of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who—

(a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project, or

(b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications—

(a) for sub-paragraph (3) substitute—

"(3) Condition B is that C does not have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the use of C's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research.",

(b) in sub-paragraph (5)(a), for "have capacity to consent" substitute " are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent ", and

(c) in sub-paragraph (5)(b), for "are competent to deal with the issue of" substitute " have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to ".

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

Adults lacking capacity: exemption relating to use of human cells etc.

16 (1) If, in relation to the proposed use under a licence of the human cells of a person who has attained the age of 18 years ("P"), the Authority is satisfied—

(a) that the conditions in paragraph 17 are met,

(b) that paragraphs (1) to (4) of paragraph 18 have been complied with, and

(c) that the condition in paragraph 18(5) is met,

the Authority may in the licence authorise the application of this paragraph in relation to P.

(2) Where a licence authorises the application of this paragraph, this Schedule does not require the consent of P—

(a) to the use (whether during P's life or after P's death) of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research,

(b) to the storage or the use for those purposes (whether during P's life or after P's death) of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of P's human cells.

(3) This paragraph has effect subject to paragraph 19.

Consent to use of human cells etc. not required: adult lacking capacity

17 (1) The conditions referred to in paragraph 16(1)(a) are as follows.

(2) Condition A is that P suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.

(3) Condition B is that P lacks capacity to consent to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research.

(4) Condition C is that the person responsible under the licence has no reason to believe that P had refused such consent at a time when P had that capacity.

(5) Condition D is that it appears unlikely that P will at some time have that capacity.

(6) Condition E is that any embryo or human admixed embryo to be created *in vitro* is to be used for the purposes of a project of research which is intended to increase knowledge about—

(a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or

(b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(7) Condition F is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation *in vitro* of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who—

(a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project, or

(b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.

(8) In this paragraph and paragraph 18 references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.

(9) In relation to Scotland—

(a) references in sub-paragraphs (3) to (5) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent, and

(b) sub-paragraph (7) is to be read with the following modifications—

(i) in paragraph (a), for "have capacity to consent" substitute " are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent ", and

(ii) in paragraph (b), for "are competent to deal with the issue of" substitute " have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to ".

Consulting carers etc. in case of adult lacking capacity

18 (1) This paragraph applies in relation to a person who has attained the age of 18 years ("P") where the person responsible under the licence ("R") wishes to use P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research, in a case where P lacks capacity to consent to their use.

(2) R must take reasonable steps to identify a person who—

(a) otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P's welfare, and

(b) is prepared to be consulted by R under this paragraph of this Schedule.

(3) If R is unable to identify such a person R must nominate a person who—

(a) is prepared to be consulted by R under this paragraph of this Schedule, but

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(b) has no connection with the project.

(4) R must provide the person identified under sub-paragraph (2) or nominated under sub-paragraph (3) ("F") with information about the proposed use of human cells to bring about the creation *in vitro* of embryos or human admixed embryos for use for the purposes of the project and ask F what, in F's opinion, P's wishes and feelings about the use of P's human cells for that purpose would be likely to be if P had capacity in relation to the matter.

(5) The condition referred to in paragraph 16(1)(c) is that, on being consulted, F has not advised R that in F's opinion P's wishes and feelings would be likely to lead P to decline to consent to the use of P's human cells for that purpose.

(6) In relation to Scotland, the references in sub-paragraphs (1) and (4) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

Effect of acquiring capacity

19 (1) Paragraph 16 does not apply to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo if, at a time before the human cells are used for that purpose, P—

(a) has capacity to consent to their use, and

(b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.

(2) Paragraph 16 does not apply to the storage or use of an embryo or human admixed embryo whose creation *in vitro* was brought about with the use of P's human cells if, at a time before the embryo or human admixed embryo is used for the purposes of the project of research, P—

(a) has capacity to consent to the storage or use, and

(b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.

(3) In relation to Scotland, the references in sub-paragraphs (1)(a) and (2)(a) to P having capacity to consent are to be read as references to P not being incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

Use of cells or cell lines in existence before relevant commencement date

20 (1) Where a licence authorises the application of this paragraph in relation to qualifying cells, this Schedule does not require the consent of a person ("P")—

(a) to the use of qualifying cells of P to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research, or

Status: *Point in time view as at 13/11/2008.*
***Changes to legislation:** Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(b) to the storage or the use for those purposes of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of qualifying cells of P.

(2) "Qualifying cells" are human cells which—

(a) were lawfully stored for research purposes immediately before the commencement date, or

(b) are derived from human cells which were lawfully stored for those purposes at that time.

(3) The "commencement date" is the date on which paragraph 9(2)(a) of Schedule 3 to the Human Fertilisation and Embryology Act 2008 (requirement for consent to use of human cells to create an embryo) comes into force.

Conditions for grant of exemption in paragraph 20

21 (1) A licence may not authorise the application of paragraph 20 unless the Authority is satisfied—

(a) that there are reasonable grounds for believing that scientific research will be adversely affected to a significant extent if the only human cells that can be used to bring about the creation *in vitro* of embryos or human admixed embryos for use for the purposes of the project of research are—

(i) human cells in respect of which there is an effective consent to their use to bring about the creation *in vitro* of embryos or human admixed embryos for use for those purposes, or

(ii) human cells which by virtue of paragraph 16 can be used without such consent, and

(b) that any of the following conditions is met in relation to each of the persons whose human cells are qualifying cells which are to be used for the purposes of the project of research.

(2) Condition A is that—

(a) it is not reasonably possible for the person responsible under the licence ("R") to identify the person falling within sub-paragraph (1)(b) ("P"), and

(b) where any information that relates to P (without identifying P or enabling P to be identified) is available to R, that information does not suggest that P would have objected to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project.

(3) Condition B is that—

(a) the person falling within sub-paragraph (1)(b) ("P") is dead or the person responsible under the licence ("R") believes on reasonable grounds that P is dead,

(b) the information relating to P that is available to R does not suggest that P would have objected to the use of P's human

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project, and

(c) a person who stood in a qualifying relationship to P immediately before P died (or is believed to have died) has given consent in writing to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project.

(4) Condition C is that—

(a) the person responsible under the licence ("R") has taken all reasonable steps to contact—

(i) the person falling within sub-paragraph (1)(b) ("P"), or

(ii) in a case where P is dead or R believes on reasonable grounds that P is dead, persons who could give consent for the purposes of sub-paragraph (3)(c),

but has been unable to do so, and

(b) the information relating to P that is available to R does not suggest that P would have objected to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project.

(5) The HTA consent provisions apply in relation to consent for the purposes of sub-paragraph (3)(c) as they apply in relation to consent for the purposes of section 3(6)(c) of the Human Tissue Act 2004; and for the purposes of this sub-paragraph the HTA consent provisions are to be treated as if they extended to Scotland.

(6) In sub-paragraph (5) "the HTA consent provisions" means subsections (4), (5), (6), (7) and (8)(a) and (b) of section 27 of the Human Tissue Act 2004.

(7) In this paragraph references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.

(8) Paragraphs 1 to 4 of this Schedule do not apply in relation to a consent given for the purposes of sub-paragraph (3)(c)."

Interpretation

15 After paragraph 21 (as inserted by paragraph 14 above) insert—

"Interpretation

22 (1) In this Schedule references to human cells are to human cells which are not—

(a) cells of the female or male germ line, or

(b) cells of an embryo.

(2) References in this Schedule to an embryo or a human admixed embryo which was used to bring about the creation of an embryo ("embryo A") or a human admixed embryo ("human admixed embryo A") include

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

an embryo or, as the case may be, a human admixed embryo which was used to bring about the creation of—

(a) an embryo or human admixed embryo which was used to bring about the creation of embryo A or human admixed embryo A, and

(b) the predecessor of that embryo or human admixed embryo mentioned in paragraph (a), and

(c) the predecessor of that predecessor, and so on.

(3) References in this Schedule to an embryo or a human admixed embryo whose creation may be brought about using an embryo or a human admixed embryo are to be read in accordance with sub-paragraph (2).

(4) References in this Schedule (however expressed) to the use of human cells to bring about the creation of an embryo or a human admixed embryo include the use of human cells to alter the embryo or, as the case may be, the human admixed embryo.

(5) References in this Schedule to parental responsibility are—

(a) in relation to England and Wales, to be read in accordance with the Children Act 1989,

(b) in relation to Northern Ireland, to be read in accordance with the Children (Northern Ireland) Order 1995, and

(c) in relation to Scotland, to be read as references to parental responsibilities and parental rights within the meaning of the Children (Scotland) Act 1995.

(6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.

(7) References in this Schedule to the age of 18 years are, in relation to Scotland, to be read as references to the age of 16 years."

SCHEDULE 4

Section 14

SCHEDULE INSERTED IN THE 1990 ACT AS SCHEDULE 3ZA

"SCHEDULE 3ZA

CIRCUMSTANCES IN WHICH OFFER OF COUNSELLING REQUIRED AS CONDITION OF LICENCE FOR TREATMENT

. . . . . .
. . . . . .

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

VALID FROM 01/10/2009

SCHEDULE 5

Section 28

SCHEDULE INSERTED IN THE 1990 ACT AS SCHEDULE 3B

"SCHEDULE 3B

INSPECTION, ENTRY, SEARCH AND SEIZURE

Inspection of statutory records

1 (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.

(2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection—

(a) in a visible and legible form, or

(b) in a form from which they can be readily produced in a visible and legible form.

(3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

Arranging inspections

2 (1) Where a person—

(a) makes an enquiry to the Authority which concerns the making of a relevant application by that person, or

(b) has made a relevant application to the Authority which the Authority has not yet considered,

the Authority may arrange for a duly authorised person to inspect any of the premises mentioned in sub-paragraph (3).

(2) For the purposes of sub-paragraph (1) a "relevant application" means—

(a) an application for authorisation for a person to carry on an activity governed by this Act which the person is not then authorised to carry on, or

(b) an application for authorisation for a person to carry on any such activity on premises where the person is not then authorised to carry it on.

(3) The premises referred to in sub-paragraph (1) are—

(a) the premises where any activity referred to in sub-paragraph (2) is to be carried on;

(b) any premises that will be relevant third party premises for the purposes of any application.

(4) The power in sub-paragraph (1) is exercisable for purposes of the Authority's functions in relation to licences and third party agreements.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

Entry and inspection of premises

3 (1) A duly authorised person may at any reasonable time enter and inspect any premises to which a licence relates or relevant third party premises.

(2) The power in sub-paragraph (1) is exercisable for purposes of the Authority's functions in relation to licences and third party agreements.

4 (1) Subject to sub-paragraph (2), the Authority shall arrange for any premises to which a licence relates to be inspected under paragraph 3 by a duly authorised person at intervals not exceeding two years.

(2) The Authority need not comply with sub-paragraph (1) where the premises in question have been inspected in pursuance of paragraph 2 or 3 at any point within the previous two years.

Entry and search in connection with suspected offence

5 (1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath that there are reasonable grounds for believing—

(a) that an offence under this Act is being, or has been committed on any premises, and

(b) that any of the conditions in sub-paragraph (2) is met in relation to the premises,

the justice of the peace may by signed warrant authorise a duly authorised person, together with any constables, to enter the premises, if need be by force, and search them.

(2) The conditions referred to are—

(a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;

(b) that the premises are unoccupied;

(c) that the occupier is temporarily absent;

(d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) In relation to Scotland—

(a) any reference in sub-paragraph (1) to a justice of the peace includes a reference to a sheriff, and

(b) the reference in that sub-paragraph to "on sworn information" is to be read as a reference to "by evidence on oath".

Execution of warrants

6 (1) Entry and search under a warrant under paragraph 5 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—

(a) produce the warrant to the occupier, and

(b) give the occupier—

(i) a copy of the warrant, and

(ii) an appropriate statement.

(4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—

(a) produce the warrant to that other person,

(b) give that other person—

(i) a copy of the warrant, and

(ii) an appropriate statement, and

(c) leave a copy of the warrant in a prominent place on the premises.

(5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State.

(6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

(7) Where the premises in relation to which a warrant under paragraph 5 is executed are unoccupied or the occupier is temporarily absent, the person executing the warrant shall when leaving the premises, leave them as effectively secured as the person found them.

Seizure in the course of inspection or search

7 (1) A duly authorised person entering and inspecting premises under paragraph 3 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for—

(a) the purposes of the Authority's functions relating to the grant, revocation, variation or suspension of licences, or

(b) the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction.

(2) A duly authorised person entering or searching premises under a warrant under paragraph 5 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under this Act.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(3) Where a person has power under sub-paragraph (1) or (2) to seize anything, that person may take such steps as appear to be necessary for preserving that thing or preventing interference with it.

(4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.

(5) Where by virtue of sub-paragraph (1) or (2) a person ("P") seizes anything, P shall leave on the premises from which the thing was seized a statement giving particulars of what P has seized and stating that P has seized it.

Supplementary provision

8 (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.

(2) Power under this Schedule to inspect or search any premises includes, in particular—

(a) power to inspect any equipment found on the premises,

(b) power to inspect and take copies of any records found on the premises, and

(c) in the case of premises to which a licence relates or premises which are relevant third party premises in relation to a licence, power to observe the carrying-on of the licensed activity on the premises.

(3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

9 (1) A person's right to exercise a power under this Schedule is subject to production of evidence of the person's entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having inspected premises in pursuance of arrangements made under paragraph 2 or after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall—

(a) prepare a written report of the inspection, or as the case may be, the inspection and search, and

(b) if requested to do so by the appropriate person, give the appropriate person a copy of the report.

(3) In sub-paragraph (2), the "appropriate person" means—

(a) in relation to premises to which a licence relates, the person responsible, or

(b) in relation to any other premises, the occupier.

Enforcement

10 A person who—

(a) fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 8(3), or

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(b) intentionally obstructs the exercise of any right under this Schedule,

is guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Interpretation

11 In this Schedule—

(a) "duly authorised person", in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision, and

(b) "licensed activity", in relation to a licence, means the activity which the licence authorises to be carried on."

SCHEDULE 6

Section 56

AMENDMENTS RELATING TO PARENTHOOD IN CASES INVOLVING ASSISTED REPRODUCTION

. . . . . .

SCHEDULE 7

Section 65

MINOR AND CONSEQUENTIAL AMENDMENTS

VALID FROM 01/10/2009

Congenital Disabilities (Civil Liability) Act 1976 (c. 28)

1 In section 4 of the Congenital Disabilities (Civil Liability) Act 1976 (interpretation), in subsection (2), for "section 1 of the Human Fertilisation and Embryology Act 1990" substitute " section 1(1) of the Human Fertilisation and Embryology Act 1990 and any regulations under section 1(6) of that Act ".

Human Fertilisation and Embryology Act 1990 (c. 37)

VALID FROM 01/10/2009

2 In section 2 of the 1990 Act (other terms)—

(a) in subsection (1), in the definition of "store", for "or embryos" substitute " , embryos or human admixed embryos ", and

(b) in subsection (2), for "or gametes" substitute " , gametes or human admixed embryos ".

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

VALID FROM 01/10/2009

3 In section 7 of the 1990 Act (reports to Secretary of State) for subsection (1) substitute—

"(1) The Authority shall prepare—

(a) a report for the period beginning with the 1 August preceding the relevant commencement date (or if that date is a 1 August, beginning with that date) and ending with the next 31 March, and

(b) a report for each succeeding period of 12 months ending with 31 March.

(1A) In subsection (1)(a) "the relevant commencement date" means the day on which paragraph 3 of Schedule 7 to the Human Fertilisation and Embryology Act 2008 comes into force.

(1B) The Authority shall send each report to the Secretary of State as soon as practicable after the end of the period for which it is prepared."

VALID FROM 01/10/2009

4 Omit section 10 of the 1990 Act (licensing procedure).

VALID FROM 01/10/2009

5 In section 13A of the 1990 Act (conditions of licences for non-medical fertility services), omit subsection (4).

VALID FROM 01/10/2009

6 In section 14A of the 1990 Act (conditions of licences: human application), in subsection (1)—

(a) omit the "and" at the end of paragraph (a), and

(b) at the end of paragraph (b) insert ", and

(c) every licence under paragraph 3 of that Schedule, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application."

VALID FROM 01/10/2009

7 In section 15 of the 1990 Act (conditions of research licences) after subsection (4) insert—

"(5) If by virtue of paragraph 20 of Schedule 3 (existing cells or cell lines) qualifying cells, as defined by paragraph 20(2) of that Schedule, of a person ("P") are used to bring about the creation *in vitro* of an

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

embryo or human admixed embryo without P's consent, steps shall be taken to ensure that the embryo or human admixed embryo cannot subsequently be attributed to P."

VALID FROM 01/10/2009

8 Omit section 22 of the 1990 Act (temporary suspension of licence).

VALID FROM 01/10/2009

9 In section 23 of the 1990 Act (directions: general)—

(a) in subsection (5), for paragraph (a) substitute—

"(a) in respect of any licence (including a licence which has ceased to have effect), by serving notice of the directions on the person—

(i) who is the person responsible or the holder of the licence, if different, or

(ii) who was the person responsible or the holder of the licence, if different,", and

(b) omit subsection (6).

VALID FROM 01/10/2009

10 (1) Section 31A of the 1990 Act (the Authority's register of licences) is amended as follows.

(2) In subsection (1)—

(a) omit the "and" at the end of paragraph (a), and

(b) at the end of paragraph (b) insert ", and

(c) every licence under paragraph 3 of Schedule 2 authorising activities in connection with the derivation from embryos of stem cells that are intended for human application.".

(3) In subsection (2)(c), for ", if applicable, the nominal licensee" substitute " the name of the holder of the licence (if different) ".

VALID FROM 01/10/2009

11 In section 32 of the 1990 Act (information to be provided to Registrar General), in subsection (3), for "33" substitute " 33A ".

VALID FROM 01/10/2009

12 In section 34 of the 1990 Act (disclosure in the interests of justice), in subsection (1), for "section 31(2)(b)" substitute " section 31(2)(c) to (e) ".

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

VALID FROM 01/10/2009

13 In section 47 of the 1990 Act (index)—

(a) in the first column, after "embryo" insert " (except in section 4A or in the term "human admixed embryo") ",

(b) in the first column, after "gametes, eggs or sperm", insert " (except in section 4A) ",

(c) in the first column, in the entry relating to "store", after "embryos" insert " , human admixed embryos ",

(d) at the appropriate places insert—

"Appeals committee	Section 20A(2)"
"Human admixed embryo	Section 4A(6)"
"Nuclear DNA (in relation to an embryo)	Section 2(1)", and

(e) omit the entries relating to "licence committee" and "nominal licensee".

VALID FROM 01/10/2009

14 In section 48 of the 1990 Act (application to Northern Ireland) for "sections 33(6)(h) and" substitute " sections 33A(2)(r) and ".

15 In Schedule 1 to the 1990 Act (the Authority: supplementary provision)—

(a) in paragraph 9(1), for "The" substitute " Subject to any provision of this Act, the ",

(b) in paragraph 10(3), omit "or any licence committee", and

(c) after paragraph 14, insert—

"Application of Statutory Instruments Act 1946

15 The Statutory Instruments Act 1946 applies to any power to make orders or regulations conferred by an Act on the Authority as if the Authority were a Minister of the Crown."

Commencement Information

I60 Sch. 7 para. 15 wholly in force at 1.10.2009; Sch. 7 para. 15 not in force at Royal Assent see s. 68; Sch. 7 para. 15(c) in force for certain purposes at 6.4.2009 by S.I. 2009/479, **art. 5(g)** (with Sch.); Sch. 7 para. 15 in force at 1.10.2009 otherwise by S.I. 2009/2232, **art. 2(y)**

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

VALID FROM 01/10/2009

Age of Legal Capacity (Scotland) Act 1991 (c. 50)

16 In section 2 of the Age of Legal Capacity (Scotland) Act 1991, after subsection (4) (which provides for an exception to the general rule about the age of legal capacity in relation to surgical, medical or dental procedure or treatment) insert—

"(4ZA) For the purposes of subsection (4), the storage of gametes in accordance with the Human Fertilisation and Embryology Act 1990 is to be treated as a medical procedure.

(4ZB) A person under the age of 16 years shall have legal capacity to consent to the use of the person's human cells in accordance with Schedule 3 to the Human Fertilisation and Embryology Act 1990 for the purposes of a project of research where the person is capable of understanding the nature of the research; and in this subsection "human cells" has the same meaning as in that Schedule."

VALID FROM 01/10/2009

Children (Scotland) Act 1995 (c. 36)

17 In section 15 of the Children (Scotland) Act 1995 (interpretation of Part 1), after subsection (6) insert—

"(7) No provision in this Part of this Act shall permit a person to give a consent to the storage of gametes under the Human Fertilisation and Embryology Act 1990 on behalf of a child."

VALID FROM 01/10/2009

Adults with Incapacity (Scotland) Act 2000 (asp 4)

18 After section 84 of the Adults with Incapacity (Scotland) Act 2000 insert—

"**84A Application to storage of gametes without adult's consent where adult is incapable**

(1) The storage of gametes under paragraph 10 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (storage of gametes without patient's consent where patient is incapable) is to be treated as an intervention in the affairs of an adult under this Act.

(2) Sections 2 to 5, 8, 11, 14 and 85 of this Act apply to a registered medical practitioner's decision under that paragraph as they apply to decisions taken for the purposes of this Act.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

(3) Section 52 of this Act applies to a practitioner's decision under that paragraph as it applies to decisions taken for the purposes of section 47 of this Act.

(4) Part 5 of this Act (other than section 52) does not apply to the storage of gametes under that paragraph.

(5) Section 83 of this Act applies to a practitioner's decision under that paragraph as if the practitioner were exercising powers under this Act.

(6) Nothing in this section authorises any person, other than the person whose gametes are to be stored, to consent to the storage of the gametes.

84B Application to use of human cells to create an embryo in vitro without adult's consent

(1) The use of an adult's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research—

(a) without the adult's consent, and

(b) where the adult is incapable,

is to be treated as an intervention in the affairs of an adult under this Act.

(2) Sections 2 to 5, 8, 11, 14 and 85 of this Act apply to decisions made under paragraphs 16 and 18 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (when consent to the use of human cells is not required due to adult being incapable of consenting) as they apply to decisions taken for the purposes of this Act.

(3) Section 51 of this Act does not apply to the use of an adult's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research.

(4) Section 83 of this Act applies to a decision made under paragraphs 16 and 18 of Schedule 3 to the Human Fertilisation and Embryology Act 1990 as if the person making the decision were exercising powers under this Act.

(5) Expressions used in this section and in Schedule 3 to the Human Fertilisation and Embryology Act 1990 have the same meaning in this section as in that Schedule.”

VALID FROM 01/10/2009

Criminal Justice and Police Act 2001 (c. 16)

19 In section 57 of the Criminal Justice and Police Act 2001 (retention of seized items), in subsection (1)(k), for “section 40(4) of” substitute “ paragraph 7(4) of Schedule 3B to ”.

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

20 In section 66 of the Criminal Justice and Police Act 2001 (general interpretation of Part 2)—

(a) in subsection (4), after paragraph (j) insert—

"(ja) paragraph 5 of Schedule 3B to the Human Fertilisation and Embryology Act 1990.", and

(b) in subsection (5), omit paragraph (g).

21 In Schedule 1 to the Criminal Justice and Police Act 2001 (powers of seizure) for paragraph 52 substitute—

"52 Each of the powers of seizure conferred by the provisions of paragraph 7(1) and (2) of Schedule 3B to the Human Fertilisation and Embryology Act 1990."

VALID FROM 01/10/2009

Human Tissue Act 2004 (c. 30)

22 In section 1 of the Human Tissue Act 2004 (authorisation of activities for scheduled purposes)—

(a) after subsection (9) insert—

"(9A) Subsection (1)(f) does not apply to the use of relevant material for the purpose of research where the use of the material requires consent under paragraph 6(1) or 12(1) of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (use of human cells to create an embryo or a human admixed embryo) or would require such consent but for paragraphs 16 and 20 of that Schedule.", and

(b) after subsection (10) insert—

"(10A) In the case of an activity in relation to which subsection (8) has effect, subsection (10)(c) is to be read subject to any requirements imposed by Schedule 3 to the Human Fertilisation and Embryology Act 1990 in relation to the activity."

23 In section 14 of the Human Tissue Act 2004 (remit of the Human Tissue Authority), after subsection (2) insert—

"(2ZA) The activities within the remit of the Authority do not include the use, for a scheduled purpose, of relevant material where the use of the material requires consent under paragraph 6(1) or 12(1) of Schedule 3 to the Human Fertilisation and Embryology Act 1990 (use of human cells to create an embryo or a human admixed embryo) or would require such consent but for paragraphs 16 and 20 of that Schedule."

24 In section 54 of the Human Tissue Act 2004 (general interpretation), for subsection (6), substitute—

"(6) In this Act "embryo" and "gametes" have the same meaning as they have by virtue of section 1(1), (4) and (6) of the Human Fertilisation

Status: *Point in time view as at 13/11/2008.*
Changes to legislation: *Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)*

and Embryology Act 1990 in the other provisions of that Act (apart from section 4A).”

VALID FROM 01/10/2009

Mental Capacity Act 2005 (c. 9)

25 In section 30 of the Mental Capacity Act 2005 (research), after subsection (3) insert—

“(3A) Research is not intrusive to the extent that it consists of the use of a person's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo, or the subsequent storage or use of an embryo or human admixed embryo so created.

(3B) Expressions used in subsection (3A) and in Schedule 3 to the Human Fertilisation and Embryology Act 1990 (consents to use or storage of gametes, embryos or human admixed embryos etc.) have the same meaning in that subsection as in that Schedule.”

SCHEDULE 8

Section 66

REPEALS AND REVOCATIONS

Commencement Information

I61 Sch. 8 wholly in force at 6.4.2010; Sch. 8 not in force at Royal Assent see s. 68; Sch. 8 in force for certain purposes at 6.4.2009 and at 1.9.2009 for further certain purposes by S.I. 2009/479, **arts. 5(a)**, **6(1)(e)(2)(3)** (with Sch.); Sch. 8 in force for further certain purposes at 1.10.2009 by S.I. 2009/2232, **art. 2(z)**; Sch. 8 in force at 6.4.2010 otherwise by S.I. 2010/987, **art. 2(h)**

. . . . . .

VALID FROM 01/09/2009

. . . . . .

Status:
Point in time view as at 13/11/2008.

Changes to legislation:
Human Fertilisation and Embryology Act 2008 is up to date with all changes known to be in force on or before 01 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.