

SCHEDULES

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 - (3) In this Schedule “effective consent” means a consent under this Schedule which has not been withdrawn.”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—

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“(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 ”.

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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.

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- (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
 - (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,

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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.

(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

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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—
 - (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.

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- (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.
- 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—

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“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.
- (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.

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- (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.
- (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—

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- (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”.

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,

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- (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.
 - (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)

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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
 - (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—

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- (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
 - (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

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- (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 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.

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- (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 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.”

Status:

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