SCHEDULES

SCHEDULE 3

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

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—

(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,

(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) 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—

(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

(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.

(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)."

Changes to legislation:
Human Fertilisation and Embryology Act 2008, Paragraph 14 is up to date with all changes known to be in force on or before 29 July 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.
View outstanding changes

Changes and effects yet to be applied to the whole Act associated Parts and Chapters:
Whole provisions yet to be inserted into this Act (including any effects on those provisions):

– s. 55(3)(e) and word inserted by 2022 c. 18 (N.I.) Sch. 3 para. 75(b)