

Human Fertilisation and Embryology Bill [HL]

COMMONS AMENDMENTS

[The page and line references are to Bill 70 as first printed for the Commons]

Clause 4

- 1 Page 4, line 6, leave out “the keeping or using of” and insert “keeping or using”
- 2 Page 4, line 14, at end insert –
“(4A) A licence cannot authorise keeping or using a human admixed embryo in any circumstances in which regulations prohibit its keeping or use.”
- 3 Page 4, leave out line 30 and insert –
“(e) any embryo not falling within paragraphs (a) to (d) which contains both nuclear or mitochondrial DNA of a human and nuclear or mitochondrial DNA of an animal (“animal DNA”) but in which the animal DNA is not predominant.”
- 4 Page 4, line 43, after “but” insert “(except in subsection (8))”
- 5 Page 5, line 6, leave out “(d)” and insert “(e)”

Clause 12

- 6 Page 8, leave out line 31 and insert –
“(1) Section 12 of the 1990 Act (general conditions of licences under that Act) is amended as follows.
(2) In”
- 7 Page 8, line 37, at end insert –
“(3) In subsection (2) –
(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.”.”

Clause 14

- 8 Page 9, line 30, leave out “being treated” and insert “mentioned in subsection (6A)”
9 Page 9, line 33, leave out “to be treated” and insert “mentioned in subsection (6A)”

Clause 16

- 10 Page 12, line 14, at end insert –
“() in paragraph (c), after “application” insert “or a licence under paragraph 3 of that Schedule authorising activities in connection with the derivation from embryos of stem cells that are intended for human application”, ”
11 Page 12, line 15, after “(ca)” insert “– (i)”
12 Page 12, line 16, at end insert –
“(ii) after “that Schedule” insert “authorising activities otherwise than in connection with the derivation from embryos of stem cells that are intended for human application”, and”

Clause 24

- 13 Page 23, line 7, leave out “any of”

Clause 25

- 14 Page 26, leave out lines 22 to 41 and insert –
“(g) the disclosure is made so that no individual can be identified from the information,
(h) the disclosure is of information other than identifying donor information and is made with the consent required by section 33AB,”
15 Page 26, line 41, at end insert –
“(ja) the disclosure –
(i) is made by a person who is satisfied that it is necessary to make the disclosure to avert an imminent danger to the health of an individual (“P”),
(ii) is of information falling within section 31(2)(a) which could be disclosed by virtue of paragraph (h) with P’s consent or could be disclosed to P by virtue of subsection (10), and
(iii) is made in circumstances where it is not reasonably practicable to obtain P’s consent,”
16 Page 27, leave out lines 38 to 50
17 Page 28, leave out lines 1 and 2
18 Page 28, line 7, leave out from “of” to “or” in line 12 and insert “identifying donor information,”
19 Page 28, leave out lines 18 to 30
20 Page 28, line 36, leave out “treated together with another” and insert “who is treated together with, or gives a notice under section 37 or 44 of the Human Fertilisation and Embryology Act 2008 in respect of, another”

21 Page 28, leave out lines 39 and 40

22 Page 28, line 45, at end insert –

“() In this section “identifying donor information” means information enabling a person to be identified as a person whose gametes were used in accordance with consent given under paragraph 5 of Schedule 3 for the purposes of treatment services or non-medical fertility services in consequence of which an identifiable individual was, or may have been, born.”

23 Page 28, line 45, at end insert –

“33AB Consent required to authorise certain disclosures

- (1) This section has effect for the purposes of section 33A(2)(h).
- (2) Subject to subsection (5), the consent required by this section is the consent of each individual who can be identified from the information.
- (3) Consent in respect of a person who has not attained the age of 18 years (“C”) may be given –
 - (a) by C, in a case where C is competent to deal with the issue of consent, or
 - (b) by a person having parental responsibility for C, in any other case.
- (4) Consent to disclosure given at the request of another shall be disregarded unless, before it is given, the person requesting it takes reasonable steps to explain to the individual from whom it is requested the implications of compliance with the request.
- (5) In the case of information which shows that any identifiable individual (“A”) was, or may have been, born in consequence of treatment services, the consent required by this section does not include A’s consent if the disclosure is necessarily incidental to the disclosure of information falling within section 31(2)(a).
- (6) The reference in subsection (3) to parental responsibility is –
 - (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;
 - (c) in relation to Scotland, to be read as a reference to parental responsibilities and parental rights within the meaning of the Children (Scotland) Act 1995.”

Clause 29

24 Page 32, line 26, at end insert –

“() In subsection (7), for “section 10(2)(a)” substitute “section 19B(3)(a) or 20B(3)(e)”.

25 Page 32, line 31, leave out “(7) or”

26 Page 33, line 21, leave out “, (6) and (7)” and insert “and (6)”

Clause 30

- 27 Page 34, line 14, leave out “4A(5)(e) or (10)” and insert “4A(4A) or (10)”
- 28 Page 34, line 14, at end insert –
“section 20A(3);
section 20B(2)”
- 29 Page 34, line 21, leave out “, 3(5)”

Clause 31

- 30 Page 34, leave out lines 34 and 35

Clause 37

- 31 Page 37, line 23, at end insert –
“() A notice under subsection (1)(a), (b) or (c) by a person (“S”) who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.”

Clause 40

- 32 Page 39, line 15, leave out “a” and insert “the”

Clause 43

- 33 Page 40, line 14, leave out “she” and insert “W”

Clause 44

- 34 Page 41, line 2, at end insert –
“() A notice under subsection (1)(a), (b) or (c) by a person (“S”) who is unable to sign because of illness, injury or physical disability is to be taken to comply with the requirement of subsection (2) as to signature if it is signed at the direction of S, in the presence of S and in the presence of at least one witness who attests the signature.”

Clause 46

- 35 Page 41, line 21, leave out “the woman” and insert “W”

Clause 48

- 36 Page 43, line 13, at end insert –
“(5A) In relation to England and Wales and Northern Ireland, a child who –
(a) has a parent by virtue of section 42, or
(b) has a parent by virtue of section 43 who is at any time during the period beginning with the time mentioned in section 43(b) and ending with the time of the child’s birth a party to a civil partnership with the child’s mother,

is the legitimate child of the child's parents.”

Clause 50

37 Page 44, line 2, leave out third “the” and insert “any”

38 Page 44, line 10, at end insert –

“() The reference in section 48(5A)(b) to a civil partnership includes a reference to a void civil partnership if either or both of the parties reasonably believed at the time when they registered as civil partners of each other that the civil partnership was valid; and for this purpose it is to be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the civil partnership was valid.”

Clause 53

39 Page 45, line 16, at end insert –

“() the Schedule to the Population (Statistics) Act 1938 (c. 12),”

Clause 55

40 Page 47, line 32, leave out “relating to” and insert “about”

Clause 59

41 Page 49, line 11, after first “any” insert “reasonable”

42 Page 49, line 14, after “any” insert “reasonable”

43 Page 49, line 19, after first “any” insert “reasonable”

44 Page 49, line 21, after “any” insert “reasonable”

45 Page 49, line 23, at end insert –

“(2C) Any reference in subsection (2A) or (2B) to a reasonable payment in respect of the doing of an act by a non-profit making body is a reference to a payment not exceeding the body's costs reasonably attributable to the doing of the act.”

Clause 64

46 Page 51, line 13, at end insert –

“() An order under this section which modifies an enactment in consequence of any provision of Part 2 may modify subsection (5) of section 53 (interpretation of references to father etc.).”

Clause 67

47 Page 52, line 9, at end insert –

“() Subsection (2) is subject to paragraph A1(2) of Schedule 6.”

Clause 69

48 Page 52, line 31, leave out subsection (2)

Schedule 2

- 49 Page 57, leave out lines 37 to 41 and insert –
 “(a) bringing about the creation of human admixed embryos *in vitro*,
 and
 (b) keeping or using human admixed embryos,”
- 50 Page 58, leave out lines 3 to 10
- 51 Page 58, leave out lines 17 to 19
- 52 Page 58, line 21, leave out “, (3) or (5)” and insert “or (3)”

Schedule 3

- 53 Page 59, line 22, leave out from “disability” to “and” in line 27 and insert “(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”
- 54 Page 59, line 38, leave out “a” and insert “any”
- 55 Page 60, line 1, leave out sub-paragraph (4) and insert –
 “(4) For sub-paragraph (2) substitute –
 “(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(2ZA) or 14(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.””

- 56 Page 62, line 12, after “(b)” insert “, (ba)”
- 57 Page 62, line 15, at end insert –
- “(3ZA) If the Authority is satisfied that the parental consent conditions in paragraph 15A 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 (3ZB) in relation to C.
- (3ZB) 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, is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.
- (3ZC) If C attains the age of 18 years or the condition in paragraph 15A(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 (3ZB) ceases to apply in relation to C.
- (3ZD) Sub-paragraphs (1) to (3) have effect subject to paragraphs 15B and 15F.”
- 58 Page 62, line 16, leave out “and (3)” and insert “, (3) and (3ZB)”
- 59 Page 63, line 1, at end insert –
- “(2ZA) Where a licence authorises the application of paragraph 6(3ZB) 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.
- (2ZB) If C attains the age of 18 years or the condition in paragraph 15A(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 (2ZA) ceases to apply in relation to C.”
- 60 Page 63, line 2, for “sub-paragraph (2)” substitute “sub-paragraphs (2) and (2ZA)”
- 61 Page 63, line 17, leave out “paragraph 4A(4)” and insert “paragraphs 4A(4), 15B and 15F”
- 62 Page 63, line 20, leave out “(“the child donor”)” and insert “(“C”)”
- 63 Page 63, line 21, leave out “the child donor’s” and insert “C’s”
- 64 Page 63, line 24, leave out “the child donor before the child donor” and insert “C before C”
- 65 Page 63, line 27, leave out “the child donor” and insert “C”
- 66 Page 63, line 31, leave out “the fertility of the child donor” and insert “C’s fertility”
- 67 Page 63, line 32, leave out “the best interests of the child donor” and insert “C’s best

interests”

- 68 Page 63, line 36, leave out “the child donor” and insert “C”
- 69 Page 63, line 39, leave out “the child donor” and insert “C”
- 70 Page 63, line 43, leave out “the child donor” and insert “C”
- 71 Page 64, line 4, leave out “he” and insert “C”
- 72 Page 64, leave out line 7
- 73 Page 64, line 10, leave out “the child donor” and insert “C”
- 74 Page 64, line 17, leave out (“the patient”) and insert (“P”)
- 75 Page 64, line 18, leave out “the patient’s” and insert “P’s”
- 76 Page 64, line 20, leave out “the patient after the patient” and insert “P after P”
- 77 Page 64, line 23, leave out “the patient” and insert “P”
- 78 Page 64, line 27, leave out “the patient’s” and insert “P’s”
- 79 Page 64, line 28, leave out “the patient” and insert “P”
- 80 Page 64, line 30, leave out “the patient is likely to regain” and insert “P is likely at some time to have”
- 81 Page 64, line 31, leave out “the patient’s” and insert “P’s”
- 82 Page 64, line 33, leave out “the patient” and insert “P”
- 83 Page 64, line 34, leave out “the patient has not, after regaining” and insert “P has not subsequently, at a time when P has”
- 84 Page 64, line 38, leave out “the patient” and insert “P”
- 85 Page 64, line 40, leave out “the patient” and insert “P”
- 86 Page 64, line 42, leave out “the patient” and insert “P”
- 87 Page 64, line 45, leave out “the patient regaining” and insert “P having”
- 88 Page 64, line 46, leave out “the patient no longer” and insert “P not”
- 89 Page 65, leave out lines 3 to 5
- 90 Page 65, line 29, at end insert –

“(4) If the Authority is satisfied that the parental consent conditions in paragraph 15A 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 15A(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 15B and 15F.”

91 Page 65, line 36, at end insert –

- “(2) Where a licence authorises the application of paragraph 13(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 15A(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 15B and 15F.”

92 Page 66, line 5, at end insert –

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

After paragraph 15 (as inserted by paragraph 13 above) insert –

“Parental consent conditions

- 15A (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(3ZA) and 13(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.

- 15B (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 15C are met,
 - (b) that paragraphs (1) to (4) of paragraph 15D have been complied with, and
 - (c) that the condition in paragraph 15D(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 15E.

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

15C (1) The conditions referred to in paragraph 15B(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 15D 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

- 15D (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 15B(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

- 15E (1) Paragraph 15B 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 15B 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 cell lines in existence before relevant commencement date

- 15F (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 15F

15G (1) A licence may not authorise the application of paragraph 15F 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 15B 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—

(15)

- (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).”

93 Page 66, line 31, at end insert –

- “(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 6

94 Page 72, line 25, at end insert –

“*Population (Statistics) Act 1938 (c. 12)*

- A1 (1) In the Schedule to the Population (Statistics) Act 1938 (particulars which may be required), in paragraph 1 (which relates to the registration of a birth) –

- (a) in paragraph (b), after “child,” insert “or as a parent of the child by virtue of section 42 or 43 of the Human Fertilisation and Embryology Act 2008,” and
- (b) in paragraph (c) –
 - (i) in sub-paragraph (i), after “marriage” insert “or of their formation of a civil partnership”, and
 - (ii) at the beginning of each of sub-paragraphs (ii) and (iii) insert “where the parents are married,”.

(2) Sub-paragraph (1)(b)(ii) does not extend to Scotland.”

- 95 Page 76, line 26, leave out “that person” and insert “the woman concerned”
- 96 Page 79, line 3, after “of” insert “the formation of”
- 97 Page 79, line 19, after “time” insert “of the formation”
- 98 Page 86, line 26, leave out from third “the” to “shall” in line 28 and insert “woman concerned (in which case the woman concerned”
- 99 Page 86, line 32, leave out “person” and insert “woman concerned”
- 100 Page 87, line 24, leave out second “a” and insert “the”
- 101 Page 90, line 29, after “of” insert “the formation of”
- 102 Page 91, line 3, after “time” insert “of the formation”
- 103 Page 98, line 15, after “domiciled” insert “immediately”

Schedule 7

- 104 Page 99, line 24, at end insert –
 - “2A 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 2A 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.””
- 105 Page 99, line 27, at end insert –
 - “ 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.””

106 Page 99, line 27, at end insert –

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

“(5) If by virtue of paragraph 15F of Schedule 3 (existing cell lines) qualifying cells, as defined by paragraph 15F(2) of that Schedule, of a person (“P”) are used to bring about the creation *in vitro* of an 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.””

107 Page 100, leave out line 1 and insert –

“(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”

108 Page 100, line 41, at end insert –

“(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.””

109 Page 101, line 28, at end insert –

“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 15B and 15D 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 15B and 15D 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.”

110 Page 102, line 14, after “embryo)” insert “or would require such consent but for paragraphs 15B and 15F of that Schedule”

111 Page 102, line 18, leave out from beginning to “in” in line 21 and insert “requirements imposed by Schedule 3 to the Human Fertilisation and Embryology Act 1990”

112 Page 102, line 28, at end insert “or would require such consent but for paragraphs 15B and 15F of that Schedule”

113 Page 102, line 34, at end insert –

“*Mental Capacity Act 2005 (c. 9)*

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

114 Page 103, column 2, leave out lines 15 and 16 and insert –

“In section 12 –

(a) in subsection (1)(c), the words “or non-medical fertility services”, and

(b) in subsection (2), the word “and” at the end of paragraph (a).”

115 Page 103, line 21, column 2, at end insert –

“In section 14A(1), the word “and” at the end of paragraph (a).”

116 Page 103, line 26, column 2, at end insert—

“In section 31A(1), the word “and” at the end of paragraph (a).”

117 Page 103, line 33, column 2, leave out “, (6) and (7)” and insert “and (6)”

118 Page 103, line 34, column 2, leave out “(7) or”

