



# Human Fertilisation and Embryology Act 2008

## 2008 CHAPTER 22

### PART 1

#### AMENDMENTS OF THE HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

##### *Principal terms used in the 1990 Act*

#### **1 Meaning of “embryo” and “gamete”**

(1) Section 1 of the 1990 Act (meaning of “embryo”, “gamete” and associated expressions) is amended as follows.

(2) For subsection (1) substitute—

“(1) In this Act (except in section 4A or in the term “human admixed embryo”)—

- (a) embryo means a live human embryo and does not include a human admixed embryo (as defined by section 4A(6)), and
- (b) references to an embryo include an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.”

(3) In subsection (2), for paragraph (a) substitute—

“(a) references to embryos the creation of which was brought about *in vitro* (in their application to those where fertilisation or any other process by which an embryo is created is complete) are to those where fertilisation or any other process by which the embryo was created began outside the human body whether or not it was completed there, and”.

(4) For subsection (4) substitute—

“(4) In this Act (except in section 4A)—

- (a) references to eggs are to live human eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,
- (b) references to sperm are to live human sperm, including cells of the male germ line at any stage of maturity, and
- (c) references to gametes are to be read accordingly.”

(5) After subsection (5) insert—

“(6) If it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine, regulations may provide that in this Act (except in section 4A) “embryo”, “eggs”, “sperm” or “gametes” includes things specified in the regulations which would not otherwise fall within the definition.

(7) Regulations made by virtue of subsection (6) may not provide for anything containing any nuclear or mitochondrial DNA that is not human to be treated as an embryo or as eggs, sperm or gametes.”

## 2 **Meaning of “nuclear DNA”**

In section 2(1) of the 1990 Act (other terms), after the definition of “non-medical fertility services” insert—

““nuclear DNA”, in relation to an embryo, includes DNA in the pronucleus of the embryo.”

### *Activities governed by the 1990 Act*

## 3 **Prohibitions in connection with embryos**

(1) Section 3 of the 1990 Act (prohibitions in connection with embryos) is amended as follows.

(2) For subsection (2) substitute—

“(2) No person shall place in a woman—

- (a) an embryo other than a permitted embryo (as defined by section 3ZA),  
or
- (b) any gametes other than permitted eggs or permitted sperm (as so defined).”

(3) In subsection (3)—

- (a) at the end of paragraph (b), insert “or”, and
- (b) omit paragraph (d) and the word “or” immediately before it.

(4) In subsection (4), for “the day when the gametes are mixed” substitute “the day on which the process of creating the embryo began”.

(5) After section 3 insert—

### **“3ZA Permitted eggs, permitted sperm and permitted embryos**

- (1) This section has effect for the interpretation of section 3(2).
  - (2) A permitted egg is one—
    - (a) which has been produced by or extracted from the ovaries of a woman, and
    - (b) whose nuclear or mitochondrial DNA has not been altered.
  - (3) Permitted sperm are sperm—
    - (a) which have been produced by or extracted from the testes of a man, and
    - (b) whose nuclear or mitochondrial DNA has not been altered.
  - (4) An embryo is a permitted embryo if—
    - (a) it has been created by the fertilisation of a permitted egg by permitted sperm,
    - (b) no nuclear or mitochondrial DNA of any cell of the embryo has been altered, and
    - (c) no cell has been added to it other than by division of the embryo’s own cells.
  - (5) Regulations may provide that—
    - (a) an egg can be a permitted egg, or
    - (b) an embryo can be a permitted embryo,even though the egg or embryo has had applied to it in prescribed circumstances a prescribed process designed to prevent the transmission of serious mitochondrial disease.
  - (6) In this section—
    - (a) “woman” and “man” include respectively a girl and a boy (from birth), and
    - (b) “prescribed” means prescribed by regulations.”
- (6) The Human Reproductive Cloning Act 2001 (c. 23) (which is superseded by the preceding provisions of this section) ceases to have effect.

## **4 Prohibitions in connection with genetic material not of human origin**

- (1) In section 4 of the 1990 Act (prohibitions in connection with gametes)—
  - (a) in subsection (1), omit—
    - (i) paragraph (c), and
    - (ii) the word “or” immediately before it, and
  - (b) in subsection (5), after “section 3” insert “or 4A”.
- (2) After section 4 of the 1990 Act insert—

### **“4A Prohibitions in connection with genetic material not of human origin**

- (1) No person shall place in a woman—
  - (a) a human admixed embryo,

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- (b) any other embryo that is not a human embryo, or
  - (c) any gametes other than human gametes.
- (2) No person shall—
  - (a) mix human gametes with animal gametes,
  - (b) bring about the creation of a human admixed embryo, or
  - (c) keep or use a human admixed embryo,except in pursuance of a licence.
- (3) A licence cannot authorise keeping or using a human admixed embryo after the earliest of the following—
  - (a) the appearance of the primitive streak, or
  - (b) the end of the period of 14 days beginning with the day on which the process of creating the human admixed embryo began, but not counting any time during which the human admixed embryo is stored.
- (4) A licence cannot authorise placing a human admixed embryo in an animal.
- (5) A licence cannot authorise keeping or using a human admixed embryo in any circumstances in which regulations prohibit its keeping or use.
- (6) For the purposes of this Act a human admixed embryo is—
  - (a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with—
    - (i) two human pronuclei,
    - (ii) one nucleus of a human gamete or of any other human cell, or
    - (iii) one human gamete or other human cell,
  - (b) any other embryo created by using—
    - (i) human gametes and animal gametes, or
    - (ii) one human pronucleus and one animal pronucleus,
  - (c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal into one or more cells of the embryo,
  - (d) a human embryo that has been altered by the introduction of one or more animal cells, or
  - (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.
- (7) In subsection (6)—
  - (a) references to animal cells are to cells of an animal or of an animal embryo, and
  - (b) references to human cells are to cells of a human or of a human embryo.
- (8) For the purposes of this section an “animal” is an animal other than man.
- (9) In this section “embryo” means a live embryo, including an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.

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- (10) In this section—
- (a) references to eggs are to live eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (9)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo, and
  - (b) references to gametes are to eggs (as so defined) or to live sperm, including cells of the male germ line at any stage of maturity.
- (11) If it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine, regulations may—
- (a) amend (but not repeal) paragraphs (a) to (e) of subsection (6);
  - (b) provide that in this section “embryo”, “eggs” or “gametes” includes things specified in the regulations which would not otherwise fall within the definition.
- (12) Regulations made by virtue of subsection (11)(a) may make any amendment of subsection (7) that appears to the Secretary of State to be appropriate in consequence of any amendment of subsection (6).”

*The Human Fertilisation and Embryology Authority*

**5 Membership of Authority: disqualification and tenure**

Schedule 1 contains amendments of Schedule 1 to the 1990 Act (which are about disqualification for appointment to membership of the Authority and the tenure of office of members).

**6 Additional general functions of Authority**

- (1) In section 8 of the 1990 Act (general functions of the Authority), renumber the existing provision as subsection (1) of that section.
- (2) In that subsection—
- (a) omit the word “and” immediately after paragraph (c), and
  - (b) after that paragraph insert—
    - “(ca) maintain a statement of the general principles which it considers should be followed—
      - (i) in the carrying-on of activities governed by this Act, and
      - (ii) in the carrying-out of its functions in relation to such activities,
    - (cb) promote, in relation to activities governed by this Act, compliance with—
      - (i) requirements imposed by or under this Act, and
      - (ii) the code of practice under section 25 of this Act, and”.
- (3) After that subsection, insert—
- “(2) The Authority may, if it thinks fit, charge a fee for any advice provided under subsection (1)(c).”

## 7 **Duties in relation to carrying out its functions**

After section 8 (general functions of the Authority) insert—

### **“8ZA Duties in relation to carrying out its functions**

- (1) The Authority must carry out its functions effectively, efficiently and economically.
- (2) In carrying out its functions, the Authority must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).”

## 8 **Power to contract out functions etc.**

After section 8A of the 1990 Act (duty of Authority to communicate with competent authorities of other EEA states) insert—

### **“8B Agency arrangements and provision of services**

- (1) Arrangements may be made between the Authority and a government department, a public authority or the holder of a public office (“the other authority”) for—
  - (a) any functions of the Authority to be exercised by, or by members of the staff of, the other authority, or
  - (b) the provision by the other authority of administrative, professional or technical services to the Authority.
- (2) Arrangements under subsection (1)(a) do not affect responsibility for the carrying-out of the Authority’s functions.
- (3) Subsection (1)(a) does not apply to any function of making subordinate legislation (within the meaning of the Interpretation Act 1978).

### **8C Contracting out functions of Authority**

- (1) This section applies to any function of the Authority other than—
  - (a) any function which, by virtue of any enactment, may be exercised only by members of the Authority,
  - (b) a function excluded from this section by subsection (2), or
  - (c) a function excluded from this section by the Secretary of State by order.
- (2) A function is excluded from this section if—
  - (a) it relates to the grant, revocation or variation of any licence,
  - (b) it is a power or right of entry, search or seizure into or of any property, or
  - (c) it is a function of making subordinate legislation (within the meaning of the Interpretation Act 1978).
- (3) The Authority may make arrangements with any person (“the authorised person”) for the exercise by that person, or by the employees of that person, of any function of the Authority to which this section applies.

- (4) Any arrangements made by the Authority under this section—
  - (a) may be revoked at any time by the Authority, and
  - (b) do not prevent the Authority from exercising any function to which the arrangements relate.
- (5) Subject to subsection (6), anything done or omitted to be done by or in relation to the authorised person (or an employee of the authorised person) in, or in connection with, the exercise or purported exercise of any function to which the arrangements relate is to be treated for all purposes as done or omitted to be done by or in relation to the Authority.
- (6) Subsection (5) does not apply—
  - (a) for the purposes of so much of any contract between the authorised person and the Authority as relates to the exercise of the function, or
  - (b) for the purposes of any criminal proceedings brought in respect of anything done or omitted to be done by the authorised person (or any employee of the authorised person).
- (7) Section 38A(2) of this Act (which relates to the keeping of embryos, human admixed embryos and gametes) applies in relation to the authorised person or any employee of the authorised person, when exercising functions of the Authority, as it applies in relation to any member or employee of the Authority exercising functions as member or employee.

#### **8D Disclosure of information where functions of Authority exercised by others**

- (1) This section applies to—
  - (a) the Authority,
  - (b) any public authority or other person exercising functions of the Authority by virtue of section 8B,
  - (c) any member of staff of any person falling within paragraph (b),
  - (d) any person exercising functions of the Authority by virtue of section 8C,
  - (e) an employee of any person falling within paragraph (d), or
  - (f) any person engaged by the Authority to provide services to the Authority.
- (2) No obligation of confidence is to prevent the disclosure of information by a person to whom this section applies to another such person if the disclosure is necessary or expedient for the purposes of the exercise of any function of the Authority.”

#### **9 Power to assist other public authorities**

After section 8D (inserted by section 8 above) insert—

**“8E Power to assist other public authorities**

- (1) The Authority may if it thinks it appropriate to do so provide assistance to any other public authority in the United Kingdom for the purpose of the exercise by that authority of its functions.
- (2) Assistance provided by the Authority under this section may be provided on such terms, including terms as to payment, as it thinks fit.”

**10 Power to delegate and establish committees**

For section 9 (licence committees and other committees) of the 1990 Act substitute—

**“9A Power to delegate and establish committees**

- (1) The Authority may delegate a function to a committee, to a member or to staff.
- (2) The Authority may establish such committees or sub-committees as it thinks fit (whether to advise the Authority or to exercise a function delegated to it by the Authority).
- (3) Subject to any provision made by regulations under section 20A (appeals committees), the members of the committees or sub-committees may include persons who are not members of the Authority.
- (4) Subsection (1) has effect subject to any enactment requiring a decision to be taken by members of the Authority or by a committee consisting of members of the Authority.”

*Scope of licences*

**11 Activities that may be licensed**

- (1) In section 11 of the 1990 Act (licences for treatment, storage and research), in subsection (1)(b), for “and embryos” substitute “, embryos or human admixed embryos”.
- (2) Schedule 2 contains amendments of Schedule 2 to the 1990 Act (which relates to the activities for which licences may be granted under the Act).
- (3) The Human Fertilisation and Embryology (Research Purposes) Regulations 2001 ([S.I. 2001/188](#)) (which are superseded by the amendments made by Schedule 2) cease to have effect.

*Licence conditions*

**12 General conditions of licences**

- (1) Section 12 of the 1990 Act (general conditions of licences under that Act) is amended as follows.
- (2) In subsection (1)—



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- (a) in paragraph (c) (condition relating to compliance with Schedule 3 to the Act), omit “or non-medical fertility services”, and
  - (b) in paragraphs (e) and (f) (which relate to the supply of gametes or embryos), for “or embryos” substitute “, embryos or human admixed embryos”.
- (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.”

### **13 Consent to use or storage of gametes, embryos, human admixed embryos etc.**

Schedule 3 contains amendments of Schedule 3 to the 1990 Act (which relates to consent to the use or storage of gametes or embryos).

### **14 Conditions of licences for treatment**

- (1) Section 13 of the 1990 Act (conditions of licences for treatment) is amended in accordance with subsections (2) to (4).
- (2) In subsection (5)—
- (a) omit “, other than basic partner treatment services,”, and
  - (b) for “a father” substitute “supportive parenting”.
- (3) For subsection (6) substitute—
- “(6) A woman shall not be provided with treatment services of a kind specified in Part 1 of Schedule 3ZA unless she and any man or woman who is to be treated together with her have been given a suitable opportunity to receive proper counselling about the implications of her being provided with treatment services of that kind, and have been provided with such relevant information as is proper.
- (6A) A woman shall not be provided with treatment services after the happening of any event falling within any paragraph of Part 2 of Schedule 3ZA unless (before or after the event) she and the intended second parent have been given a suitable opportunity to receive proper counselling about the implications of the woman being provided with treatment services after the happening of that event, and have been provided with such relevant information as is proper.
- (6B) The reference in subsection (6A) to the intended second parent is a reference to—
- (a) any man as respects whom the agreed fatherhood conditions in section 37 of the Human Fertilisation and Embryology Act 2008 (“the 2008 Act”) are for the time being satisfied in relation to treatment provided to the woman mentioned in subsection (6A), and
  - (b) any woman as respects whom the agreed female parenthood conditions in section 44 of the 2008 Act are for the time being satisfied in relation to treatment provided to the woman mentioned in subsection (6A).

- (6C) In the case of treatment services falling within paragraph 1 of Schedule 3ZA (use of gametes of a person not receiving those services) or paragraph 3 of that Schedule (use of embryo taken from a woman not receiving those services), the information provided by virtue of subsection (6) or (6A) must include such information as is proper about—
- (a) the importance of informing any resulting child at an early age that the child results from the gametes of a person who is not a parent of the child, and
  - (b) suitable methods of informing such a child of that fact.
- (6D) Where the person responsible receives from a person (“X”) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of X’s withdrawal of consent to X being treated as the parent of any child resulting from the provision of treatment services to a woman (“W”), the person responsible—
- (a) must notify W in writing of the receipt of the notice from X, and
  - (b) no person to whom the licence applies may place an embryo or sperm and eggs in W, or artificially inseminate W, until W has been so notified.
- (6E) Where the person responsible receives from a woman (“W”) who has previously given notice under section 37(1)(b) or 44(1)(b) of the 2008 Act that she consents to another person (“X”) being treated as a parent of any child resulting from the provision of treatment services to W—
- (a) notice under section 37(1)(c) or 44(1)(c) of the 2008 Act of the withdrawal of W’s consent, or
  - (b) a notice under section 37(1)(b) or 44(1)(b) of the 2008 Act in respect of a person other than X,
- the person responsible must take reasonable steps to notify X in writing of the receipt of the notice mentioned in paragraph (a) or (b).”
- (4) After subsection (7) insert—
- “(8) Subsections (9) and (10) apply in determining any of the following—
- (a) the persons who are to provide gametes for use in pursuance of the licence in a case where consent is required under paragraph 5 of Schedule 3 for the use in question;
  - (b) the woman from whom an embryo is to be taken for use in pursuance of the licence, in a case where her consent is required under paragraph 7 of Schedule 3 for the use of the embryo;
  - (c) which of two or more embryos to place in a woman.
- (9) Persons or embryos that are known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop—
- (a) a serious physical or mental disability,
  - (b) a serious illness, or
  - (c) any other serious medical condition,
- must not be preferred to those that are not known to have such an abnormality.
- (10) Embryos that are known to be of a particular sex and to carry a particular risk, compared with embryos of that sex in general, that any resulting child will have or develop—

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- (a) a gender-related serious physical or mental disability,
  - (b) a gender-related serious illness, or
  - (c) any other gender-related serious medical condition,
- must not be preferred to those that are not known to carry such a risk.
- (11) For the purposes of subsection (10), a physical or mental disability, illness or other medical condition is gender-related if—
- (a) it affects only one sex, or
  - (b) it affects one sex significantly more than the other.
- (12) No embryo appropriated for the purpose mentioned in paragraph 1(1)(ca) of Schedule 2 (training in embryological techniques) shall be kept or used for the provision of treatment services.
- (13) The person responsible shall comply with any requirement imposed on that person by section 31ZD.”
- (5) After Schedule 3 to the 1990 Act insert the Schedule set out in Schedule 4 to this Act (circumstances in which offer of counselling required as condition of licence for treatment).
- (6) In any licence under paragraph 1 of Schedule 2 to the 1990 Act (licences for treatment) that is in force immediately before the commencement of subsection (2)(b) of this section, the condition required by virtue of section 13(5) of that Act is to have effect as the condition required by that provision as amended by subsection (2)(b) of this section.

## **15 Conditions of storage licences**

- (1) Section 14 of the 1990 Act (conditions of storage licences) is amended as follows.
- (2) In subsection (1)—
- (a) for “authorising the storage of gametes or embryos” substitute “authorising the storage of gametes, embryos or human admixed embryos”,
  - (b) for paragraph (a) substitute—
    - “(a) that gametes of a person shall be placed in storage only if—
      - (i) received from that person,
      - (ii) acquired in circumstances in which by virtue of paragraph 9 or 10 of Schedule 3 that person’s consent to the storage is not required, or
      - (iii) acquired from a person to whom a licence or third party agreement applies,
    - (aa) that an embryo taken from a woman shall be placed in storage only if—
      - (i) received from that woman, or
      - (ii) acquired from a person to whom a licence or third party agreement applies,
    - (ab) that an embryo the creation of which has been brought about *in vitro* otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence or third party agreement applies,

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- (ac) that a human admixed embryo the creation of which has been brought about *in vitro* otherwise than in pursuance of that licence shall be placed in storage only if acquired from a person to whom a licence under paragraph 2 or 3 of Schedule 2 applies,”
  - (c) after paragraph (b) insert—
    - “(ba) that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,” and
  - (d) in paragraph (c), for “or embryos” substitute “, embryos or human admixed embryos”.
- (3) In subsection (4), for “five years” substitute “ten years”.
- (4) After subsection (4) insert—
- “(4A) The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.”
- (5) In subsection (5)—
- (a) for “or (4)” substitute “, (4) or (4A)”, and
  - (b) omit “or, as the case may be, five years”.

#### *Grant, revocation and suspension of licences*

### **16 Grant of licence**

- (1) Section 16 of the 1990 Act (grant of licence) is amended as follows.
- (2) For subsection (1) substitute—
- “(1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.”
- (3) In subsection (2)—
- (a) for “licence committee” substitute “Authority” in each place it occurs,
  - (b) 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”,
  - (c) in paragraph (ca)—
    - (i) for “or embryos” substitute “, embryos or human admixed embryos”, and
    - (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
  - (d) in paragraph (d), after “granted” insert “and any premises which will be relevant third party premises”.
- (4) In subsection (4) for “licence committee” substitute “Authority”.
- (5) In subsection (5) for “licence committee” substitute “Authority”.
- (6) Omit subsections (6) and (7) (which concern the power to charge fees).

## **17 The person responsible**

- (1) Section 17 of the 1990 Act (the person responsible) is amended as follows.
- (2) In subsection (1)(c)—
  - (a) for “and embryos” substitute “, embryos and human admixed embryos”, and
  - (b) for “or embryos” substitute “, embryos or human admixed embryos”.
- (3) Omit subsection (3) (which defines “the nominal licensee”).

## **18 Revocation and variation of licence**

For section 18 of the 1990 Act (revocation and variation of licence) substitute—

### **“18 Revocation of licence**

- (1) The Authority may revoke a licence on application by—
  - (a) the person responsible, or
  - (b) the holder of the licence (if different).
- (2) The Authority may revoke a licence otherwise than on application under subsection (1) if—
  - (a) it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading,
  - (b) it is satisfied that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17,
  - (c) it is satisfied that the person responsible has failed to comply with directions given in connection with any licence,
  - (d) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,
  - (e) it ceases to be satisfied that any premises which are relevant third party premises in relation to a licence are suitable for the activities entrusted to the third party by the person who holds the licence,
  - (f) it ceases to be satisfied that the holder of the licence is a suitable person to hold the licence,
  - (g) it ceases to be satisfied that the person responsible is a suitable person to supervise the licensed activity,
  - (h) the person responsible dies or is convicted of an offence under this Act, or
  - (i) it is satisfied that there has been any other material change of circumstances since the licence was granted.

### **18A Variation of licence**

- (1) The Authority may on application by the holder of the licence vary the licence so as to substitute another person for the person responsible if—
  - (a) the application is made with the consent of that other person, and
  - (b) the Authority is satisfied that the other person is a suitable person to supervise the licensed activity.

- (2) The Authority may vary a licence on application by—
  - (a) the person responsible, or
  - (b) the holder of the licence (if different).
- (3) The Authority may vary a licence without an application under subsection (2) if it has the power to revoke the licence under section 18(2).
- (4) The powers under subsections (2) and (3) do not extend to making the kind of variation mentioned in subsection (1).
- (5) The Authority may vary a licence without an application under subsection (2) by—
  - (a) removing or varying a condition of the licence, or
  - (b) adding a condition to the licence.
- (6) The powers conferred by this section do not extend to the conditions required by sections 12 to 15 of this Act.”

## **19 Procedure for refusal, variation or revocation of licence**

For section 19 of the 1990 Act (procedure for refusal, variation or revocation of licence) substitute—

### **“19 Procedure in relation to licensing decisions**

- (1) Before making a decision—
  - (a) to refuse an application for the grant, revocation or variation of a licence, or
  - (b) to grant an application for a licence subject to a condition imposed under paragraph 1(2), 1A(2), 2(2) or 3(6) of Schedule 2,
 the Authority shall give the applicant notice of the proposed decision and of the reasons for it.
- (2) Before making a decision under section 18(2) or 18A(3) or (5) the Authority shall give notice of the proposed decision and of the reasons for it to—
  - (a) the person responsible, and
  - (b) the holder of the licence (if different).
- (3) Where an application has been made under section 18A(2) to vary a licence, but the Authority considers it appropriate to vary the licence otherwise than in accordance with the application, before so varying the licence the Authority shall give notice of its proposed decision and of the reasons for it to—
  - (a) the person responsible, and
  - (b) the holder of the licence (if different).
- (4) A person to whom notice is given under subsection (1), (2) or (3) has the right to require the Authority to give him an opportunity to make representations of one of the following kinds about the proposed decision, namely—
  - (a) oral representations by him, or a person acting on his behalf;
  - (b) written representations by him.

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- (5) The right under subsection (4) is exercisable by giving the Authority notice of the exercise of the right before the end of the period of 28 days beginning with the day on which the notice under subsection (1), (2) or (3) was given.
- (6) The Authority may by regulations make such additional provision about procedure in relation to the carrying out of functions under sections 18 and 18A and this section as it thinks fit.

### **19A Notification of licensing decisions**

- (1) In the case of a decision to grant a licence, the Authority shall give notice of the decision to—
  - (a) the applicant, and
  - (b) the person who is to be the person responsible.
- (2) In the case of a decision to revoke a licence, the Authority shall give notice of the decision to—
  - (a) the person responsible, and
  - (b) the holder of the licence (if different).
- (3) In the case of a decision to vary a licence on application under section 18A(1), the Authority shall give notice of the decision to—
  - (a) the holder of the licence, and
  - (b) (if different) the person who is to be the person responsible.
- (4) In the case of any other decision to vary a licence, the Authority shall give notice of the decision to—
  - (a) the person responsible, and
  - (b) the holder of the licence (if different).
- (5) In the case of a decision to refuse an application for the grant, revocation or variation of a licence, the Authority shall give notice of the decision to the applicant.
- (6) Subject to subsection (7), a notice under subsection (2), (4) or (5) shall include a statement of the reasons for the decision.
- (7) In the case of a notice under subsection (2) or (4), the notice is not required to include a statement of the reasons for the decision if the decision is made on an application under section 18(1) or 18A(2).

### **19B Applications under this Act**

- (1) Directions may make provision about—
  - (a) the form and content of applications under this Act, and
  - (b) the information to be supplied with such an application.
- (2) The Secretary of State may by regulations make other provision about applications under this Act.
- (3) Such regulations may, in particular, make provision about procedure in relation to the determination of applications under this Act and may, in particular, include—

- (a) provision for requiring persons to give evidence or to produce documents;
- (b) provision about the admissibility of evidence.”

## 20 Power to suspend licence

After section 19B (inserted by section 19 above) insert—

### “19C Power to suspend licence

- (1) Where the Authority—
  - (a) has reasonable grounds to suspect that there are grounds for revoking a licence, and
  - (b) is of the opinion that the licence should immediately be suspended, it may by notice suspend the licence for such period not exceeding three months as may be specified in the notice.
- (2) The Authority may continue suspension under subsection (1) by giving a further notice under that subsection.
- (3) Notice under subsection (1) shall be given to the person responsible or where the person responsible has died or appears to be unable because of incapacity to discharge the duty under section 17—
  - (a) to the holder of the licence, or
  - (b) to some other person to whom the licence applies.
- (4) Subject to subsection (5), a licence shall be of no effect while a notice under subsection (1) is in force.
- (5) An application may be made under section 18(1) or section 18A(1) or (2) even though a notice under subsection (1) is in force.”

## 21 Reconsideration and appeals

For sections 20 and 21 of the 1990 Act (appeals to Authority against determinations of licence committees and further appeals) substitute—

### “20 Right to reconsideration of licensing decisions

- (1) If an application for the grant, revocation or variation of a licence is refused, the applicant may require the Authority to reconsider the decision.
- (2) Where the Authority decides to vary or revoke a licence, any person to whom notice of the decision was required to be given (other than a person who applied for the variation or revocation) may require the Authority to reconsider the decision.
- (3) The right under subsections (1) and (2) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under section 19A.
- (4) If the Authority decides —



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- (a) to suspend a licence under section 19C(1), or
  - (b) to continue the suspension of a licence under section 19C(2),
- any person to whom notice of the decision was required to be given may require the Authority to reconsider the decision.

- (5) The right under subsection (4) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 14 days beginning with the day on which notice of the decision concerned was given under section 19C.
- (6) The giving of any notice to the Authority in accordance with subsection (5) shall not affect the continuation in force of the suspension of the licence in respect of which that notice was given.
- (7) Subsections (1), (2) and (4) do not apply to a decision on reconsideration.

## **20A Appeals committee**

- (1) The Authority shall maintain one or more committees to carry out its functions in pursuance of notices under section 20.
- (2) A committee under subsection (1) is referred to in this Act as an appeals committee.
- (3) Regulations shall make provision about the membership and proceedings of appeals committees.
- (4) Regulations under subsection (3) may, in particular, provide—
  - (a) for the membership of an appeals committee to be made up wholly or partly of persons who are not members of the Authority, and
  - (b) for the appointment of any person to advise an appeals committee on prescribed matters.
- (5) For the purposes of subsection (4) “prescribed” means prescribed by regulations under subsection (3).

## **20B Procedure on reconsideration**

- (1) Reconsideration shall be by way of a fresh decision.
- (2) Regulations shall make provision about the procedure in relation to reconsideration.
- (3) Regulations under subsection (2) may, in particular, make provision—
  - (a) entitling a person by whom reconsideration is required, (“the appellant”) to require that the appellant or the appellant’s representative be given an opportunity to appear before and be heard by the appeals committee dealing with the matter,
  - (b) entitling the person who made the decision which is the subject of reconsideration to appear at any meeting at which such an opportunity is given, and to be heard in person or by a representative,
  - (c) requiring the appeals committee dealing with the matter to consider any written representations received from the appellant or the person who made the decision which is the subject of reconsideration,

- (d) preventing any person who made the decision which is the subject of reconsideration from sitting as a member of the appeals committee dealing with the matter,
  - (e) requiring persons to give evidence or to produce documents,
  - (f) concerning the admissibility of evidence, and
  - (g) requiring the appellant and any prescribed person to be given notice of the decision on reconsideration and a statement of reasons for the appeals committee’s decision.
- (4) Regulations under subsection (2) may, in particular, make different provision about the procedure on reconsideration depending upon whether the reconsideration is in pursuance of a notice under section 20(3) or a notice under section 20(5).
- (5) Such regulations may, in particular, make provision—
- (a) in relation to cases where a person requires reconsideration of a decision to suspend a licence and reconsideration of a decision to continue the suspension of that licence, and
  - (b) in relation to cases where reconsideration of a decision is required under section 20(2) by only one of two persons by whom it could have been required.
- (6) In this section—
- (a) “prescribed” means prescribed by regulations under subsection (2), and
  - (b) “reconsideration” means reconsideration in pursuance of a notice under section 20.

## **21 Appeal on a point of law**

A person aggrieved by a decision on reconsideration in pursuance of a notice under section 20 may appeal to the High Court or, in Scotland, the Court of Session on a point of law.”

### *Directions and guidance*

## **22 Directions**

- (1) Section 24 of the 1990 Act (directions as to particular matters) is amended as follows.
- (2) After subsection (3A) insert—
- “(3B) Directions may authorise, in such circumstances and subject to such conditions as may be specified in the directions, the keeping, by or on behalf of a person to whom a licence applies, of human admixed embryos in the course of their carriage to or from any premises.”
- (3) In subsection (4) for “or embryos”, in both places, substitute “, embryos or human admixed embryos”.
- (4) After subsection (4A) insert—
- “(4B) Regulations may make provision requiring or authorising the giving of directions in relation to particular matters which are specified in the

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regulations and relate to activities falling within section 4A(2) (activities involving genetic material of animal origin).”

(5) For subsections (5) to (10) substitute—

“(5A) Directions may make provision for the purpose of dealing with a situation arising in consequence of—

- (a) the variation of a licence, or
- (b) a licence ceasing to have effect.

(5B) Directions under subsection (5A)(a) may impose requirements—

- (a) on the holder of the licence,
- (b) on the person who is the person responsible immediately before or immediately after the variation, or
- (c) on any other person, if that person consents.

(5C) Directions under subsection (5A)(b) may impose requirements—

- (a) on the person who holds the licence immediately before the licence ceases to have effect,
- (b) on the person who is the person responsible at that time, or
- (c) on any other person, if that person consents.

(5D) Directions under subsection (5A) may, in particular, require anything kept, or information held, in pursuance of the licence to be transferred in accordance with the directions.

(5E) Where a licence has ceased to have effect by reason of the death or dissolution of its holder, anything subsequently done by a person before directions are given under subsection (5A) shall, if the licence would have been authority for doing it, be treated as authorised by a licence.”

(6) In subsection (11), for “3(5)” substitute “3(2)”.

## **23 Code of practice**

(1) Section 25 of the 1990 Act (code of practice) is amended as follows.

(2) In subsection (2), for “a father” substitute “supportive parenting”.

(3) After that subsection insert—

“(2A) The code shall also give guidance about—

- (a) the giving of a suitable opportunity to receive proper counselling, and
- (b) the provision of such relevant information as is proper,

in accordance with any condition that is by virtue of section 13(6) or (6A) a condition of a licence under paragraph 1 of Schedule 2.”

(4) In subsection (6)(a) and (b), for “a licence committee” substitute “the Authority”.

## *Information*

## **24 Register of information**

For section 31 of the 1990 Act (the Authority’s register of information) substitute—

### **“31 Register of information**

- (1) The Authority shall keep a register which is to contain any information which falls within subsection (2) and which—
  - (a) immediately before the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008, was contained in the register kept under this section by the Authority, or
  - (b) is obtained by the Authority.
- (2) Subject to subsection (3), information falls within this subsection if it relates to—
  - (a) the provision for any identifiable individual of treatment services other than basic partner treatment services,
  - (b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual,
  - (c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,
  - (d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services, or
  - (e) the use of an embryo taken from any identifiable woman,or if it shows that any identifiable individual is a relevant individual.
- (3) Information does not fall within subsection (2) if it is provided to the Authority for the purposes of any voluntary contact register as defined by section 31ZF(1).
- (4) In this section “relevant individual” means an individual who was or may have been born in consequence of—
  - (a) treatment services, other than basic partner treatment services, or
  - (b) the procurement or distribution of any sperm (other than partner-donated sperm which has not been stored) in the course of providing non-medical fertility services.

### **31ZA Request for information as to genetic parentage etc.**

- (1) A person who has attained the age of 16 (“the applicant”) may by notice to the Authority require the Authority to comply with a request under subsection (2).
- (2) The applicant may request the Authority to give the applicant notice stating whether or not the information contained in the register shows that a person (“the donor”) other than a parent of the applicant would or might, but for the relevant statutory provisions, be the parent of the applicant, and if it does show that—
  - (a) giving the applicant so much of that information as relates to the donor as the Authority is required by regulations to give (but no other information), or
  - (b) stating whether or not that information shows that there are other persons of whom the donor is not the parent but would or might, but for the relevant statutory provisions, be the parent and if so—
    - (i) the number of those other persons,

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- (ii) the sex of each of them, and
  - (iii) the year of birth of each of them.
- (3) The Authority shall comply with a request under subsection (2) if—
- (a) the information contained in the register shows that the applicant is a relevant individual, and
  - (b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (4) Where a request is made under subsection (2)(a) and the applicant has not attained the age of 18 when the applicant gives notice to the Authority under subsection (1), regulations cannot require the Authority to give the applicant any information which identifies the donor.
- (5) Regulations cannot require the Authority to give any information as to the identity of a person whose gametes have been used or from whom an embryo has been taken if a person to whom a licence applied was provided with the information at a time when the Authority could not have been required to give information of the kind in question.
- (6) The Authority need not comply with a request made under subsection (2)(b) by any applicant if it considers that special circumstances exist which increase the likelihood that compliance with the request would enable the applicant—
- (a) to identify the donor, in a case where the Authority is not required by regulations under subsection (2)(a) to give the applicant information which identifies the donor, or
  - (b) to identify any person about whom information is given under subsection (2)(b).
- (7) In this section—
- “relevant individual” has the same meaning as in section 31;
  - “the relevant statutory provisions” means sections 27 to 29 of this Act and sections 33 to 47 of the Human Fertilisation and Embryology Act 2008.

### **31ZB Request for information as to intended spouse etc.**

- (1) Subject to subsection (4), a person (“the applicant”) may by notice to the Authority require the Authority to comply with a request under subsection (2).
- (2) The applicant may request the Authority to give the applicant notice stating whether or not information contained in the register shows that, but for the relevant statutory provisions, the applicant would or might be related to a person specified in the request (“the specified person”) as—
- (a) a person whom the applicant proposes to marry,
  - (b) a person with whom the applicant proposes to enter into a civil partnership, or
  - (c) a person with whom the applicant is in an intimate physical relationship or with whom the applicant proposes to enter into an intimate physical relationship.
- (3) Subject to subsection (5), the Authority shall comply with a request under subsection (2) if—

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- (a) the information contained in the register shows that the applicant is a relevant individual,
  - (b) the Authority receives notice in writing from the specified person consenting to the request being made and that notice has not been withdrawn, and
  - (c) the applicant and the specified person have each been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (4) A request may not be made under subsection (2)(c) by a person who has not attained the age of 16.
- (5) Where a request is made under subsection (2)(c) and the specified person has not attained the age of 16 when the applicant gives notice to the Authority under subsection (1), the Authority must not comply with the request.
- (6) Where the Authority is required under subsection (3) to comply with a request under subsection (2), the Authority must take all reasonable steps to give the applicant and the specified person notice stating whether or not the information contained in the register shows that, but for the relevant statutory provisions, the applicant and the specified person would or might be related.
- (7) In this section—  
     “relevant individual” has the same meaning as in section 31;  
     “the relevant statutory provisions” has the same meaning as in section 31ZA.

### **31ZC Power of Authority to inform donor of request for information**

- (1) Where—
- (a) the Authority has received from a person (“the applicant”) a notice containing a request under subsection (2)(a) of section 31ZA, and
  - (b) compliance by the Authority with its duty under that section has involved or will involve giving the applicant information relating to a person other than the parent of the applicant who would or might, but for the relevant statutory provisions, be a parent of the applicant (“the donor”),
- the Authority may notify the donor that a request under section 31ZA(2)(a) has been made, but may not disclose the identity of the applicant or any information relating to the applicant.
- (2) In this section “the relevant statutory provisions” has the same meaning as in section 31ZA.

### **31ZD Provision to donor of information about resulting children**

- (1) This section applies where a person (“the donor”) has consented under Schedule 3 (whether before or after the coming into force of this section) to—
- (a) the use of the donor’s gametes, or an embryo the creation of which was brought about using the donor’s gametes, for the purposes of treatment services provided under a licence, or

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- (b) the use of the donor’s gametes for the purposes of non-medical fertility services provided under a licence.
- (2) In subsection (1)—
- (a) “treatment services” do not include treatment services provided to the donor, or to the donor and another person together, and
  - (b) “non-medical fertility services” do not include any services involving partner-donated sperm.
- (3) The donor may by notice request the appropriate person to give the donor notice stating—
- (a) the number of persons of whom the donor is not a parent but would or might, but for the relevant statutory provisions, be a parent by virtue of the use of the gametes or embryos to which the consent relates,
  - (b) the sex of each of those persons, and
  - (c) the year of birth of each of those persons.
- (4) Subject to subsections (5) to (7), the appropriate person shall notify the donor whether the appropriate person holds the information mentioned in subsection (3) and, if the appropriate person does so, shall comply with the request.
- (5) The appropriate person need not comply with a request under subsection (3) if the appropriate person considers that special circumstances exist which increase the likelihood that compliance with the request would enable the donor to identify any of the persons falling within paragraphs (a) to (c) of subsection (3).
- (6) In the case of a donor who consented as described in subsection (1)(a), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(a) continues to hold a licence under paragraph 1 of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible—
- (a) has notified the donor that the information concerned is not held, or
  - (b) has failed to comply with the request within a reasonable period.
- (7) In the case of a donor who consented as described in subsection (1)(b), the Authority need not comply with a request made to it under subsection (3) where the person who held the licence referred to in subsection (1)(b) continues to hold a licence under paragraph 1A of Schedule 2, unless the donor has previously made a request under subsection (3) to the person responsible and the person responsible—
- (a) has notified the donor that the information concerned is not held, or
  - (b) has failed to comply with the request within a reasonable period.
- (8) In this section “the appropriate person” means—
- (a) in the case of a donor who consented as described in paragraph (a) of subsection (1)—
    - (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1 of Schedule 2, the person responsible, or
    - (ii) the Authority, and

- (b) in the case of a donor who consented as described in paragraph (b) of subsection (1)—
  - (i) where the person who held the licence referred to in that paragraph continues to hold a licence under paragraph 1A of Schedule 2, the person responsible, or
  - (ii) the Authority.

(9) In this section “the relevant statutory provisions” has the same meaning as in section 31ZA.

### **31ZE Provision of information about donor-conceived genetic siblings**

- (1) For the purposes of this section two relevant individuals are donor-conceived genetic siblings of each other if a person (“the donor”) who is not the parent of either of them would or might, but for the relevant statutory provisions, be the parent of both of them.
- (2) Where—
  - (a) the information on the register shows that a relevant individual (“A”) is the donor-conceived genetic sibling of another relevant individual (“B”),
  - (b) A has provided information to the Authority (“the agreed information”) which consists of or includes information which enables A to be identified with the request that it should be disclosed to—
    - (i) any donor-conceived genetic sibling of A, or
    - (ii) such siblings of A of a specified description which includes B, and
  - (c) the conditions in subsection (3) are satisfied,
 then, subject to subsection (4), the Authority shall disclose the agreed information to B.
- (3) The conditions referred to in subsection (2)(c) are—
  - (a) that each of A and B has attained the age of 18,
  - (b) that B has requested the disclosure to B of information about any donor-conceived genetic sibling of B, and
  - (c) that each of A and B has been given a suitable opportunity to receive proper counselling about the implications of disclosure under subsection (2).
- (4) The Authority need not disclose any information under subsection (2) if it considers that the disclosure of information will lead to A or B identifying the donor unless—
  - (a) the donor has consented to the donor’s identity being disclosed to A or B, or
  - (b) were A or B to make a request under section 31ZA(2)(a), the Authority would be required by regulations under that provision to give A or B information which would identify the donor.
- (5) In this section—
  - “relevant individual” has the same meaning as in section 31;
  - “the relevant statutory provisions” has the same meaning as in section 31ZA.



### **31ZF Power of Authority to keep voluntary contact register**

- (1) In this section and section 31ZG, a “voluntary contact register” means a register of persons who have expressed their wish to receive information about any person to whom they are genetically related as a consequence of the provision to any person of treatment services in the United Kingdom before 1 August 1991.
- (2) The Authority may—
  - (a) set up a voluntary contact register in such manner as it thinks fit,
  - (b) keep a voluntary contact register in such manner as it thinks fit,
  - (c) determine criteria for eligibility for inclusion on the register and the particulars that may be included,
  - (d) charge a fee to persons who wish their particulars to be entered on the register,
  - (e) arrange for samples of the DNA of such persons to be analysed at their request,
  - (f) make such arrangements as it thinks fit for the disclosure of information on the register between persons who appear to the Authority to be genetically related, and
  - (g) impose such conditions as it thinks fit to prevent a person (“A”) from disclosing information to a person to whom A is genetically related (“B”) where that information would identify any person who is genetically related to both A and B.
- (3) The Authority may make arrangements with any person by whom a voluntary contact register is kept before the commencement of this section for the supply by that person to the Authority of the information contained in the register maintained by that person.

### **31ZG Financial assistance for person setting up or keeping voluntary contact register**

- (1) The Authority may, instead of keeping a voluntary contact register, give financial assistance to any person who sets up or keeps a voluntary contact register.
- (2) Financial assistance under subsection (1) may be given in any form, and in particular, may be given by way of—
  - (a) grants,
  - (b) loans,
  - (c) guarantees, or
  - (d) incurring expenditure for the person assisted.
- (3) Financial assistance under subsection (1) may be given on such terms and conditions as the Authority considers appropriate.
- (4) A person receiving assistance under subsection (1) must comply with the terms and conditions on which it is given, and compliance may be enforced by the Authority.”

## 25 Restrictions on disclosure of information

For section 33 of the 1990 Act (restrictions on disclosure of information) substitute—

### “33A Disclosure of information

- (1) No person shall disclose any information falling within section 31(2) which the person obtained (whether before or after the coming into force of section 24 of the Human Fertilisation and Embryology Act 2008) in the person’s capacity as—
- (a) a member or employee of the Authority,
  - (b) any person exercising functions of the Authority by virtue of section 8B or 8C of this Act (including a person exercising such functions by virtue of either of those sections as a member of staff or as an employee),
  - (c) any person engaged by the Authority to provide services to the Authority,
  - (d) any person employed by, or engaged to provide services to, a person mentioned in paragraph (c),
  - (e) a person to whom a licence applies,
  - (f) a person to whom a third party agreement applies, or
  - (g) a person to whom directions have been given.
- (2) Subsection (1) does not apply where—
- (a) the disclosure is made to a person as a member or employee of the Authority or as a person exercising functions of the Authority as mentioned in subsection (1)(b),
  - (b) the disclosure is made to or by a person falling within subsection (1)(c) for the purpose of the provision of services which that person is engaged to provide to the Authority,
  - (c) the disclosure is made by a person mentioned in subsection (1)(d) for the purpose of enabling a person falling within subsection (1)(c) to provide services which that person is engaged to provide to the Authority,
  - (d) the disclosure is made to a person to whom a licence applies for the purpose of that person’s functions as such,
  - (e) the disclosure is made to a person to whom a third party agreement applies for the purpose of that person’s functions under that agreement,
  - (f) the disclosure is made in pursuance of directions given by virtue of section 24,
  - (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 33B,
  - (i) 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 (5), and

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- (iii) is made in circumstances where it is not reasonably practicable to obtain P's consent,
  - (j) the disclosure is of information which has been lawfully made available to the public before the disclosure is made,
  - (k) the disclosure is made in accordance with sections 31ZA to 31ZE,
  - (l) the disclosure is required or authorised to be made—
    - (i) under regulations made under section 33D, or
    - (ii) in relation to any time before the coming into force of the first regulations under that section, under regulations made under section 251 of the National Health Service Act 2006,
  - (m) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) for the purpose of carrying out the Authority's duties under section 8A,
  - (n) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) in pursuance of an order of a court under section 34 or 35,
  - (o) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to the Registrar General in pursuance of a request under section 32,
  - (p) the disclosure is made by a person acting in the capacity mentioned in subsection (1)(a) or (b) to any body or person discharging a regulatory function for the purpose of assisting that body or person to carry out that function,
  - (q) the disclosure is made for the purpose of establishing in any proceedings relating to an application for an order under subsection (1) of section 54 of the Human Fertilisation and Embryology Act 2008 whether the condition specified in paragraph (a) or (b) of that subsection is met,
  - (r) the disclosure is made under section 3 of the Access to Health Records Act 1990,
  - (s) the disclosure is made under Article 5 of the Access to Health Records (Northern Ireland) Order 1993, or
  - (t) the disclosure is made necessarily for—
    - (i) the purpose of the investigation of any offence (or suspected offence), or
    - (ii) any purpose preliminary to proceedings, or for the purposes of, or in connection with, any proceedings.
- (3) Subsection (1) does not apply to the disclosure of information in so far as—
- (a) the information identifies a person who, but for sections 27 to 29 of this Act or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008, would or might be a parent of a person who instituted proceedings under section 1A of the Congenital Disabilities (Civil Liability) Act 1976, and
  - (b) the disclosure is made for the purpose of defending such proceedings, or instituting connected proceedings for compensation against that parent.

- (4) Paragraph (t) of subsection (2), so far as relating to disclosure for the purpose of the investigation of an offence or suspected offence, or for any purpose preliminary to, or in connection with proceedings, does not apply—
- (a) to disclosure of identifying donor information, or
  - (b) to disclosure, in circumstances in which subsection (1) of section 34 of this Act applies, of information relevant to the determination of the question mentioned in that subsection, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1).
- (5) Subsection (1) does not apply to the disclosure to any individual of information which—
- (a) falls within subsection (2) of section 31 of this Act by virtue of any of paragraphs (a) to (e) of that subsection, and
  - (b) relates only to that individual or, in the case of an individual 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, only to that individual and that other.
- (6) In subsection (2)—
- (a) in paragraph (p) “regulatory function” has the same meaning as in section 32 of the Legislative and Regulatory Reform Act 2006, and
  - (b) in paragraph (t) references to “proceedings” include any formal procedure for dealing with a complaint.
- (7) 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.

### **33B 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.

### **33C Power to provide for additional exceptions from section 33A(1)**

- (1) Regulations may provide for additional exceptions from section 33A(1).
- (2) No exception may be made under this section for—
- (a) disclosure of a kind mentioned in paragraph (a) or (b) of subsection (4) of section 33A, or
  - (b) disclosure in circumstances in which section 32 of this Act applies of information having the tendency mentioned in subsection (2) of that section, made by any person acting in a capacity mentioned in any of paragraphs (c) to (g) of subsection (1) of section 33A.

### **33D Disclosure for the purposes of medical or other research**

- (1) Regulations may—
- (a) make such provision for and in connection with requiring or regulating the processing of protected information for the purposes of medical research as the Secretary of State considers is necessary or expedient in the public interest or in the interests of improving patient care, and
  - (b) make such provision for and in connection with requiring or regulating the processing of protected information for the purposes of any other research as the Secretary of State considers is necessary or expedient in the public interest.
- (2) Regulations under subsection (1) may, in particular, make provision—
- (a) for requiring or authorising the disclosure or other processing of protected information to or by persons of any prescribed description subject to compliance with any prescribed conditions (including conditions requiring prescribed undertakings to be obtained from such persons as to the processing of such information),
  - (b) for securing that, where prescribed protected information is processed by a person in accordance with the regulations, anything done by that person in so processing the information must be taken to be lawfully done despite any obligation of confidence owed by the person in respect of it,
  - (c) for requiring fees of a prescribed amount to be paid to the Authority in prescribed circumstances by persons in relation to the disclosure to those persons of protected information under those regulations,
  - (d) for the establishment of one or more bodies to exercise prescribed functions in relation to the processing of protected information under those regulations,

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*Status: This is the original version (as it was originally enacted).*

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- (e) as to the membership and proceedings of any such body, and
  - (f) as to the payment of remuneration and allowances to any member of any such body and the reimbursement of expenses.
- (3) Where regulations under subsection (1) require or regulate the processing of protected information for the purposes of medical research, such regulations may enable any approval given under regulations made under section 251 of the National Health Service Act 2006 (control of patient information) to have effect for the purposes of the regulations under subsection (1) in their application to England and Wales.
- (4) Subsections (1) to (3) are subject to subsections (5) to (8).
- (5) Regulations under subsection (1) may not make any provision requiring or authorising the disclosure or other processing, for any purpose, of protected information, where that information is information from which an individual may be identified, if it would be reasonably practicable to achieve that purpose otherwise than pursuant to such regulations, having regard to the cost of and technology available for achieving that purpose.
- (6) Regulations under this section may not make provision for or in connection with the processing of protected information in a manner inconsistent with any provision made by or under the Data Protection Act 1998.
- (7) Subsection (6) does not affect the operation of provisions made under subsection (2)(b).
- (8) Before making any regulations under this section the Secretary of State shall consult such bodies appearing to the Secretary of State to represent the interests of those likely to be affected by the regulations as the Secretary of State considers appropriate.
- (9) In this section—
- “prescribed” means prescribed by regulations made by virtue of this section,
  - “processing”, in relation to information, means the use, disclosure, or obtaining of the information or the doing of such other things in relation to it as may be prescribed for the purposes of this definition, and
  - “protected information” means information falling within section 31(2).”

### *Mitochondrial donation*

## **26 Mitochondrial donation**

After section 35 of the 1990 Act insert—

*“Mitochondrial donation*

**35A Mitochondrial donation**

- (1) Regulations may provide for any of the relevant provisions to have effect subject to specified modifications in relation to cases where—
- (a) an egg which is a permitted egg for the purposes of section 3(2) by virtue of regulations made under section 3ZA(5), or
  - (b) an embryo which is a permitted embryo for those purposes by virtue of such regulations,
- has been created from material provided by two women.
- (2) In this section “the relevant provisions” means—
- (a) the following provisions of this Act—
    - (i) section 13(6C) (information whose provision to prospective parents is required by licence condition),
    - (ii) section 31 (register of information),
    - (iii) sections 31ZA to 31ZE (provision of information), and
    - (iv) Schedule 3 (consents to use or storage of gametes, embryos or human admixed embryos etc.), and
  - (b) section 54 of the Human Fertilisation and Embryology Act 2008 (parental orders).”

*Miscellaneous*

**27 Fees**

After section 35A of the 1990 Act (as inserted by section 26 above) insert—

*“Fees*

**35B Fees**

- (1) The Authority may charge a fee in respect of any of the following—
- (a) an application for a licence,
  - (b) the grant or renewal of a licence,
  - (c) an application for the revocation or variation of a licence, or
  - (d) the exercise by the Authority of any other function conferred on it by or under this Act or by or under any other enactment—
    - (i) in relation to a licence,
    - (ii) in relation to premises which are or have been premises to which a licence relates,
    - (iii) in relation to premises which are or have been relevant third party premises in relation to a licence, or
    - (iv) in relation to premises which, if an application is granted, will be premises to which a licence relates or relevant third party premises.

- (2) The amount of any fee charged by virtue of subsection (1) is to be fixed in accordance with a scheme made by the Authority with the approval of the Secretary of State and the Treasury.
- (3) In fixing the amount of any fee to be charged by virtue of that subsection, the Authority may have regard to the costs incurred by it—
  - (a) in exercising the functions conferred on it by or under this Act (apart from sections 31ZA to 31ZG and 33D), and
  - (b) in exercising any other function conferred on it by or under any other enactment.
- (4) The Authority may also charge such fee as it thinks fit in respect of any of the following—
  - (a) the giving of notice under section 31ZA(1) or 31ZB(1), or
  - (b) the provision of information under section 31ZA, 31ZB or 31ZE.
- (5) In fixing the amount of any fee to be charged by virtue of subsection (4) the Authority may have regard to the costs incurred by it in exercising the function to which the fee relates.
- (6) When exercising its power to charge fees under section 8(2), 31ZF(2)(d) or this section, the Authority may fix different fees for different circumstances.”

## **28 Inspection, entry, search and seizure**

- (1) Before section 39 of the 1990 Act (but after the heading “Enforcement” immediately before that section) insert—

### **“38A Inspection, entry, search and seizure**

- (1) Schedule 3B (which makes provisions about inspection, entry, search and seizure) has effect.
  - (2) Nothing in this Act makes it unlawful for a member or employee of the Authority to keep any embryo, human admixed embryo or gametes in pursuance of that person’s functions as such.”
- (2) After Schedule 3A to the 1990 Act insert the Schedule set out in Schedule 5 to this Act (inspection, entry, search and seizure).
  - (3) Section 39 of the 1990 Act (powers of members and employees of Authority) and section 40 of that Act (power to enter premises) (which are superseded by the amendments made by subsection (2)) cease to have effect.

## **29 Offences under the 1990 Act**

- (1) Section 41 of the 1990 Act (offences) is amended as follows.
- (2) In subsection (1)(a), for “4(1)(c)” substitute “4A(1) or (2)”.
- (3) In subsection (2)—
  - (a) after paragraph (a) insert—
    - “(aa) contravenes section 3(1B) of this Act,”,



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*Status: This is the original version (as it was originally enacted).*

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- (b) after paragraph (ba) insert—
    - “(bb) contravenes section 4(1A) of this Act,” and
  - (c) in paragraph (d), for “section 24(7)(a)” substitute “section 24(5D)”.
- (4) In subsection (4), omit “, other than an offence to which subsection (4B) applies,”.
- (5) In subsection (5), for “section 33” substitute “section 33A”.
- (6) In subsection (7), for “section 10(2)(a)” substitute “section 19B(3)(a) or 20B(3)(e)”.
- (7) In subsection (8)—
- (a) for “or the nominal licensee” substitute “or the holder of the licence”, and
  - (b) for “or embryos” substitute “, embryos or human admixed embryos”.
- (8) In subsection (9), omit “(6),”.
- (9) For subsection (10) substitute—
- “(10) It is a defence for a person (“the defendant”) charged with an offence of doing anything which, under section 3(1) or (1A), 4(1) or 4A(2), cannot be done except in pursuance of a licence to prove—
- (a) that the defendant was acting under the direction of another, and
  - (b) that the defendant believed on reasonable grounds—
    - (i) that the other person was at the material time the person responsible under a licence, a person designated by virtue of section 17(2)(b) of this Act as a person to whom a licence applied, or a person to whom directions had been given under section 24(5A) to (5D), and
    - (ii) that the defendant was authorised by virtue of the licence or directions to do the thing in question.
- (10A) It is a defence for a person (“the defendant”) charged with an offence of doing anything which, under section 3(1A) or (1B) or 4(1A), cannot be done except in pursuance of a licence or a third party agreement to prove—
- (a) that the defendant was acting under the direction of another, and
  - (b) that the defendant believed on reasonable grounds—
    - (i) that the other person was at the material time the person responsible under a licence, a person designated by virtue of section 17(2)(b) of this Act as a person to whom a licence applied, a person to whom a third party agreement applied, or a person to whom directions had been given under section 24(5A) to (5D), and
    - (ii) that the defendant was authorised by virtue of the licence, third party agreement or directions to do the thing in question.”
- (10) Omit subsections (2A), (4A), (4B) and (6).
- (11) Section 41(2) of the 1990 Act as amended by subsection (3) is to be treated as a relevant enactment for the purposes of section 282 of the Criminal Justice Act 2003 (c. 44) (increase in maximum term that may be imposed on summary conviction of offence triable either way).

### **30 Regulations under the 1990 Act**

(1) Section 45 of the 1990 Act (regulations) is amended as follows.

(2) After subsection (1) insert—

“(1A) Subsection (1) does not enable the Secretary of State to make regulations by virtue of section 19(6) (which confers regulation-making powers on the Authority).”

(3) In subsection (2), after “regulations” insert “under this Act”.

(4) For subsection (3) substitute—

“(3) The power to make regulations under this Act may be exercised—

- (a) either in relation to all cases to which the power extends, or in relation to those cases subject to specified exceptions, or in relation to any specified cases or classes of case, and
- (b) so as to make, as respects the cases in relation to which it is exercised

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- (i) the full provision to which the power extends or any less provision (whether by way of exception or otherwise);
- (ii) the same provision for all cases in relation to which the power is exercised, or different provision as respects the same case or class of case for different purposes;
- (iii) any such provision either unconditionally, or subject to any specified condition.

(3A) Any power of the Secretary of State or the Authority to make regulations under this Act includes power to make such transitional, incidental or supplemental provision as the Secretary of State or the Authority considers appropriate.”

(5) For subsection (4) substitute—

“(4) The Secretary of State shall not make regulations by virtue of any of the provisions specified in subsection (4A) unless a draft has been laid before and approved by a resolution of each House of Parliament.

(4A) Those provisions are—

- section 1(6);
- section 3(3)(c);
- section 3ZA(5);
- section 4(2) or (3);
- section 4A(5) or (11);
- section 20A(3);
- section 20B(2);
- section 24(4B);
- section 31ZA(2)(a);
- section 33C;
- section 33D;
- section 35A;
- section 43;
- paragraph 1(1)(g), 1ZC or 3A(1)(c) of Schedule 2.”

(6) In subsection (5), after “regulations” insert “made by the Secretary of State”.

### **31 Power to make consequential provision**

After section 45 of the 1990 Act (regulations) insert—

#### **“45A Power to make consequential provision**

- (1) The Secretary of State may by order make such provision modifying any provision made by or under any enactment as the Secretary of State considers necessary or expedient in consequence of any provision made by regulations under any of the relevant provisions of this Act.
- (2) For the purposes of subsection (1), “the relevant provisions of this Act” are—
  - (a) section 1(6) (power to include things within the meaning of “embryo” and “gametes” etc.);
  - (b) section 4A(11) (power to amend definition of “human admixed embryo” and other terms).
- (3) Before making an order under this section containing provision which would, if included in an Act of the Scottish Parliament, be within the legislative competence of that Parliament, the Secretary of State must consult the Scottish Ministers.
- (4) Before making an order under this section containing provision which would be within the legislative competence of the National Assembly for Wales if it were included in a Measure of the Assembly (or, if the order is made after the Assembly Act provisions come into force, an Act of the Assembly), the Secretary of State must consult the Welsh Ministers.
- (5) Before making an order under this section containing provision which would if included in an Act of the Northern Ireland Assembly, be within the legislative competence of that Assembly, the Secretary of State must consult the Department of Health, Social Services and Public Safety.
- (6) In this section—

“enactment” means—

  - (a) an Act of Parliament (other than this Act),
  - (b) an Act of the Scottish Parliament,
  - (c) a Measure or Act of the National Assembly for Wales, or
  - (d) Northern Ireland legislation,

whenever passed or made;

“modify” includes amend, add to, revoke or repeal;

“the Assembly Act provisions” has the meaning given by section 103(8) of the Government of Wales Act 2006.”

### **32 Orders under the 1990 Act**

After section 45A (inserted by section 31 above) insert—

**“45B Orders**

- (1) The power to make an order under section 8C(1)(c) or 45A of this Act shall be exercisable by statutory instrument.
- (2) The power to make an order under section 8C(1)(c) or 45A of this Act includes power to make such transitional, incidental or supplemental provision as the Secretary of State considers appropriate.
- (3) A statutory instrument containing an order made by the Secretary of State by virtue of section 8C(1)(c) shall be subject to annulment in pursuance of a resolution of either House of Parliament.
- (4) The Secretary of State shall not make an order by virtue of section 45A unless a draft has been laid before and approved by a resolution of each House of Parliament.”