

Human Fertilisation and Embryology Act 1990

As amended: an illustrative text

This text is for illustrative purposes only

*It shows the Human Fertilisation and Embryology Act 1990 (c. 37) as it would be once the amendments to it contained in the Human Fertilisation and Embryology Act 2008 have been brought into force (**text shown in bold**). This text has no official status.*

CHAPTER 37

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Principal terms used

1 Meaning of "embryo", "gamete" and associated expressions

- (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.**
- (2) This Act, so far as it governs bringing about the creation of an embryo, applies only to bringing about the creation of an embryo outside the human body; and in this Act—
- (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**
 - (b) references to embryos taken from a woman do not include embryos whose creation was brought about *in vitro*.
- (3) This Act, so far as it governs the keeping or use of an embryo, applies only to keeping or using an embryo outside the human body.
- (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) For the purposes of this Act, sperm is to be treated as partner-donated sperm if the donor of the sperm and the recipient of the sperm declare that they have an intimate physical relationship.
- (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.**

1A Reference to Directives

In this Act—

“the first Directive” means Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells,

“the second Directive” means Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, and

“the third Directive” means Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

2 Other terms

(1) In this Act—

“the Authority” means the Human Fertilisation and Embryology Authority established under section 5 of this Act,

“basic partner treatment services” means treatment services that are provided for a woman and a man together without using—

- (a) the gametes of any other person, or
- (b) embryos created outside the woman’s body,

“competent authority”, in relation to an EEA state other than the United Kingdom or in relation to Gibraltar, means an authority designated in accordance with the law of that state or territory as responsible for implementing the requirements of the first, second and third Directives,

"directions" means directions under section 23 of this Act,

“distribution”, in relation to gametes or embryos intended for human application, means transportation or delivery, and related terms are to be interpreted accordingly,

“human application” means use in a human recipient,

"licence" means a licence under Schedule 2 to this Act and, in relation to a licence, "the person responsible" has the meaning given by section 17 of this Act,

“non-medical fertility services” means any services that are provided, in the course of a business, for the purpose of assisting women to carry children, but are not medical, surgical or obstetric services,

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

“processing”, in relation to gametes or embryos intended for human application, means any operation involved in their preparation, manipulation or packaging, and related terms are to be interpreted accordingly,

“procurement”, in relation to gametes or embryos intended for human application, means any process by which they are made available, and related terms are to be interpreted accordingly,

“serious adverse event” means—

(a) any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a donor of gametes or a person who receives treatment services or non-medical fertility services—

(i) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or

(ii) might result in, or prolong, hospitalisation or illness, or

(b) any type of gametes or embryo misidentification or mix-up,

“serious adverse reaction” means an unintended response, including a communicable disease, in a donor of gametes intended for human application or a person who receives treatment services or non-medical fertility services, which may be associated with the procurement or human application of gametes or embryos and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or illness,

“store”, in relation to gametes, **embryos or human admixed embryos**, means preserve, whether by cryopreservation or in any other way, and “storage” and “stored” are to be interpreted accordingly,

“traceability” means the ability—

(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,

(b) identify the donor and recipient of particular gametes or embryos,

(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and

(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety, and

"treatment services" means medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.

- (2) References in this Act to keeping, in relation to embryos, **gametes or human admixed embryos**, include keeping while preserved in storage.
- (2A) For the purposes of this Act, a person who, from any premises, controls the provision of services for transporting gametes or embryos is to be taken to distribute gametes or embryos on those premises.
- (2B) In this Act, any reference to a requirement of a provision of the first, second or third Directive is a reference to a requirement which that provision requires to be imposed.
- (3) For the purposes of this Act, a woman is not to be treated as carrying a child until the embryo has become implanted.

2A Third party agreements

- (1) For the purposes of this Act, a “third party agreement” is an agreement in writing between a person who holds a licence and another person which is made in accordance with any licence conditions imposed by the Authority for the purpose of securing compliance with the requirements of Article 24 of the first Directive (relations between tissue establishments and third parties) and under which the other person-
 - (a) procures, tests or processes gametes or embryos (or both), on behalf of the holder of the licence, or
 - (b) supplies to the holder of the licence any goods or services (including distribution services) which may affect the quality or safety of gametes or embryos.
- (2) In this Act—

“relevant third party premises”, in relation to a licence, means any premises (other than premises to which the licence relates)—

 - (a) on which a third party procures, tests, processes or distributes gametes or embryos on behalf of any person in connection with activities carried out by that person under a licence, or
 - (b) from which a third party provides any goods or services which may affect the quality and safety of gametes or embryos to any person in connection with activities carried out by that person under a licence;

“third party” means a person with whom a person who holds a licence has a third party agreement.
- (3) References in this Act to the persons to whom a third party agreement applies are to—
 - (a) the third party,
 - (b) any person designated in the third party agreement as a person to whom the agreement applies, and
 - (c) any person acting under the direction of a third party or of any person so designated.

3 Prohibitions in connection with embryos

(1) No person shall bring about the creation of an embryo except in pursuance of a licence.

(1A) No person shall keep or use an embryo except—

(a) in pursuance of a licence, or

(b) in the case of-

(i) the keeping, without storage, of an embryo intended for human application, or

(ii) the processing, without storage, of such an embryo

in pursuance of a third party agreement.

(1B) No person shall procure or distribute an embryo intended for human application except in pursuance of a licence or a third party agreement.

(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) A licence cannot authorise—

(a) keeping or using an embryo after the appearance of the primitive streak,

(b) placing an embryo in any animal, **or**

(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use.

(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with **the day on which the process of creating the embryo began**, not counting any time during which the embryo is stored.

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.

3A Prohibitions in connection with germ cells

(1) No person shall, for the purpose of providing fertility services for any woman, use female germ cells taken or derived from an embryo or a foetus or use embryos created by using such cells.

(2) In this section—

“female germ cells” means cells of the female germ line and includes such cells at any stage of maturity and accordingly includes eggs; and

“fertility services” means medical, surgical or obstetric services provided for the purpose of assisting women to carry children.

4 Prohibitions in connection with gametes

(1) No person shall—

(a) store any gametes, or

(b) in the course of providing treatment services for any woman, use—

(i) any sperm, other than partner-donated sperm which has been neither processed nor stored,

(ii) the woman's eggs after processing or storage, or

(iii) the eggs of any other woman,

except in pursuance of a licence.

- (1A) No person shall procure, test, process or distribute any gametes intended for human application except in pursuance of a licence or a third party agreement.
- (2) A licence cannot authorise storing or using gametes in any circumstances in which regulations prohibit their storage or use.
- (3) No person shall place sperm and eggs in a woman in any circumstances specified in regulations except in pursuance of a licence.
- (4) Regulations made by virtue of subsection (3) above may provide that, in relation to licences only to place sperm and eggs in a woman in such circumstances, sections 12 to 22 of this Act shall have effect with such modifications as may be specified in the regulations.
- (5) Activities regulated by this section or section 3 or 4A of this Act are referred to in this Act as “activities governed by this Act”.

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

- (1) **No person shall place in a woman -**
 - (a) **a human admixed embryo,**
 - (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 procuclei,**
 - (ii) **one nucleus of a human gamete or of any other human cell, or**

- (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, its functions and procedure

5 The Human Fertilisation and Embryology Authority

- (1) There shall be a body corporate called the Human Fertilisation and Embryology Authority.
- (2) The Authority shall consist of –
 - (a) a chairman and deputy chairman, and
 - (b) such number of other members as the Secretary of State appoints.
- (3) Schedule 1 to this Act (which deals with the membership of the Authority, etc) shall have effect.

6 Accounts and audit

- (1) The Authority shall keep proper accounts and proper records in relation to the accounts and shall prepare for each accounting year a statement of accounts.
- (2) The annual statement of accounts shall comply with any direction given by the Secretary of State, with the approval of the Treasury, as to the information to be contained in the statement, the way in which the information is to be presented or the methods and principles according to which the statement is to be prepared.
- (3) Not later than five months after the end of an accounting year, the Authority shall send a copy of the statement of accounts for that year to the Secretary of State and to the Comptroller and Auditor General.
- (4) The Comptroller and Auditor General shall examine, certify and report on every statement of accounts received by him under subsection (3) above and shall lay a copy of the statement and of his report before each House of Parliament.
- (5) The Secretary of State and the Comptroller and Auditor General may inspect any records relating to the accounts.
- (6) In this section “accounting year” means the period beginning with the day when the Authority is established and ending with the following 31st March, or any later period of twelve months ending with the 31st March.

7 Reports to Secretary of State

- (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.**
- (2) A report prepared under this section for any period shall deal with the activities of the Authority in the period and the activities the Authority proposes to undertake in the succeeding period of twelve months.
- (3) The Secretary of State shall lay before each House of Parliament a copy of every report received by him under this section.

8 General functions of the Authority

- (1) The Authority shall
- (a) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State, if he asks it to do so, about those matters,
 - (b) publicise the services provided to the public by the Authority or provided in pursuance of licences,
 - (c) provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so,
 - (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**
 - (d) perform such other functions as may be specified in regulations.

- (2) The Authority may, if it thinks fit, charge a fee for any advice provided under subsection (1)(c).**

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).**

8A Duty of Authority to communicate with competent authorities of other EEA states

The Authority shall communicate to the competent authorities of EEA states other than the United Kingdom or of Gibraltar, and to the European Commission, such information in relation to serious adverse events and serious adverse reactions as is necessary for the purpose of enabling appropriate action to be taken, including where necessary the withdrawal from use of gametes and embryos that are intended for human application but are known or suspected to be unsuitable for such application.

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.

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.**

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).**
- (4) 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.**

- (5) **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 Licences for treatment, storage and research

- (1) The Authority may grant the following and no other licences—
- (a) licences under paragraph 1 of Schedule 2 to this Act authorising activities in the course of providing treatment services,
 - (aa) licences under paragraph 1A of that Schedule authorising activities in the course of providing non-medical fertility services,
 - (b) licences under that Schedule authorising the storage of gametes, **embryos or human admixed embryos**, and
 - (c) licences under paragraph 3 of that Schedule authorising activities for the purposes of a project of research.
- (2) Paragraph 4 of that Schedule has effect in the case of all licences.

Licence conditions

12 General conditions

- (1) The following shall be conditions of every licence granted under this Act—
- (a) except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible,
 - (aa) that any activities to which section 3(1A)(b) or (1B) or 4(1A) applies shall be carried on only on the premises to which the licence relates or on relevant third party premises,
 - (b) that any member or employee of the Authority, on production, if so required, of a document identifying the person as such, shall at all reasonable times be permitted to enter those premises and inspect them (which includes inspecting any equipment or records and observing any activity),
 - (c) except in relation to the use of gametes in the course of providing basic partner treatment services, that the provisions of Schedule 3 to this Act shall be complied with,
 - (d) that proper records shall be maintained in such form as the Authority may specify in directions,

- (e) that no money or other benefit shall be given or received in respect of any supply of gametes, **embryos or human admixed embryos** unless authorised by directions,
 - (f) that, where gametes, **embryos or human admixed embryos** are supplied to a person to whom another licence applies, that person shall also be provided with such information as the Authority may specify in directions, and
 - (g) that the Authority shall be provided, in such form and at such intervals as it may specify in directions, with such copies of or extracts from the records, or such other information, as the directions may specify.
- (2) Subsection (3) applies to—
- (a) every licence under paragraph 1 or 1A of Schedule 2,
 - (b) every licence under paragraph 2 of that Schedule, so far as authorising the storage of gametes or embryos intended for human application, **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.**
- (3) It shall be a condition of every licence to which this subsection applies that—
- (a) such information as is necessary to facilitate the traceability of gametes and embryos, and
 - (b) any information relating to the quality or safety of gametes or embryos, shall be recorded and provided to the Authority upon request.

13 Conditions of licences for treatment

- (1) The following shall be conditions of every licence under paragraph 1 of Schedule 2 to this Act.
- (2) Such information shall be recorded as the Authority may specify in directions about the following—
 - (a) the persons for whom services are provided in pursuance of the licence,
 - (b) the services provided for them,
 - (c) the persons whose gametes are kept or used for the purposes of services provided in pursuance of the licence or whose gametes have been used in bringing about the creation of embryos so kept or used,
 - (d) any child appearing to the person responsible to have been born as a result of treatment in pursuance of the licence,
 - (e) any mixing of egg and sperm and any taking of an embryo from a woman or other acquisition of an embryo, and
 - (f) such other matters as the Authority may specify in directions.

- (3) The records maintained in pursuance of the licence shall include any information recorded in pursuance of subsection (2) above and any consent of a person whose consent is required under Schedule 3 to this Act.
- (4) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.
- (5) A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for **supportive parenting**), and of any other child who may be affected by the birth.
- (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).**
- (7) Suitable procedures shall be maintained—**
- (a) for determining the persons providing gametes or from whom embryos are taken for use in pursuance of the licence, and**
 - (b) for the purpose of securing that consideration is given to the use of practices not requiring the authority of a licence as well as those requiring such authority.**
- (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 –**
- (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.**

13A Conditions of licences for non-medical fertility services.

- (1) The following shall be conditions of every licence under paragraph 1A of Schedule 2.**
- (2) The requirements of section 13(2) to (4) and (7) shall be complied with.**
- (3) A woman shall not be provided with any non-medical fertility services involving the use of sperm other than partner-donated sperm unless the woman being provided with the services has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such relevant information as is proper.**

14 Conditions of storage licences

- (1) The following shall be conditions of every licence authorising the storage of gametes, embryos or human admixed embryos-**
 - (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,**
- (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,**
- (b) that gametes or embryos which are or have been stored shall not be supplied to a person otherwise than in the course of providing treatment services unless that person is a person to whom a licence applies,
- (ba) **that human admixed embryos shall not be supplied to a person unless that person is a person to whom a licence applies,**
- (c) that no gametes, **embryos or human admixed embryo** shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish, and
- (d) that such information as the Authority may specify in directions as to the persons whose consent is required under Schedule 3 to this Act, the terms of their consent and the circumstances of the storage and as to such other matters as the Authority may specify in directions shall be included in the records maintained in pursuance of the licence.
- (2) No information shall be removed from any records maintained in pursuance of such a licence before the expiry of such period as may be specified in directions for records of the class in question.
- (3) The statutory storage period in respect of gametes is such period not exceeding ten years as the licence may specify.
- (4) The statutory storage period in respect of embryos is such period not exceeding **ten years** as the licence may specify.
- (4A) The statutory storage period in respect of human admixed embryos is such period not exceeding ten years as the licence may specify.**
- (5) Regulations may provide that subsection (3), **(4) or (4A)** above shall have effect as if for ten years there were substituted—
 - (a) such shorter period, or
 - (b) in such circumstances as may be specified in the regulations, such longer period,
 as may be specified in the regulations.

14A Conditions of licences: human application

- (1) This section applies to—

- (a) every licence under paragraph 1 or 1A of Schedule 2,
 - (b) every licence under paragraph 2 of that Schedule, so far as authorising storage of gametes or embryos intended for human application, **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.**
- (2) A licence to which this section applies may not authorise the storage, procurement, testing, processing or distribution of gametes or embryos unless it contains the conditions required by Schedule 3A.
- (3) In relation to any gametes or embryos imported into the United Kingdom from an EEA state other than the United Kingdom or from Gibraltar, compliance with the requirements of the laws or other measures adopted in the relevant state or territory for the purpose of implementing the first, second and third Directives shall be taken to be compliance with the conditions required by Schedule 3A.
- (4) Subsection (3) shall not apply to any licence conditions imposed by the Authority which amount to more stringent protective measures for the purposes of Article 4(2) of the first Directive.

15 Conditions of research licences

- (1) The following shall be conditions of every licence under paragraph 3 of Schedule 2 to this Act.
- (2) The records maintained in pursuance of the licence shall include such information as the Authority may specify in directions about such matters as the Authority may so specify.
- (3) No information shall be removed from any records maintained in pursuance of the licence before the expiry of such period as may be specified in directions for records of the class in question.
- (4) No embryo appropriated for the purposes of any project of research shall be kept or used otherwise than for the purposes of such a project.
- (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.**

15A Duties of the Authority in relation to serious adverse events and serious adverse reactions

- (1) The Authority shall investigate serious adverse events and serious adverse reactions and take appropriate control measures.
- (2) In investigating any serious adverse event or serious adverse reaction, the Authority shall, where it is appropriate to do so, arrange for—

- (a) any premises to which a licence relates and any relevant third party premises to be inspected on its behalf, and
 - (b) a report on the inspection to be made to it.
- (3) If the Authority receives a request from a competent authority in an EEA state other than the United Kingdom or in Gibraltar to carry out an inspection in relation to a serious adverse event or serious adverse reaction, the Authority must arrange for such an inspection to be carried out, for a report to be made of the inspection and for appropriate control measures to be taken.

Grant, revocation and suspension of licences

16 Grant of licence

- (1) **The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.**
- (2) The requirements mentioned in subsection (1) above are—
- (a) that the application is for a licence designating an individual as the person under whose supervision the activities to be authorised by the licence are to be carried on,
 - (b) that either that individual is the applicant or—
 - (i) the application is made with the consent of that individual, and
 - (ii) the **Authority** is satisfied that the applicant is a suitable person to hold a licence,
 - (c) in relation to a licence under paragraph 1 or 1A of Schedule 2 or a licence under paragraph 2 of that Schedule authorising the storage of gametes or embryos intended for human application **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**, that the individual—
 - (i) possesses a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences, awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or is otherwise considered by the **Authority** to be suitably qualified on the basis of academic qualifications in the field of nursing, and
 - (ii) has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence,
 - (ca) in relation to a licence under paragraph 2 of Schedule 2 authorising storage of gametes, **embryos or human admixed embryos** not intended for human application or a licence under paragraph 3 of that Schedule **authorising activities otherwise than in connection with the derivation from embryos of stem cells that are intended for human application**, and that the **Authority** is satisfied that the

qualifications and experience of that individual are such as are required for the supervision of the activities,

- (cb) that the **Authority** is satisfied that the character of that individual is such as is required for the supervision of the activities and that the individual will discharge the duty under section 17 of this Act,
 - (d) that the **Authority** is satisfied that the premises in respect of which the licence is to be granted **and any premises which will be relevant third party premises** are suitable for the activities, and
 - (e) that all the other requirements of this Act in relation to the granting of the licence are satisfied.
- (3) The grant of a licence to any person may be by way of renewal of a licence granted to that person, whether on the same or different terms.
 - (4) Where the **Authority** is of the opinion that the information provided in the application is insufficient to enable it to determine the application, it need not consider the application until the applicant has provided it with such further information as it may require him to provide.
 - (5) The **Authority** shall not grant a licence unless a copy of the conditions to be imposed by the licence has been shown to, and acknowledged in writing by, the applicant and (where different) the person under whose supervision the activities are to be carried on.

17 The person responsible

- (1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the "person responsible") to secure—
 - (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,
 - (b) that proper equipment is used,
 - (c) that proper arrangements are made for the keeping of gametes, **embryos and human admixed embryos** and for the disposal of gametes, **embryos or human admixed embryos** that have been allowed to perish,
 - (d) that suitable practices are used in the course of the activities,
 - (e) that the conditions of the licence are complied with,
 - (f) that conditions of third party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with, and
 - (g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.

- (2) References in this Act to the persons to whom a licence applies are to—
- (a) the person responsible,
 - (b) any person designated in the licence, or in a notice given to the Authority by the person who holds the licence or the person responsible, as a person to whom the licence applies, and
 - (c) any person acting under the direction of the person responsible or of any person so designated.

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 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.
- (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.

19C Power to suspend a 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.

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-
- (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

23 Directions: general

- (1) The Authority may from time to time give directions for any purpose for which directions may be given under this Act or directions varying or revoking such directions.
- (2) A person to whom any requirement contained in directions is applicable shall comply with the requirement.
- (3) Anything done by a person in pursuance of directions is to be treated for the purposes of this Act as done in pursuance of a licence.
- (4) Where directions are to be given to a particular person, they shall be given by serving notice of the directions on the person.
- (5) In any other case, directions may be given—
 - (a) **in respect of any licence (including a licence which has ceased to have effect), by serving notice of the directions on the person -**
 - (i) **who is the person responsible or the holder of the licence, if different, or**
 - (ii) **who was the person responsible or the holder of the licence, if different, and**
 - (b) if the directions appear to the Authority to be general directions or it appears to the Authority that it is not practicable to give notice in pursuance of paragraph (a) above, by publishing the directions in such way as, in the opinion of the Authority, is likely to bring the directions to the attention of the persons to whom they are applicable.

24 Directions as to particular matters

- (1) If, in the case of any information about persons for whom treatment services, other than basic partner treatment services, were provided, the person responsible does not know that any child was born following the treatment, the period specified in directions by virtue of section 13(4) of this Act shall not expire less than 50 years after the information was first recorded.
- (2) In the case of every licence under paragraph 1 or 1A of Schedule 2 to this Act, directions shall require information to be recorded and given to the Authority about each of the matters referred to in section 13(2)(a) to (e) of this Act.
- (3) In relation to gametes or embryos that are not intended for human application, 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 gametes or embryos in the course of their carriage to or from any premises.

(3A) In relation to gametes and embryos that are intended for human application, directions may authorise the keeping of gametes or embryos by or on behalf of a person to whom a licence applies, in the course of their carriage—

- (a) between premises to which licences relate,
- (b) between such premises and relevant third party premises,
- (c) between premises referred to in paragraphs (a) and (b) and tissue establishments accredited, designated, authorised or licensed under the laws, or other measures, of an EEA state other than the United Kingdom or of Gibraltar which implement the first, second and third Directives, or
- (d) between premises referred to in paragraphs (a) and (b) and tissue establishments in a country which is not an EEA state, pursuant to the directions given under subsection (4),

in such circumstances and subject to such conditions as may be specified in directions.

(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.

(4) Directions may authorise any person to whom a licence applies to receive gametes, **embryos or human admixed embryos** from outside the United Kingdom or to send gametes, **embryos or human admixed embryos** outside the United Kingdom in such circumstances and subject to such conditions as may be specified in the directions, and directions made by virtue of this subsection may provide for sections 12 to 14 of this Act to have effect with such modifications as may be specified in the directions.

(4A) In giving any directions under subsection (4) authorising any person to whom a licence applies to import into the United Kingdom from a country which is not an EEA state, or to export from the United Kingdom to such a country, gametes or embryos intended for human application, the Authority shall—

- (a) include directions specifying the measures that persons to whom a licence applies shall take to ensure that all such imports or exports meet standards of quality and safety equivalent to those laid down in this Act, and
- (b) have regard to ensuring traceability.

(4B) Regulations may make provision requiring or authorising the giving of directions in relation to particular matters which are specified in the regulations and relate to activities falling within section 4A(2) (activities involving genetic material of animal origin).

(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.**
- (11) Where the Authority proposes to give directions specifying any animal for the purposes of paragraph 1(1)(f) or 3(2) of Schedule 2 to this Act, it shall report the proposal to the Secretary of State; and the directions shall not be given until the Secretary of State has laid a copy of the report before each House of Parliament.
- (12) Directions may require a unique code to be assigned to each donation of gametes and embryos intended for human application received pursuant to a licence.
- (13) The Authority may give directions as to the information to be provided to it and any measures to be taken by the person responsible in the event of—
- (a) any occurrence which may adversely influence the quality or safety of gametes or embryos intended for human application,
 - (b) any adverse incident which may be linked to the quality or safety of gametes or embryos intended for human application, or
 - (c) any misidentification or mix-up of gametes or embryos intended for human application.
- (14) In this section, “tissue establishment” has the meaning given by Article 3(o) of the first Directive.

25 Code of practice

- (1) The Authority shall maintain a code of practice giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act

and the proper discharge of the functions of the person responsible and other persons to whom the licence applies.

- (2) The guidance given by the code shall include guidance for those providing treatment services about the account to be taken of the welfare of children who may be born as a result of treatment services (including a child's need for **supportive parenting**), and of other children who may be affected by such births.

(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.

- (3) The code may also give guidance about the use of any technique involving the placing of sperm and eggs in a woman.
- (4) The Authority may from time to time revise the whole or any part of the code.
- (5) The Authority shall publish the code as for the time being in force.
- (6) A failure on the part of any person to observe any provision of the code shall not of itself render the person liable to any proceedings, but—
 - (a) **the Authority** shall, in considering whether there has been any failure to comply with any conditions of a licence and, in particular, conditions requiring anything to be "proper" or "suitable", take account of any relevant provision of the code, and
 - (b) **the Authority** may, in considering, where it has power to do so, whether or not to vary or revoke a licence, take into account any observance of or failure to observe the provisions of the code.

26 Procedure for approval of code

- (1) The Authority shall send a draft of the proposed first code of practice under section 25 of this Act to the Secretary of State within twelve months of the commencement of section 5 of this Act.
- (2) If the Authority proposes to revise the code or, if the Secretary of State does not approve a draft of the proposed first code, to submit a further draft, the Authority shall send a draft of the revised code or, as the case may be, a further draft of the proposed first code to the Secretary of State.
- (3) Before preparing any draft, the Authority shall consult such persons as the Secretary of State may require it to consult and such other persons (if any) as it considers appropriate.
- (4) If the Secretary of State approves a draft, he shall lay it before Parliament and, if he does not approve it, he shall give reasons to the Authority.
- (5) A draft approved by the Secretary of State shall come into force in accordance with directions.

27 Meaning of "mother"

- (1) The woman who is carrying or has carried a child as a result of the placing in her of an embryo or of sperm and eggs, and no other woman, is to be treated as the mother of the child.
- (2) Subsection (1) above does not apply to any child to the extent that the child is treated by virtue of adoption as not being the woman's child.
- (3) Subsection (1) above applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs.

28 Meaning of "father"

- (1) Subject to subsections (5A) to (5I) below, this section applies in the case of a child who is being or has been carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination.
- (2) If—
 - (a) at the time of the placing in her of the embryo or the sperm and eggs or of her insemination, the woman was a party to a marriage, and
 - (b) the creation of the embryo carried by her was not brought about with the sperm of the other party to the marriage,then, subject to subsection (5) below, the other party to the marriage shall be treated as the father of the child unless it is shown that he did not consent to the placing in her of the embryo or the sperm and eggs or to her insemination (as the case may be).
- (3) If no man is treated, by virtue of subsection (2) above, as the father of the child but—
 - (a) the embryo or the sperm and eggs were placed in the woman, or she was artificially inseminated, in the course of treatment services provided for her and a man together by a person to whom a licence applies, and
 - (b) the creation of the embryo carried by her was not brought about with the sperm of that man,then, subject to subsection (5) below, that man shall be treated as the father of the child.
- (4) Where a person is treated as the father of the child by virtue of subsection (2) or (3) above, no other person is to be treated as the father of the child.
- (5) Subsections (2) and (3) above do not apply—
 - (a) in relation to England and Wales and Northern Ireland, to any child who, by virtue of the rules of common law, is treated as the legitimate child of the parties to a marriage,

- (b) in relation to Scotland, to any child who, by virtue of any enactment or other rule of law, is treated as the child of the parties to a marriage, or
- (c) to any child to the extent that the child is treated by virtue of adoption as not being the man's child.

(5A) If—

- (a) a child has been carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,
- (b) the creation of the embryo carried by her was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in the woman after his death,
- (c) the woman was a party to a marriage with the man immediately before his death,
- (d) the man consented in writing (and did not withdraw the consent)—
 - (i) to the use of his sperm after his death which brought about the creation of the embryo carried by the woman or (as the case may be) to the placing in the woman after his death of the embryo which was brought about using his sperm before his death, and
 - (ii) to being treated for the purpose mentioned in subsection (5I) below as the father of any resulting child,
- (e) the woman has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (5I) below as the father of the child, and
- (f) no-one else is to be treated as the father of the child by virtue of subsection (2) or (3) above or by virtue of adoption or the child being treated as mentioned in paragraph (a) or (b) of subsection (5) above,

then the man shall be treated for the purpose mentioned in subsection (5I) below as the father of the child.

(5B) If—

- (a) a child has been carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination,
- (b) the creation of the embryo carried by her was brought about by using the sperm of a man after his death, or the creation of the embryo was brought about using the sperm of a man before his death but the embryo was placed in the woman after his death,
- (c) the woman was not a party to a marriage with the man immediately before his death but treatment services were being provided for the woman and the man together before his death either by a person to whom a licence applies or outside the United Kingdom,
- (d) the man consented in writing (and did not withdraw the consent)—

- (i) to the use of his sperm after his death which brought about the creation of the embryo carried by the woman or (as the case may be) to the placing in the woman after his death of the embryo which was brought about using his sperm before his death, and
 - (ii) to being treated for the purpose mentioned in subsection (5I) below as the father of any resulting child,
- (e) the woman has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (5I) below as the father of the child, and
- (f) no-one else is to be treated as the father of the child by virtue of subsection (2) or (3) above or by virtue of adoption or the child being treated as mentioned in paragraph (a) or (b) of subsection (5) above,

then the man shall be treated for the purpose mentioned in subsection (5I) below as the father of the child.

(5C) If—

- (a) a child has been carried by a woman as the result of the placing in her of an embryo,
- (b) the embryo was created at a time when the woman was a party to a marriage,
- (c) the creation of the embryo was not brought about with the sperm of the other party to the marriage,
- (d) the other party to the marriage died before the placing of the embryo in the woman,
- (e) the other party to the marriage consented in writing (and did not withdraw the consent) —
 - (i) to the placing of the embryo in the woman after his death, and
 - (ii) to being treated for the purpose mentioned in subsection (5I) below as the father of any resulting child,
- (f) the woman has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the other party to the marriage to be treated for the purpose mentioned in subsection (5I) below as the father of the child, and
- (g) no-one else is to be treated as the father of the child by virtue of subsection (2) or (3) above or by virtue of adoption or the child being treated as mentioned in paragraph (a) or (b) of subsection (5) above,

then the other party to the marriage shall be treated for the purpose mentioned in subsection (5I) below as the father of the child.

(5D) If—

- (a) a child has been carried by a woman as the result of the placing in her of an embryo,

- (b) the embryo was not created at a time when the woman was a party to a marriage but was created in the course of treatment services provided for the woman and a man together either by a person to whom a licence applies or outside the United Kingdom,
- (c) the creation of the embryo was not brought about with the sperm of that man,
- (d) the man died before the placing of the embryo in the woman,
- (e) the man consented in writing (and did not withdraw the consent) —
 - (i) to the placing of the embryo in the woman after his death, and
 - (ii) to being treated for the purpose mentioned in subsection (5I) below as the father of any resulting child,
- (f) the woman has elected in writing not later than the end of the period of 42 days from the day on which the child was born for the man to be treated for the purpose mentioned in subsection (5I) below as the father of the child, and
- (g) no-one else is to be treated as the father of the child by virtue of subsection (2) or (3) above or by virtue of adoption or the child being treated as mentioned in paragraph (a) or (b) of subsection (5) above,

then the man shall be treated for the purpose mentioned in subsection (5I) below as the father of the child.

- (5E) In the application of subsections (5A) to (5D) above to Scotland, for any reference to a period of 42 days there shall be substituted a reference to a period of 21 days.
- (5F) The requirement under subsection (5A), (5B), (5C) or (5D) above as to the making of an election (which requires an election to be made either on or before the day on which the child was born or within the period of 42 or, as the case may be, 21 days from that day) shall nevertheless be treated as satisfied if the required election is made after the end of that period but with the consent of the Registrar General under subsection (5G) below.
- (5G) The Registrar General may at any time consent to the making of an election after the end of the period mentioned in subsection (5F) above if, on an application made to him in accordance with such requirements as he may specify, he is satisfied that there is a compelling reason for giving his consent to the making of such an election.
- (5H) In subsections (5F) and (5G) above “the Registrar General” means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or (as the case may be) the Registrar General for Northern Ireland.
- (5I) The purpose referred to in subsections (5A) to (5D) above is the purpose of enabling the man’s particulars to be entered as the particulars of the child’s father in (as the case may be) a register of live-births or still-births kept under the Births and Deaths Registration Act 1953 or the Births and Deaths Registration (Northern Ireland) Order 1976 or a register of births or still-births

kept under the Registration of Births, Deaths and Marriages (Scotland) Act 1965.

- (6) Where—
- (a) the sperm of a man who had given such consent as is required by paragraph 5 of Schedule 3 to this Act was used for a purpose for which such consent was required, or
 - (b) the sperm of a man, or any embryo the creation of which was brought about with his sperm, was used after his death,
- he is not, subject to subsections (5A) and (5B) above, to be treated as the father of the child.
- (7) The references in subsection (2) above and subsections (5A) to (5D) above to the parties to a marriage at the time there referred to—
- (a) are to the parties to a marriage subsisting at that time, unless a judicial separation was then in force, but
 - (b) include the parties to a void marriage if either or both of them reasonably believed at that time that the marriage was valid; and for the purposes of this subsection it shall be presumed, unless the contrary is shown, that one of them reasonably believed at that time that the marriage was valid.
- (8) This section applies whether the woman was in the United Kingdom or elsewhere at the time of the placing in her of the embryo or the sperm and eggs or her artificial insemination.
- (9) In subsection (7)(a) above, "judicial separation" includes a legal separation obtained in a country outside the British Islands and recognised in the United Kingdom.

29 Effect of sections 27 and 28

- (1) Where by virtue of section 27 or 28 of this Act a person is to be treated as the mother or father of a child, that person is to be treated in law as the mother or, as the case may be, father of the child for all purposes.
- (2) Where by virtue of section 27 or 28 of this Act a person is not to be treated as the mother or father of a child, that person is to be treated in law as not being the mother or, as the case may be, father of the child for any purpose.
- (3) Where subsection (1) or (2) above has effect, references to any relationship between two people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.
- (3A) Subsections (1) to (3) above do not apply in relation to the treatment in law of a deceased man in a case to which section 28(5A), (5B), (5C) or (5D) of this Act applies.
- (3B) Where subsection (5A), (5B), (5C) or (5D) of section 28 of this Act applies, the deceased man—
- (a) is to be treated in law as the father of the child for the purpose referred to in that subsection, but

- (b) is to be treated in law as not being the father of the child for any other purpose.
- (3C) Where subsection (3B) above has effect, references to any relationship between two people in any enactment, deed or other instrument or document (whenever passed or made) are to be read accordingly.
- (3D) In subsection (3C) above “enactment” includes an enactment comprised in, or in an instrument made under, an Act of the Scottish Parliament or Northern Ireland legislation.
- (4) In relation to England and Wales and Northern Ireland, nothing in the provisions of section 27(1) or 28(2) to (4) or (5A) to (5I), read with this section, affects—
 - (a) the succession to any dignity or title of honour or renders any person capable of succeeding to or transmitting a right to succeed to any such dignity or title, or
 - (b) the devolution of any property limited (expressly or not) to devolve (as nearly as the law permits) along with any dignity or title of honour.
- (5) In relation to Scotland—
 - (a) those provisions do not apply to any title, coat of arms, honour or dignity transmissible on the death of the holder thereof or affect the succession thereto or the devolution thereof, and
 - (b) where the terms of any deed provide that any property or interest in property shall devolve along with a title, coat of arms, honour or dignity, nothing in those provisions shall prevent that property or interest from so devolving.

Information

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,
 - (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-**

- (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-
- (a) “relevant individual” has the same meaning as in section 31; and
 - (b) “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**
 - (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) and (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 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 had 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-
- (a) “relevant individual” has the same meaning as in section 31; and
 - (b) “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.**

31A The Authority's register of licences

- (1) **The Authority shall keep a register recording the grant, suspension or revocation of—**
 - (a) every licence under paragraph 1 or 2 of Schedule 2 authorising activities in relation to gametes or embryos intended for use for human application,
 - (b) every licence under paragraph 1A of Schedule 2, **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.**
- (2) **The register shall specify, in relation to each such licence—**
 - (a) the activities authorised,
 - (b) the address of the premises to which the licence relates,
 - (c) the name of the person responsible and **the name of the holder of the licence (if different),** and
 - (d) any variations made.
- (3) **The Authority shall make such of the information included in the register as it considers appropriate available to the public in such manner as it considers appropriate.**

31B The Authority's register of serious adverse events and serious adverse reactions

- (1) The Authority shall keep a register containing information provided to it under this Act about any serious adverse event or serious adverse reaction.
- (2) The Authority shall make such of the information included in the register as it considers appropriate available to the public in such manner as it considers appropriate.

32 Information to be provided to Registrar General

- (1) This section applies where a claim is made before the Registrar General that a **person** is or is not the **parent** of a child and it is necessary or desirable for the purpose of any function of the Registrar General to determine whether the claim is or may be well-founded.
- (2) The Authority shall comply with any request made by the Registrar General by notice to the Authority to disclose whether any information on the register kept in pursuance of section 31 of this Act tends to show **that the person may be a parent of the child by virtue of any of the relevant statutory provisions** and, if it does, disclose that information.

(2A) In subsection (2) "the relevant statutory provisions" means –

- (a) **section 28 of this Act, and**
- (b) **sections 35 to 47 of the Human Fertilisation and Embryology Act 2008.**
- (3) In this section and **section 33A** of this Act, "the Registrar General" means the Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or the Registrar General for Northern Ireland, as the case may be.

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 33AB,**
- (i) the disclosure is made in accordance with sections 31ZA to 31ZE,**
- (j) 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,**
- (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 practical to obtain P's consent,**

- (k) 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,**
 - (l) 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,**
 - (m) 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,**
 - (n) 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,**
 - (o) 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,**
 - (p) the disclosure is made under section 3 of the Access to Health Records Act 1990,**
 - (q) the disclosure is made under Article 5 of the Access to Health Records (Northern Ireland) Order 1993, or**
 - (r) 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)—
- (i) in paragraph (p) “regulatory function” has the same meaning as in section 32 of the Legislative and Regulatory Reform Act 2006, and
 - (ii) 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,**
 - (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).**

- (1) Where in any proceedings before a court the question whether a person is or is not the parent of a child by virtue of sections 27 to 29 of this Act **or sections 33 to 47 of the Human Fertilisation and Embryology Act 2008** falls to be determined, the court may on the application of any party to the proceedings make an order requiring the Authority—
 - (a) to disclose whether or not any information relevant to that question is contained in the register kept in pursuance of section 31 of this Act, and
 - (b) if it is, to disclose so much of it as is specified in the order,
 but such an order may not require the Authority to disclose any information falling within section **31(2) (c) to (e)** of this Act.
- (2) The court must not make an order under subsection (1) above unless it is satisfied that the interests of justice require it to do so, taking into account—
 - (a) any representations made by any individual who may be affected by the disclosure, and
 - (b) the welfare of the child, if under 18 years old, and of any other person under that age who may be affected by the disclosure.
- (3) If the proceedings before the court are civil proceedings, it—
 - (a) may direct that the whole or any part of the proceedings on the application for an order under subsection (2) above shall be heard in camera, and
 - (b) if it makes such an order, may then or later direct that the whole or any part of any later stage of the proceedings shall be heard in camera.
- (4) An application for a direction under subsection (3) above shall be heard in camera unless the court otherwise directs.

35 Disclosure in interests of justice: congenital disabilities, etc

- (1) Where for the purpose of instituting proceedings under section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled) it is necessary to identify a person who would or might be the parent of a child but for **the relevant statutory provisions**, the court may, on the application of the child, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.
- (2) Where, for the purposes of any action for damages in Scotland (including any such action which is likely to be brought) in which the damages claimed consist of or include damages or solatium in respect of personal injury (including any disease and any impairment of physical or mental condition), it is necessary to identify a person who would or might be the parent of a child but for **the relevant statutory provisions**, the court may, on the application of any party to the action or, if the proceedings have not been commenced, the prospective pursuer, make an order requiring the Authority to disclose any information contained in the register kept in pursuance of section 31 of this Act identifying that person.

(2A) In subsections (1) and (2) “the relevant statutory provisions” means –

(a) sections 27 to 29 of this Act, and

(b) sections 33 to 47 of the Human Fertilisation and Embryology Act 2008.

(3) Subsections (2) to (4) of section 34 of this Act apply for the purposes of this section as they apply for the purposes of that.

(4) After section 4(4) of the Congenital Disabilities (Civil Liability) Act 1976 there is inserted—

"(4A) In any case where a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled, any reference in section 1 of this Act to a parent includes a reference to a person who would be a parent but for sections 27 to 29 of the Human Fertilisation and Embryology Act 1990."

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).

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.**

Surrogacy

36 Amendment of Surrogacy Arrangements Act 1985

- (1) After section 1 of the Surrogacy Arrangements Act 1985 there is inserted—**
- "Surrogacy arrangements unenforceable.**
- 1A. No surrogacy arrangement is enforceable by or against any of the persons making it."**

- (2) In section 1 of that Act (meaning of "surrogate mother", etc.)—
- (a) in subsection (6), for "or, as the case may be, embryo insertion" there is substituted "or of the placing in her of an embryo, of an egg in the process of fertilisation or of sperm and eggs, as the case may be," and
 - (b) in subsection (9), the words from "and whether" to the end are repealed.

Abortion

37 Amendment of law relating to termination of pregnancy

- (1) For paragraphs (a) and (b) of section 1(1) of the Abortion Act 1967 (grounds for medical termination of pregnancy) there is substituted—
- “ (a) that the pregnancy has not exceeded its twenty-fourth week and that the continuance of the pregnancy would involve risk, greater than if the pregnancy were terminated, of injury to the physical or mental health of the pregnant woman or any existing children of her family; or
- (b) that the termination is necessary to prevent grave permanent injury to the physical or mental health of the pregnant woman; or
- (c) that the continuance of the pregnancy would involve risk to the life of the pregnant woman, greater than if the pregnancy were terminated; or
- (d) that there is a substantial risk that if the child were born it would suffer from such physical or mental abnormalities as to be seriously handicapped.”
- (2) In section 1(2) of that Act, after "(a)" there is inserted "or (b)".
- (3) After section 1(3) of that Act there is inserted -
- "(3A)The power under subsection (3) of this section to approve a place includes power, in relation to treatment consisting primarily in the use of such medicines as may be specified in the approval and carried out in such manner as may be so specified, to approve a class of places."
- (4) For section 5(1) of that Act (effect on Infant Life (Preservation) Act 1929) there is substituted -
- "(1) No offence under the Infant Life (Preservation) Act 1929 shall be committed by a registered medical practitioner who terminates a pregnancy in accordance with the provisions of this Act."
- (5) In section 5(2) of that Act, for the words from "the miscarriage" to the end there is substituted "a woman's miscarriage (or, in the case of a woman carrying more than one foetus, her miscarriage of any foetus) is unlawfully done unless authorised by section 1 of this Act and, in the case of a woman carrying more than one foetus, anything done with intent to procure her miscarriage of any foetus is authorised by that section if -
- (a) the ground for termination of the pregnancy specified in subsection (1)(d) of that section applies in relation to any

foetus and the thing is done for the purpose of procuring the miscarriage of that foetus, or

- (b) any of the other grounds for termination of the pregnancy specified in that section applies".

Conscientious objection

38 Conscientious objection

- (1) No person who has a conscientious objection to participating in any activity governed by this Act shall be under any duty, however arising, to do so.
- (2) In any legal proceedings the burden of proof of conscientious objection shall rest on the person claiming to rely on it.
- (3) In any proceedings before a court in Scotland, a statement on oath by any person to the effect that he has a conscientious objection to participating in a particular activity governed by this Act shall be sufficient evidence of that fact for the purpose of discharging the burden of proof imposed by subsection (2) above.

Enforcement

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.**

Offences

41 Offences

- (1) A person who—
 - (a) contravenes section 3(2), 3A or **4A(1) or (2)** of this Act, or
 - (b) does anything which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,is guilty of an offence and liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.
- (2) A person who—
 - (a) contravenes section 3(1) or (1A) of this Act, otherwise than by doing something which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,
 - (aa) **contravenes section 3(1B) of this Act,**

- (b) keeps any gametes in contravention of section 4(1)(a) of this Act,
 - (ba) uses any gametes in contravention of section 4(1)(b),
 - (bb) contravenes section 4(1A) of this Act,**
 - (c) contravenes section 4(3) of this Act, or
 - (d) fails to comply with any directions given by virtue of **section 24(5D)** of this Act,
- is guilty of an offence.
- (3) If a person—
- (a) provides any information for the purposes of the grant of a licence, being information which is false or misleading in a material particular, and
 - (b) either he knows the information to be false or misleading in a material particular or he provides the information recklessly,
- he is guilty of an offence.
- (4) A person guilty of an offence under subsection (2) or (3) above is liable—
- (a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and
 - (b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.
- (5) A person who discloses any information in contravention of **section 33A** of this Act is guilty of an offence and liable—
- (a) on conviction on indictment, to imprisonment for a term not exceeding two years or a fine or both, and
 - (b) on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding the statutory maximum or both.
- (7) A person who without reasonable excuse fails to comply with a requirement imposed by regulations made by virtue of **section 19B(3)(a) or 20B(3)(e)** of this Act is guilty of an offence.
- (8) Where a person to whom a licence applies **or the holder of the licence** gives or receives any money or other benefit, not authorised by directions, in respect of any supply of gametes, **embryos or human admixed embryos**, he is guilty of an offence.
- (9) A person guilty of an offence under subsection (7) or (8) above is liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both.
- (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.**

(11) It is a defence for a person charged with an offence under this Act to prove—

- (a) that at the material time he was a person to whom a licence or third party agreement applied or to whom directions had been given, and**
- (b) that he took all such steps as were reasonable and exercised all due diligence to avoid committing the offence.**

42 Consent to prosecution

No proceedings for an offence under this Act shall be instituted—

- (a) in England and Wales, except by or with the consent of the Director of Public Prosecutions, and**
- (b) in Northern Ireland, except by or with the consent of the Director of Public Prosecutions for Northern Ireland.**

Miscellaneous and General

43 Keeping and examining gametes and embryos in connection with crime, etc

(1) Regulations may provide—

- (a) for the keeping and examination of gametes or embryos, in such manner and on such conditions (if any) as may be specified in regulations, in connection with the investigation of, or proceedings for, an offence (wherever committed), or
 - (b) for the storage of gametes, in such manner and on such conditions (if any) as may be specified in regulations, where they are to be used only for such purposes, other than treatment services, as may be specified in regulations.
- (2) Nothing in this Act makes unlawful the keeping or examination of any gametes or embryos in pursuance of regulations made by virtue of this section.
- (3) In this section "examination" includes use for the purposes of any test.

44 Civil liability to child with disability

- (1) After section 1 of the Congenital Disabilities (Civil Liability) Act 1976 (civil liability to child born disabled) there is inserted—
- “1A Extension of section 1 to cover infertility treatments**
- (1) In any case where—
- (a) a child carried by a woman as the result of the placing in her of an embryo or of sperm and eggs or her artificial insemination is born disabled,
 - (b) the disability results from an act or omission in the course of the selection, or the keeping or use outside the body, of the embryo carried by her or of the gametes used to bring about the creation of the embryo, and
 - (c) a person is under this section answerable to the child in respect of the act or omission,
- the child's disabilities are to be regarded as damage resulting from the wrongful act of that person and actionable accordingly at the suit of the child.
- (2) Subject to subsection (3) below and the applied provisions of section 1 of this Act, a person (here referred to as "the defendant") is answerable to the child if he was liable in tort to one or both of the parents (here referred to as "the parent or parents concerned") or would, if sued in due time, have been so; and it is no answer that there could not have been such liability because the parent or parents concerned suffered no actionable injury, if there was a breach of legal duty which, accompanied by injury, would have given rise to the liability.
- (3) The defendant is not under this section answerable to the child if at the time the embryo, or the sperm and eggs, are placed in the woman or the time of her insemination (as the case may be) either or both of the parents knew the risk of their child being born disabled (that is to say, the particular risk created by the act or omission).

- (4) Subsections (5) to (7) of section 1 of this Act apply for the purposes of this section as they apply for the purposes of that but as if references to the parent or the parent affected were references to the parent or parents concerned.”
- (5) In section 4 of that Act (interpretation, etc)—
- (a) at the end of subsection (2) there is inserted -

"and references to embryos shall be construed in accordance with section 1 of the Human Fertilisation and Embryology Act 1990",
 - (b) in subsection (3), after "section 1" there is inserted "1A", and
 - (c) in subsection (4), for "either" there is substituted "any".

45 Regulations

- (1) The Secretary of State may make regulations for any purpose for which regulations may be made under this Act.
- (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).**
- (2) The power to make regulations **under this Act** shall be exercisable by statutory instrument.
- (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 -**
 - (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.**
- (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.

- (5) A statutory instrument containing regulations **made by the Secretary of State** shall, if made without a draft having been approved by resolution of each House of Parliament, be subject to annulment in pursuance of a resolution of either House of Parliament.
- (6) In this Act "regulations" means regulations under this section.

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(10) (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.

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.

46 Notices

(1) This section has effect in relation to any notice required or authorised by this Act to be given to or served on any person.

(2) The notice may be given to or served on the person—

(a) by delivering it to the person,

(b) by leaving it at the person's proper address, or

(c) by sending it by post to the person at that address.

(3) The notice may—

- (a) in the case of a body corporate, be given to or served on the secretary or clerk of the body,
 - (b) in the case of a partnership, be given to or served on any partner, and
 - (c) in the case of an unincorporated association other than a partnership, be given to or served on any member of the governing body of the association.
- (4) For the purposes of this section and section 7 of the Interpretation Act 1978 (service of documents by post) in its application to this section, the proper address of any person is the person's last known address and also—
- (a) in the case of a body corporate, its secretary or its clerk, the address of its registered or principal office, and
 - (b) in the case of an unincorporated association or a member of its governing body, its principal office.
- (5) Where a person has notified the Authority of an address or a new address at which notices may be given to or served on him under this Act, that address shall also be his proper address for the purposes mentioned in subsection (4) above or, as the case may be, his proper address for those purposes in substitution for that previously notified.

47 Index

The expressions listed in the left-hand column below are respectively defined or (as the case may be) are to be interpreted in accordance with the provisions of this Act listed in the right-hand column in relation to those expressions.

Expression	Relevant provision
Activities governed by this Act	Section 4(5)
Appeals committee	Section 20A(2)
Authority	Section 2(1)
Basic partner treatment services	Section 2(1)
Carry, in relation to a child	Section 2(3)
Competent authority	Section 2(1)
Directions	Section 2(1)
Distribution, in relation to gametes or embryos intended for human application	Section 2(1)
Embryo (except in section 4A or in the term “human admixed embryo”)	Section 1
First Directive	Section 1A
Gametes, eggs or sperm (except in section 4A)	Section 1

Human admixed embryo	Section 4A(6)
Human application	Section 2(1)
Keeping, in relation to embryos or gametes	Section 2(2)
Licence	Section 2(1)
Non-medical fertility services	Section 2(1)
Nuclear DNA (in relation to an embryo)	Section 2(1)
Partner-donated sperm	Section 1(5)
Person responsible	Section 17(1)
Person to whom a licence applies	Section 17(2)
Person to whom a third party agreement applies	Section 2A(3)
Processing, in relation to gametes or embryos intended for human application	Section 2(1)
Procurement, in relation to gametes or embryos intended for human application	Section 2(1)
Relevant third party premises, in relation to a licence	Section 2A(2)
Second Directive	Section 1A
Serious adverse event	Section 2(1)
Serious adverse reaction	Section 2(1)
Statutory storage period	Section 14(3) to (5)
Store, and similar expressions, in relation to embryos, human admixed embryos or gametes	Section 2(1)
Third Directive	Section 1A
Third party	Section 2A(2)
Third party agreement	Section 2A(1)
Traceability	Section 2(1)
Treatment services	Section 2(1)

48 Northern Ireland

(1) This Act (except sections 33A(2)(r) and 37) extends to Northern Ireland.

49 Short title, commencement, etc

- (1) This Act may be cited as the Human Fertilisation and Embryology Act 1990.
- (2) This Act shall come into force on such day as the Secretary of State may by order made by statutory instrument appoint and different days may be appointed for different provisions and for different purposes.
- (3) Sections 27 to 29 of this Act shall have effect only in relation to children carried by women as a result of the placing in them of embryos or of sperm and eggs, or of their artificial insemination (as the case may be), after the commencement of those sections.
- (4) Section 27 of the Family Law Reform Act 1987 (artificial insemination) does not have effect in relation to children carried by women as the result of their artificial insemination after the commencement of sections 27 to 29 of this Act.
- (5) Schedule 4 to this Act (which makes minor and consequential amendments) shall have effect.
- (6) An order under this section may make such transitional provision as the Secretary of State considers necessary or desirable and, in particular, may provide that where activities are carried on under the supervision of a particular individual, being activities which are carried on under the supervision of that individual at the commencement of sections 3 and 4 of this Act, those activities are to be treated, during such period as may be specified in or determined in accordance with the order, as authorised by a licence (having, in addition to the conditions required by this Act, such conditions as may be so specified or determined) under which that individual is the person responsible.
- (7) Her Majesty may by Order in Council direct that any of the provisions of this Act shall extend, with such exceptions, adaptations and modifications (if any) as may be specified in the Order, to any of the Channel Islands.

SCHEDULE 1
THE AUTHORITY: SUPPLEMENTARY PROVISIONS

Section 5

Status and capacity

1. The Authority shall not be regarded as the servant or agent of the Crown, or as enjoying any status, privilege or immunity of the Crown; and its property shall not be regarded as property of, or property held on behalf of, the Crown.

2. The Authority shall have power to do anything which is calculated to facilitate the discharge of its functions, or is incidental or conducive to their discharge, except the power to borrow money.

Expenses

3. The Secretary of State may, with the consent of the Treasury, pay the Authority out of money provided by Parliament such sums as he thinks fit towards its expenses.

Appointment of members

4.

- (1) All the members of the Authority (including the chairman and deputy chairman who shall be appointed as such) shall be appointed by the Secretary of State.
- (2) In making appointments the Secretary of State shall have regard to the desirability of ensuring that the proceedings of the Authority, and the discharge of its functions, are informed by the views of both men and women.
- (3) The following persons are disqualified for being appointed as chairman or deputy chairman of the Authority—
 - (a) any person who is, or has been, a medical practitioner registered under the Medical Act 1983 (whether fully, provisionally or with limited registration), or under any repealed enactment from which a provision of that Act is derived,
 - (b) any person who is, or has been, concerned with keeping or using gametes or embryos outside the body, and
 - (c) any person who is, or has been, directly concerned with commissioning or funding any research involving such keeping or use, or who has actively participated in any decision to do so.
- (4) The Secretary of State shall secure that at least one-third but fewer than half of the other members of the Authority fall within sub-paragraph (3)(a), (b) or (c) above, and that at least one member falls within each of paragraphs (a) and (b).

4A

- (1) A person (“P”) is disqualified for being appointed as chairman, deputy chairman, or as any other member of the Authority if—**
 - (a) P is the subject of a bankruptcy restrictions order or interim order,**
 - (b) a bankruptcy order has been made against P by a court in Northern Ireland, P’s estate has been sequestered by a court in Scotland, or under the law of Northern Ireland or Scotland, P has made a composition or arrangement with, or granted a trust deed for, P’s creditors, or**
 - (c) in the last five years P has been convicted in the United Kingdom, the Channel Islands or the Isle of Man of an offence and has had a qualifying sentence passed on P.**
- (2) Where P is disqualified under sub-paragraph (1)(b) because a bankruptcy order has been made against P or P’s estate has been sequestered, the disqualification ceases—**
 - (a) on P obtaining a discharge, or**

- (b) if the bankruptcy order is annulled or the sequestration of P's estate is recalled or reduced, on the date of that event.
- (3) Where P is disqualified under sub-paragraph (1)(b) because of P having made a composition or arrangement with, or granted a trust deed for, P's creditors, the disqualification ceases—
 - (a) at the end of the period of five years beginning with the date on which the terms of the deed of composition or arrangement or trust deed are fulfilled, or
 - (b) if, before then, P pays P's debts in full, on the date on which the payment is completed.
- (4) For the purposes of sub-paragraph (1)(c), the date of conviction is to be taken to be the ordinary date on which the period allowed for making an appeal or application expires or, if an appeal or application is made, the date on which the appeal or application is finally disposed of or abandoned or fails by reason of its non-prosecution.
- (5) In sub-paragraph (1)(c), the reference to a qualifying sentence is to a sentence of imprisonment for a period of not less than three months (whether suspended or not) without the option of a fine.

Tenure of office

5

- (1) Subject to the following provisions of this paragraph, a person shall hold and vacate office as a member of the Authority in accordance with the terms of his appointment.
- (2) A person shall not be appointed as a member of the Authority for more than three years at a time.
- (3) A member may at any time resign his office by giving notice to the Secretary of State.
- (4) A person who ceases to be a member of the Authority shall be eligible for re-appointment (whether or not in the same capacity).
- (4A) A person holding office as chairman, deputy chairman or other member of the Authority is to cease to hold that office if the person becomes disqualified for appointment to it.**
- (5) If the Secretary of State is satisfied that a member of the Authority—
 - (a) has been absent from meetings of the Authority for six consecutive months or longer without the permission of the Authority, or
 - (c) is unable or unfit to discharge the **person's functions as chairman, deputy chairman or other member,**

the Secretary of State may **remove the member from office as chairman, deputy chairman or other member.**

Disqualification of members of Authority for House of Commons and Northern Ireland Assembly

6. In Part II of Schedule 1 to the [1975 c. 24.] House of Commons Disqualification Act 1975 and in Part II of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975 (bodies of which all members are disqualified) the following entry shall be inserted at the appropriate place in alphabetical order—

“The Human Fertilisation and Embryology Authority”.

Remuneration and pensions of members

7

- (1) The Authority may—
- (a) pay to the chairman such remuneration, and
 - (b) pay or make provision for paying to or in respect of the chairman or any other member such pensions, allowances, fees, expenses or gratuities,
- as the Secretary of State may, with the approval of the Treasury, determine.
- (2) Where a person ceases to be a member of the Authority otherwise than on the expiry of his term of office and it appears to the Secretary of State that there are special circumstances which make it right for him to receive compensation, the Authority may make to him a payment of such amount as the Secretary of State may, with the consent of the Treasury, determine.

Staff

8

- (1) The Authority may appoint such employees as it thinks fit, upon such terms and conditions as the Authority, with the approval of the Secretary of State and the consent of the Treasury, may determine.
- (2) The Authority shall secure that any employee whose function is, or whose functions include, the inspection of premises is of such character, and is so qualified by training and experience, as to be a suitable person to perform that function.
- (3) The Authority shall, as regards such of its employees as with the approval of the Secretary of State it may determine, pay to or in respect of them such pensions, allowances or gratuities (including pensions, allowances or gratuities by way of compensation for loss of employment), or provide and maintain for them such pension schemes (whether contributory or not), as may be so determined.

- (4) If an employee of the Authority—
- (a) is a participant in any pension scheme applicable to that employment, and
 - (b) becomes a member of the Authority,
- he may, if the Secretary of State so determines, be treated for the purposes of the pension scheme as if his service as a member of the Authority were service as employee of the Authority, whether or not any benefits are to be payable to or in respect of him by virtue of paragraph 7 above.

Proceedings

9

- (1) **Subject to any provision of this Act, the** Authority may regulate its own proceedings, and make such arrangements as it thinks appropriate for the discharge of its functions.
- (2) The Authority may pay to the members of any committee or sub-committee such fees and allowances as the Secretary of State may, with the consent of the Treasury, determine.

10

- (1) A member of the Authority who is in any way directly or indirectly interested in a licence granted or proposed to be granted by the Authority shall, as soon as possible after the relevant circumstances have come to his knowledge, disclose the nature of his interest to the Authority.
- (2) Any disclosure under sub-paragraph (1) above shall be recorded by the Authority.
- (3) Except in such circumstances (if any) as may be determined by the Authority under paragraph 9(1) above, the member shall not participate after the disclosure in any deliberation or decision of the Authority with respect to the licence, and if he does so the deliberation or decision shall be of no effect.

11

The validity of any proceedings of the Authority, or of any committee or sub-committee, shall not be affected by any vacancy among the members or by any defect in the appointment of a member.

Instruments

12

The fixing of the seal of the Authority shall be authenticated by the signature of the chairman or deputy chairman of the Authority or some other member of the Authority authorised by the Authority to act for that purpose.

13

A document purporting to be duly executed under the seal of the Authority, or to be signed on the Authority's behalf, shall be received in evidence and shall be deemed to be so executed or signed unless the contrary is proved.

Investigation by Parliamentary Commissioner

14

The Authority shall be subject to investigation by the Parliamentary Commissioner and accordingly, in Schedule 2 to the Parliamentary Commissioner Act 1967 (which lists the authorities subject to investigation under that Act), the following entry shall be inserted at the appropriate place in alphabetical order—

“Human Fertilisation and Embryology Authority”.

Application of Statutory Instruments Act 1946

15

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

SCHEDULE 2

ACTIVITIES FOR WHICH LICENCES MAY BE GRANTED

Section 11 etc

Licences for treatment

- 1** (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services—
- (a) bringing about the creation of embryos *in vitro*,
 - (b) procuring, keeping, testing, processing or distributing embryos,
 - (c) procuring, testing, processing, distributing or using gametes,
 - (ca) using embryos for the purpose of training persons in embryo biopsies, embryo storage or other embryological techniques,**
 - (d) other practices designed to secure that embryos are in a suitable condition to be placed in a woman,
 - (e) placing any **permitted** embryo in a woman,

- (f) mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of testing the fertility or normality of the sperm, but only where anything which forms is destroyed when the test is complete and, in any event, not later than the two cell stage, and
 - (g) such other practices, **apart from practices falling within section 4A(2)**, as may be specified in, or determined in accordance with, regulations.
- (2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such manner as may be so specified.
- (3) A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services.
- (4) A licence under this paragraph cannot authorise altering the nuclear or mitochondrial DNA of a cell while it forms part of an embryo, except for the purpose of creating something that will by virtue of regulations under section 3ZA(5) be a permitted embryo.**
- (4A) A licence under this paragraph cannot authorise the use of embryos for the purpose mentioned in sub-paragraph (1)(ca) unless the Authority is satisfied that the proposed use of embryos is necessary for that purpose.**
- (5) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.
- (6) In this paragraph, references to a permitted embryo are to be read in accordance with section 3ZA.**

Embryo testing

- 1ZA (1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes—**
- (a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,**
 - (b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,**
 - (c) in a case where there is a particular risk that any resulting child will have or develop -**
 - (i) a gender-related serious physical or mental disability,**
 - (ii) a gender-related serious illness, or**
 - (iii) any other gender-related serious medical condition,**

establishing the sex of the embryo,

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

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

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

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

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

that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.

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

(a) it affects only one sex, or

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

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

Sex selection

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

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

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

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

(b) a gender-related serious illness, or

- (c) any other gender-related serious medical condition.
- (4) For the purposes of sub-paragraph (3), a physical or mental disability, illness or other medical condition is gender-related if the Authority is satisfied that –
 - (a) it affects only one sex, or
 - (b) it affects one sex significantly more than the other.

Power to amend paragraphs 1ZA and 1ZB

1ZC

- (1) Regulations may make any amendment of paragraph 1ZA (embryo testing).
- (2) Regulations under this paragraph which amend paragraph 1ZA may make any amendment of sub-paragraphs (2) to (4) of paragraph 1ZB (sex selection) which appears to the Secretary of State to be necessary or expedient in consequence of the amendment of paragraph 1ZA.
- (3) Regulations under this paragraph may not enable the authorisation of-
 - (a) the testing of embryos for the purpose of establishing their sex, or
 - (b) other practices falling within paragraph 1ZB(1),except on grounds relating to the health of any resulting child.
- (4) For the purposes of this paragraph, “amend” includes add to and repeal, and references to “amendment” are to be read accordingly.

Licences for non-medical fertility services

- 1A** (1) A licence under this paragraph may authorise any of the following in the course of providing non-medical fertility services—
 - (a) processing sperm, and
 - (b) distributing sperm.
- (1A) A licence under this paragraph cannot authorise the procurement or distribution of sperm to which there has been applied any process designed to secure that any resulting child will be of one sex rather than the other.**
- (2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such manner as may be so specified.
- (3) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

Licences for storage

2

- (1) A licence under this paragraph or paragraph 1 or 3 of this Schedule may authorise the storage of gametes or embryos or both.
- (1A) A licence under this paragraph or paragraph 3 may authorise the storage of human admixed embryos (whether or not the licence also authorises the storage of gametes or embryos or both).**
- (2) Subject to the provisions of this Act, a licence authorising such storage **as is mentioned in sub-paragraph (1) or (1A)** may be granted subject to such conditions as may be specified in the licence and may authorise storage in such manner as may be so specified.
- (3) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

Licences for Research

3

- (1) A licence under this paragraph may authorise any of the following-**
 - (a) bringing about the creation of embryos *in vitro*, and**
 - (b) keeping or using embryos,****for the purposes of a project of research specified in the licence.**
- (2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.**
- (3) A licence under this paragraph may authorise any of the following –**
 - (a) bringing about the creation of human admixed embryos *in vitro*, and**
 - (b) keeping or using human admixed embryos,****for the purposes of a project of research specified in the licence.**
- (4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).**

- (5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.**
- (6) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence.**
- (7) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.**
- (8) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.**
- (9) This paragraph has effect subject to paragraph 3A.**

Purposes for which activities may be licensed under paragraph 3

- 3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority -**
- (a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) (“the principal purposes”),**
 - (b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or**
 - (c) to be necessary or desirable for such other purposes as may be specified in regulations.**
- (2) The principal purposes are -**
- (a) increasing knowledge about serious disease or other serious medical conditions,**
 - (b) developing treatments for serious disease or other serious medical conditions,**
 - (c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),**
 - (d) promoting advances in the treatment of infertility,**
 - (e) increasing knowledge about the causes of miscarriage,**
 - (f) developing more effective techniques of contraception,**
 - (g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or**
 - (h) increasing knowledge about the development of embryos.**

- 4 (1) A licence under this Schedule can only authorise activities to be carried on -
- (a) on premises specified in the licence or, in the case of activities to which section 3(1A)(b) or (1B) or 4(1A) applies, on relevant third party premises, and
 - (b) under the supervision of an individual designated in the licence.
- (1A) A licence which authorises activities falling within paragraph 1 or 1A above may not also authorise activities falling within paragraph 3 above.
- (2) A licence cannot—
- (b) apply to more than one project of research,
 - (c) authorise activities to be carried on under the supervision of more than one individual, or
 - (d) apply to premises of the person who holds the licence in different places.

SCHEDULE 3

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

Section 12 etc

Consent

1

- (1) A consent under this Schedule, and any notice under paragraph 4 varying or withdrawing a consent under this Schedule, must be in writing and, subject to sub-paragraph (2), must be signed by the person giving it.**
- (2) A consent under this Schedule by a person who is unable to sign because of illness, injury or physical disability (a “person unable to sign”), and any notice under paragraph 4 by a person unable to sign varying or withdrawing a consent under this Schedule, is to be taken to comply with the requirement of sub-paragraph (1) as to signature if it is signed at the direction of the person unable to sign, in the presence of the person unable to sign and in the presence of at least one witness who attests the signature.**
- (3) In this Schedule “effective consent” means a consent under this Schedule which has not been withdrawn.**

2

- (1) A consent to the use of any embryo must specify one or more of the following purposes—
 - (a) use in providing treatment services to the person giving consent, or that person and another specified person together,
 - (b) use in providing treatment services to persons not including the person giving consent,
 - (ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or**
 - (c) use for the purposes of any project of research,and may specify conditions subject to which the embryo may be so used.
- (1A) A consent to the use of any human admixed embryo must specify use for the purposes of any project of research and may specify conditions subject to which the human admixed embryo may be so used.**

- (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 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies,**
- and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.**
- (2A) **A consent to the use of a person’s human cells to bring about the creation *in vitro* of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person’s death.**
- (2B) **In relation to Scotland, the reference in sub-paragraph (2)(b) to the person lacking capacity is to be read as a reference to the person-**
- (a) **lacking capacity within the meaning of the Age of Legal Capacity (Scotland) Act 1991, or**
 - (b) **being incapable within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000.**
- (3) **A consent under this Schedule must provide for such other matters as the Authority may specify in directions.**
- (4) **A consent under this Schedule may apply—**
- (a) **to the use or storage of a particular embryo or human admixed embryo, or**
 - (b) **in the case of a person providing gametes or human cells, to the use or storage of –**
 - (i) **any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and**
 - (ii) **any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.**
- (5) **In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to –**
- (a) **a particular embryo or particular embryos, or**
 - (b) **a particular human admixed embryo or particular human admixed embryos.**

Procedure for giving consent

- 3 (1) Before a person gives consent under this Schedule—
- (a) he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and
 - (b) he must be provided with such relevant information as is proper.
- (2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4 **and, if relevant, paragraph 4A** below.

Variation and withdrawal of consent

4

- (1) The terms of any consent under this Schedule may from time to time be varied, and the consent may be withdrawn, by notice given by the person who gave the consent to the person keeping the gametes, **human cells, embryo or human admixed embryo** to which the consent is relevant.
- (2) **Subject to sub-paragraph (3), the** terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used—
 - (a) in providing treatment services,
 - (aa) **in training persons in embryo biopsy, embryo storage or other embryological techniques, or**
 - (b) for the purposes of any project of research.
- (3) **Where the terms of any consent to the use of an embryo (“embryo A”) include consent to the use of an embryo or human admixed embryo whose creation may be brought about *in vitro* using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).**
- (4) **Subject to sub-paragraph (5), the terms of any consent to the use of any human admixed embryo cannot be varied, and such consent cannot be withdrawn, once the human admixed embryo has been used for the purposes of any project of research.**
- (5) **Where the terms of any consent to the use of a human admixed embryo (“human admixed embryo A”) include consent to the use of a human admixed embryo or embryo whose creation may be brought about *in vitro* using human admixed embryo A, that consent to the use of that subsequent human admixed embryo or embryo cannot be**

varied or withdrawn once human admixed embryo A has been used for the purposes of any project of research.

- 4A (1) This paragraph applies where -**
- (a) a permitted embryo, the creation of which was brought about *in vitro*, is in storage,**
 - (b) it was created for use in providing treatment services,**
 - (c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation (“P”) gives the person keeping the embryo notice withdrawing P’s consent to the storage of the embryo, and**
 - (d) the embryo was not to be used in providing treatment services to P alone.**
- (2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P’s withdrawal of consent.**
- (3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.**
- (4) Storage of the embryo remains lawful until-**
- (a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or**
 - (b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P’s withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.**
- (5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA.**

Use of gametes for treatment of others

5

- (1) A person's gametes must not be used for the purposes of treatment services **or non-medical fertility services** unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.**
- (2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.**
- (3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.**

- (1) A person's gametes **or human cells** must not be used to bring about the creation of any embryo *in vitro* unless there is an effective consent by that person to any embryo, the creation of which may be brought about with the use of those gametes **or human cells**, being used for one or more of the purposes mentioned in **paragraph 2(1)(a), (b) and (c)** above.
 - (2) An embryo the creation of which was brought about *in vitro* must not be received by any person unless there is an effective consent by **each relevant person in relation to** the embryo to the use for one or more of the purposes mentioned in **paragraph 2(1)(a), (b), (ba) and (c)** above of the embryo.
 - (3) An embryo the creation of which was brought about *in vitro* must not be used for any purpose unless there is an effective consent by each **relevant person in relation to** the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.
- (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.**
- (3A) For the purposes of sub-paragraphs (2), (3) and (3ZB) each of the following is a relevant person in relation to an embryo the creation of which was brought about *in vitro* (“embryo A”) –**
- (a) each person whose gametes or human cells were used to bring about the creation of embryo A,**

- (b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A, and
 - (c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A.
- (4) Any consent required by this paragraph is in addition to any consent that may be required by paragraph 5 above.

Embryos obtained by lavage, etc

7

- (1) An embryo taken from a woman must not be used for any purpose unless there is an effective consent by her to the use of the embryo for that purpose and it is used in accordance with the consent.
- (2) An embryo taken from a woman must not be received by any person for use for any purpose unless there is an effective consent by her to the use of the embryo for that purpose.
- (3) **Sub-paragraphs (1) and (2) do not apply to the use, for the purpose of providing a woman with treatment services, of an embryo taken from her.**
- (4) **An embryo taken from a woman must not be used to bring about the creation of any embryo *in vitro* or any human admixed embryo *in vitro*.**

Storage of gametes and embryos

8

- (1) A person's gametes must not be kept in storage unless there is an effective consent by that person to their storage and they are stored in accordance with the consent.
- (2) An embryo the creation of which was brought about *in vitro* must not be kept in storage unless there is an effective consent, by each **relevant person in relation to** the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.
- (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.

- (2A) For the purposes of sub-paragraphs (2) and (2ZA), each of the following is a relevant person in relation to an embryo the creation of which was brought about *in vitro* (“embryo A”)—
- (a) each person whose gametes or human cells were used to bring about the creation of embryo A,
 - (b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A, and
 - (c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A.
- (3) An embryo taken from a woman must not be kept in storage unless there is an effective consent by her to its storage and it is stored in accordance with the consent.
- (4) Sub-paragraph (1) has effect subject to paragraphs 9 and 10; and sub-paragraph (2) has effect subject to paragraphs 4A(4), 15B and 15F.

Cases where consent not required for storage

9

- (1) The gametes of a person (“C”) may be kept in storage without C’s consent if the following conditions are met.
- (2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.
- (3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner—
 - (a) the treatment is likely to cause a significant impairment of C’s fertility, and
 - (b) the storage of the gametes is in C’s best interests.
- (4) Condition C is that, at the time when the gametes are first stored, either—
 - (a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or
 - (b) C has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.
- (5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes—

- (a) given consent under this Schedule to the storage of the gametes, or
 - (b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.
- (6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications-
- (a) for sub-paragraph (4), substitute-
 - “(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.”, and
 - (b) in sub-paragraph (5), for “becoming competent to deal with the issue of consent to the storage of the gametes” substitute “acquiring such capacity”.

10

- (1) The gametes of a person (“P”) may be kept in storage without P’s consent if the following conditions are met.
- (2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.
- (3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner-
 - (a) the treatment is likely to cause a significant impairment of P’s fertility,
 - (b) P lacks capacity to consent to the storage of the gametes,
 - (c) P is likely at some time to have that capacity, and
 - (d) the storage of the gametes is in P’s best interests.
- (4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.
- (5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule—
 - (a) given consent to the storage of the gametes, or
 - (b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.
- (6) In relation to Scotland -
 - (a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,
 - (b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and

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

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

Creation, use and storage of human admixed embryos

13

- (1) A person's gametes or human cells must not be used to bring about the creation of any human admixed embryo *in vitro* unless there is an effective consent by that person to any human admixed embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for the purposes of any project of research.
- (2) A human admixed embryo the creation of which was brought about *in vitro* must not be received by any person unless there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for the purposes of any project of research.
- (3) A human admixed embryo the creation of which was brought about *in vitro* must not be used for the purposes of a project of research unless –
 - (a) there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for that purpose, and
 - (b) the human admixed embryo is used in accordance with those consents.
- (4) If the Authority is satisfied that the parental consent conditions in paragraph 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 16 and 20.

14

- (1) A human admixed embryo the creation of which was brought about *in vitro* must not be kept in storage unless -
 - (a) there is an effective consent by each relevant person in relation to the human admixed embryo to the storage of the human admixed embryo, and
 - (b) the human admixed embryo is stored in accordance with those consents.
- (2) Where a licence authorises the application of paragraph 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.

- 14 For the purposes of paragraphs 12 and 13, each of the following is a relevant person in relation to a human admixed embryo the creation of which was brought about *in vitro* (“human admixed embryo A”)—
- (a) each person whose gametes or human cells were used to bring about the creation of human admixed embryo A,
 - (b) each person whose gametes or human cells were used to bring about the creation of any embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of human admixed embryo A, and
 - (c) each person whose gametes or human cells were used to bring about the creation of any other human admixed embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of human admixed embryo A.

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 cells or cell lines

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 20

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

- (6) In sub-paragraph (5) “the HTA consent provisions” means subsections (4), (5), (6), (7) and (8)(a) and (b) of section 27 of the Human Tissue Act 2004.**
- (7) In this paragraph references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.**
- (8) Paragraphs 1 to 4 of this Schedule do not apply in relation to a consent given for the purposes of sub-paragraph (3)(c).**

Interpretation

16

- (1) In this Schedule references to human cells are to human cells which are not-**
 - (a) cells of the female or male germ line, or**
 - (b) cells of an embryo.**
- (2) References in this Schedule to an embryo or a human admixed embryo which was used to bring about the creation of an embryo (“embryo A”) or a human admixed embryo (“human admixed embryo A”) include an embryo or, as the case may be, a human admixed embryo which was used to bring about the creation of –**
 - (a) an embryo or human admixed embryo which was used to bring about the creation of embryo A or human admixed embryo A, and**
 - (b) the predecessor of that embryo or human admixed embryo mentioned in paragraph (a), and**
 - (c) the predecessor of that predecessor, and so on.**
- (3) Reference in this Schedule to an embryo or a human admixed embryo whose creation may be brought about using an embryo or a human admixed embryo are to be read in accordance with sub-paragraph (2).**
- (4) Reference in this Schedule (however expressed) to the use of human cells to bring about the creation of an embryo or a human admixed embryo include the use of human cells to alter the embryo or, as the case may be, the human admixed embryo.**
- (5) References in this Schedule to parental responsibility are-**
 - (a) in relation to England and Wales, to be read in accordance with the Children Act 1989,**
 - (b) in relation to Northern Ireland, to be read in accordance with the Children (Northern Ireland) Order 1995, and**

- (c) in relation to Scotland, to be read as references to parental responsibilities and parental rights within the meaning of the Children (Scotland) Act 1995.**
- (6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.**
- (7) References in this Schedule to the age of 18 years are, in relation to Scotland, to be read as references to the age of 16 years.**

SCHEDULE 3ZA

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

PART 1

KINDS OF TREATMENT IN RELATION TO WHICH COUNSELLING MUST BE OFFERED

- 1 The treatment services involve the use of the gametes of any person and that person's consent is required under paragraph 5 of Schedule 3 for the use in question.**
- 2 The treatment services involve the use of any embryo the creation of which was brought about *in vitro*.**
- 3 The treatment services involve the use of an embryo taken from a woman and the consent of the woman from whom the embryo was taken was required under paragraph 7 of Schedule 3 for the use in question.**

PART 2

EVENTS IN CONNECTION WITH WHICH COUNSELLING MUST BE OFFERED

- 4 A man gives the person responsible a notice under paragraph (a) of subsection (1) of section 37 of the Human Fertilisation and Embryology Act 2008 (agreed fatherhood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to the man.**
- 5 The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the man to whom the notice relates has previously given a notice under paragraph (a) of that subsection.**
- 6 A woman gives the person responsible notice under paragraph (a) of subsection (1) of section 44 of that Act (agreed female parenthood conditions) in a case where the woman for whom the treatment services are provided has previously given a notice under paragraph (b) of that subsection referring to her.**
- 7 The woman for whom the treatment services are provided gives the person responsible a notice under paragraph (b) of that subsection in a case where the other woman to whom the notice relates has previously given a notice under paragraph (a) of that subsection.**

SCHEDULE 3A

SUPPLEMENTARY LICENCE CONDITIONS: HUMAN APPLICATION

Section 14A

Traceability and coding system

- 1 Licence conditions shall require that all persons to whom a licence applies adopt such systems as the Authority considers appropriate to secure—
 - (a) in relation to traceability, compliance with the requirements of Article 8 (traceability) of the first Directive and Article 9 (traceability) of the third Directive, and
 - (b) in relation to the coding of information, compliance with the requirements of Article 25 (coding of information) of the first Directive and Article 10 (European coding system) of the third Directive.
- 2 Licence conditions imposed in accordance with paragraph 1 may specify the coding system which must be applied in relation to gametes and embryos intended for human application.

Serious adverse events and serious adverse reactions

- 3 Licence conditions shall require such—
 - (a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and
 - (b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,to be in place as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.

Third party agreements and termination of licensed activities

- 4 For the purpose of securing compliance with the requirements of Articles 21(5) (tissue and cell storage conditions) and 24 (relations between tissue establishments and third parties) of the first Directive, licence conditions shall specify the requirements that must be met in relation to the termination of storage activities authorised by the licence and in relation to third party agreements.

Requirements for procurement of gametes and embryos

- 5 Licence conditions shall require all persons to whom a licence applies who are authorised to procure gametes or embryos, or both, to comply with the requirements (including as to staff training, written agreements with staff, standard operating procedures, and appropriate facilities and equipment) laid down in Article 2 (requirements for the procurement of human tissues and cells) of the second Directive.

Selection criteria and laboratory tests required for donors of reproductive cells

- 6 In relation to partner-donated sperm which is not intended to be used without processing or storage, licence conditions shall require compliance with the selection criteria for donors and the requirements for laboratory tests laid down in section 2 (partner donation (not direct use)) of Annex III (selection criteria and laboratory tests required for donors of reproductive cells) to the second Directive.
- 7 In relation to donations of gametes or embryos other than partner-donated sperm or partner-created embryos, licence conditions shall require compliance with the selection criteria for donors and the requirements for laboratory tests laid down in section 3 (donations other than by partners) of Annex III to the second Directive.
- 8 Licence conditions shall require that the laboratory tests required by sections 2 and 3 of Annex III to the second Directive to be carried out for the purpose of selecting gametes or embryos for donation, meet the requirements of section 4 (general requirements to be met for determining biological markers) of Annex III to the second Directive.

Donation and procurement procedures and reception at the tissue establishment

- 9 In relation to—
- (a) donation and procurement procedures, and
 - (b) the reception of gametes and embryos at the premises to which a licence relates or at relevant third party premises,
- licence conditions shall require compliance with the requirements of Article 15(3) (selection, evaluation and procurement) and Article 19(4) to (6) (tissue and cell reception) of the first Directive and with the requirements laid down in the provisions of the second Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

1. Donation and procurement procedures	Relevant provisions of the second Directive
Consent and donor identification (record of consent, method of identification, donor review)	Annex IV, point 1.1
Donor evaluation: other than partner-donated sperm and partner-created embryos and autologous donors (assessment of donor's medical and behavioural information)	Annex IV, point 1.2
Procurement procedures for gametes and embryos (requirements relating to procurement procedures and instruments)	Annex IV, point 1.3
Donor documentation (record of donor and the procurement)	Annex IV, point 1.4
Packaging (requirements as to packaging and shipping containers)	Annex IV, point 1.5
Labelling of the procured gametes and embryos (minimum labelling requirements)	Annex IV, point 1.6
Labelling of the shipping container (minimum labelling requirements)	Annex IV, point 1.7
2. Reception of tissues and cells at the tissue establishment	
Verification upon arrival (procedures for verification and requirement for quarantine until verification)	Annex IV, points 2.1 to 2.3
Registration of data (other than in respect of partner-donated sperm and partner-created embryos)	Annex IV, point 2.4
Registration of data (partner-donated sperm and partner-created embryos)	Annex IV, point 2.5

Requirements for holding a licence under paragraph 1, 1A or 2 of Schedule 2

- 10** Licence conditions shall require compliance with the requirements laid down in the provisions of the third Directive listed in the right-hand column, the

subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Organisation and management (requirements as to organisational structure, management systems, and third party agreements)	Annex I, Part A
Personnel (number, competence, responsibilities and training)	Annex I, Part B
Equipment and materials (appropriate for use, validation, maintenance, and specifications)	Annex I, Part C
Facilities and premises (suitability, environment, storage, and maintenance)	Annex I, Part D
Documentation and records (standard operating procedures, document control, record reliability)	Annex I, Part E
Quality review (quality management system, investigations, corrective action, and reviews)	Annex I, Part F

Requirements for holding a licence for gametes and embryo preparation processes

11 In respect of gametes and embryos preparation processes, licence conditions shall require compliance with—

- (a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and
- (b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Reception of gametes and embryos at the tissue establishment	Annex II, Part A
Processing of gametes and embryos (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of gametes and embryos (criteria to be complied with, including standard operating	Annex II, Part C

procedure)	
Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of gametes and embryo containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F

Interpretation of this Schedule

- 12** In this Schedule, “partner-created embryos” means embryos created using the gametes of a man and a woman who declare that they have an intimate physical relationship.

SCHEDULE 3B

INSPECTION, ENTRY, SEARCH AND SEIZURE

Inspection of statutory records

1

- (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.**
- (2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection—**
 - (a) in a visible and legible form, or**
 - (b) in a form from which they can be readily produced in a visible and legible form.**
- (3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.**

Arranging inspections

2

- (1) Where a person -**
 - (a) makes an enquiry to the Authority which concerns the making of a relevant application by that person, or**
 - (b) has made a relevant application to the Authority which the Authority has not yet considered,**

the Authority may arrange for a duly authorised person to inspect any of the premises mentioned in sub-paragraph (3).
- (2) For the purposes of sub-paragraph (1) a “relevant application” means-**
 - (a) an application for authorisation for a person to carry on an activity governed by this Act which the person is not then authorised to carry on, or**
 - (b) an application for authorisation for a person to carry on any such activity on premises where the person is not then authorised to carry it on.**
- (3) The premises referred to in sub-paragraph (1) are—**

- (a) the premises where any activity referred to in sub-paragraph (2) is to be carried on;
- (b) any premises that will be relevant third party premises for the purposes of any application.

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

Entry and inspection of premises

3

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

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

4

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

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

Entry and search in connection with suspected offence

5

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

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

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

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

(2) The conditions referred to are—

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

(b) that the premises are unoccupied;

(c) that the occupier is temporarily absent;

- (d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.
- (3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.
- (4) In relation to Scotland –
 - (a) any reference in sub-paragraph (1) to a justice of the peace includes any reference to a sheriff, and
 - (b) the reference in that sub-paragraph to “on sworn information” is to be read as a reference to “by evidence on oath”.

Execution of warrants

- 6**
- (1) Entry and search under a warrant under paragraph 5 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.
 - (2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.
 - (3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—
 - (a) produce the warrant to the occupier, and
 - (b) give the occupier -
 - (i) a copy of the warrant, and
 - (ii) an appropriate statement.
 - (4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—
 - (a) produce the warrant to that other person,
 - (b) give that other person -
 - (i) a copy of the warrant, and
 - (ii) an appropriate statement, and
 - (c) leave a copy of the warrant in a prominent place on the premises.
 - (5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State.
 - (6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

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

Seizure in the course of inspection or search

7

- (1) A duly authorised person entering and inspecting premises under paragraph 3 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for -
- (a) the purposes of the Authority's functions relating to the grant, revocation, variation or suspension of licences, or
 - (b) the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction.
- (2) A duly authorised person entering or searching premises under a warrant under paragraph 5 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under this Act.
- (3) Where a person has power under sub-paragraph (1) or (2) to seize anything, that person may take such steps as appear to be necessary for preserving that thing or preventing interference with it.
- (4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.
- (5) Where by virtue of sub-paragraph (1) or (2) a person ("P") seizes anything, P shall leave on the premises from which the thing was seized a statement giving particulars of what P has seized and stating that P has seized it.

Supplementary provision

8

- (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.
- (2) Power under this Schedule to inspect or search any premises includes, in particular—
- (a) power to inspect any equipment found on the premises,
 - (b) power to inspect and take copies of any records found on the premises, and

- (c) in the case of premises to which a licence relates or premises which are relevant third party premises in relation to a licence, power to observe the carrying-on of the licensed activity on the premises.
- (3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

9

- (1) A person's right to exercise a power under this Schedule is subject to production of evidence of the person's entitlement to exercise it, if required.
- (2) As soon as reasonably practicable after having inspected premises in pursuance of arrangements made under paragraph 2 or after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall—
- (a) prepare a written report of the inspection, or as the case may be, the inspection and search, and
 - (b) if requested to do so by the appropriate person, give the appropriate person a copy of the report.
- (3) In sub-paragraph (2), the "appropriate person" means—
- (a) in relation to premises to which a licence relates, the person responsible, or
 - (b) in relation to any other premises, the occupier.

Enforcement

10 A person who —

- (a) fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 8(3), or
- (b) intentionally obstructs the exercise of any right under this Schedule,

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

Interpretation

11 In this Schedule—

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

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

SCHEDULE 4

MINOR AND CONSEQUENTIAL AMENDMENTS

Section 49

Family Law Reform Act 1969 (c. 46.)

- 1** In section 25 of the Family Law Reform Act 1969 (interpretation), at the end of the definition of "excluded" there is added "to section 27 of the Family Law Reform Act 1987 and to sections 27 to 29 of the Human Fertilisation and Embryology Act 1990".

Family Law Reform (Northern Ireland) Order 1977 (S.I. 1977/1250 (N.I. 17))

- 5** In Article 13 of the Family Law Reform (Northern Ireland) Order 1977 (interpretation), at the end of the definition of "excluded" there is added "and to sections 27 to 29 of the Human Fertilisation and Embryology Act 1990".

Adoption (Scotland) Act 1978 (c. 28.)

- 6** In section 15 of the Adoption (Scotland) Act 1978 (adoption by one person), in subsection (3)(a) (conditions for making an adoption order on application of one parent), after "found" there is inserted "or, by virtue of section 28 of the Human Fertilisation and Embryology Act 1990, there is no other parent".

Adoption (Northern Ireland) Order 1987 (S.I. 1987/2203 (N.I. 22))

- 7** In Article 15 of the Adoption (Northern Ireland) Order 1987 (adoption by one person), in paragraph (3)(a) (conditions for making an adoption order on the application of one parent), after "found" there is inserted "or, by virtue of section 28 of the Human Fertilisation and Embryology Act 1990, there is no other parent".