Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)



Human Fertilisation and Embryology Act 1990

1990 CHAPTER 37

An Act to make provision in connection with human embryos and any subsequent development of such embryos; to prohibit certain practices in connection with embryos and gametes; to establish a Human Fertilisation and Embryology Authority; to make provision about the persons who in certain circumstances are to be treated in law as the parents of a child; and to amend the Surrogacy Arrangements Act 1985.

[1st November 1990]

Be it enacted by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

Modifications etc. (not altering text)

C1 Act modified (temp.) by S.I. 1991/1400, art.3
Act modified by S.I. 1991/1400, art. 4(3)
Act referred to (S.) (1.4.1997) by S.I. 1997/291, rules 2.45-2.59 (Ch. 2 Pt. VI)

Principal terms used

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

- (1) In this Act, except where otherwise stated—
 - (a) embryo means a live human embryo where fertilisation is complete, and
 - (b) references to an embryo include an egg in the process of fertilisation, and, for this purpose, fertilisation is not complete until the appearance of a two cell zygote.

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- (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 is complete) are to those where fertilisation 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) References in this Act to gametes, eggs or sperm, except where otherwise stated, are to live human gametes, eggs or sperm but references below in this Act to gametes or eggs do not include eggs in the process of fertilisation.
- [F1(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. F1]

Textual Amendments

F1 S. 1(5) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, {4}

Modifications etc. (not altering text)

- C2 S. 1(1) applied (1.4.2005 for certain purposes, 20.10.2005 for certain further purposes, 7.4.2006 for certain further purposes, 31.7.2006 for certain further purposes and 1.9.2006 otherwise) by Human Tissue Act 2004 (c. 30), s. 54(6) (with transitional provisions in s. 58); S.I 2005/919, {art. 3}, Sch. (with transitional provisions in art. 2); S.I. 2005/2792, art. 2(d); S.I. 2006/404, art. 3(3), Sch. (subject to art. 4); S.I. 2006/1997, art. 2(1)(2), 3(1)(2), Sch. (subject to arts. 4, 7, 8) (as that S.I. is amended by S.I. 2006/2169, art. 2)
- C3 S. 1(4) applied (1.4.2005 for certain purposes, 20.10.2005 for certain further purposes, 7.4.2006 for certain further purposes, 31.7.2006 for certain further purposes and 1.9.2006 otherwise) by Human Tissue Act 2004 (c. 30), s. 54(6) (with transitional provisions in s. 58); S.I 2005/919, {art. 3}, Sch. (with transitional provisions in art. 2); S.I. 2005/2792, art. 2(d); S.I. 2006/404, art. 3(3), Sch. (subject to art. 4); S.I. 2006/1997, art. 2(1)(2), 3(1)(2), Sch. (subject to arts. 4, 7, 8) (as that S.I. is amended by S.I. 2006/2169, art. 2)

Commencement Information

II S. 1 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

[F21A

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

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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.]

Textual Amendments

F2 S. 1A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 5

2 Other terms.

(1) In this Act—

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

[F3.cbasic 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,]

[F4F3ccompetent 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,]

F4" directions" means directions under section 23 of this Act,

[F5.cdistribution", in relation to gametes or embryos intended for human application, means transportation or delivery, and related terms are to be interpreted accordingly,]

[F6F5"human application" means use in a human recipient,]

F6"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, and

[^{F7} 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,]

[F8F7" 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,]

[^{F9F8}"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,]

[F10F9"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—

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- (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,

[FIIF10" 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,]

[F12F11"store", in relation to gametes or embryos, means preserve, whether by cryopreservation or in any other way, and "storage" and "stored" are to be interpreted accordingly,]

I^{F13F12} "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) to 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,]

F13"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 or gametes, include keeping while preserved [F14 in storage]F14.
- [F15(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.]
 - F15(3) For the purposes of this Act, a woman is not to be treated as carrying a child until the embryo has become implanted.

Textual Amendments

- F3 Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(2)
- F4 Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(2)
- Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(2)
- **F6** Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **6(2)**

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- F7 Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(2)
- F8 Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(2)
- Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(2)
- F10 Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(2)
- F11 Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(2)
- F12 Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(2)
- **F13** Words in s. 2(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **6(2)**
- F14 Words in s. 2(2) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(3)
- F15 S. 2(2A)(2B) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 6(4)

Commencement Information

I2 S. 2 wholly in force at 1.8.1991 see s. 49(2), S.I. 1990/2165 and S.I. 1991/1440, art. 2(2)

[F162A

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 or 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

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(c) any person acting under the direction of a third party or of any person so designated.]

Textual Amendments

F16 S. 2A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 7

Activities governed by the Act

3 Prohibitions in connection with embryos.

- I^{F17}(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.]
- F17(2) No person shall place in a woman—
 - (a) a live embryo other than a human embryo, or
 - (b) any live gametes other than human gametes.
 - (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,
 - (c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or
 - (d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.
 - (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 when the gametes are mixed, not counting any time during which the embryo is stored.

Textual Amendments

F17 S. 3(1)-(1B) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) for s. 3(1) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 8

Commencement Information

I3 S. 3 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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[F183A Prohibition 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.

Textual Amendments

F18 S. 3A inserted (10.4.1995) by 1994 c. 33, s. 156(2); S.I. 1995/721, art. 2, Sch.

4 Prohibitions in connection with gametes.

- (1) No person shall—
 - (a) store any gametes, or
 - [F19(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, or
 - F19(c) mix gametes with the live gametes of any animal, except in pursuance of a licence.
- [F20(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.]
 - F20(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 of this Act are referred to in this Act as "activities governed by this Act".

Textual Amendments

- F19 S. 4(1)(b) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 9(2)
- **F20** S. 4(1A) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **9(3)**

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Commencement Information

I4 S. 4 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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 report for the first twelve months of its existence, and a report for each succeeding period of twelve months, and 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.

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(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.

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, and
- (d) perform such other functions as may be specified in regulations.

Commencement Information

I5 S. 8 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

[F218A

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.]

Textual Amendments

F21 S. 8A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 10

9 Licence committees and other committees.

- (1) The Authority shall maintain one or more committees to discharge the Authority's functions relating to the grant, variation, suspension and revocation of licences, and a committee discharging those functions is referred to in this Act as a "licence committee".
- (2) The Authority may provide for the discharge of any of its other functions by committees or by members or employees of the Authority.
- (3) A committee (other than a licence committee) may appoint sub-committees.

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- (4) Persons, committees or sub-committees discharging functions of the Authority shall do so in accordance with any general directions of the Authority.
- (5) A licence committee shall consist of such number of persons as may be specified in or determined in accordance with regulations, all being members of the Authority, and shall include at least one person who is not authorised to carry on or participate in any activity under the authority of a licence and would not be so authorised if outstanding applications were granted.
- (6) A committee (other than a licence committee) or a sub-committee may include a minority of persons who are not members of the Authority.
- (7) Subject to subsection (10) below, a licence committee, before considering an application for authority—
 - (a) for a person to carry on an activity governed by this Act which he is not then authorised to carry on, or
 - (b) for a person to carry on any such activity on premises where he is not then authorised to carry it on,

shall arrange for the premises where the activity is to be carried on to be inspected on its behalf, and for a report on the inspection to be made to it.

- [F22(7A)] Before considering such an application, the licence committee may also arrange for—
 - (a) any premises that will be relevant third party premises for the purposes of the application to be inspected on its behalf, and
 - (b) a report on the inspection to be made to it.]
- [F23F22(8) A licence committee shall arrange for any premises to which a licence relates to be inspected on its behalf at intervals not exceeding two years, and for a report on the inspection to be made to it.]

F23(9)	F24	1																
1/	,																	

- (10) A licence committee need not comply with subsection (7) above where the premises in question have been inspected in pursuance of that subsection or subsection (8) above at some time during the period of [F25] two years] F25 ending with the date of the application, and the licence committee considers that a further inspection is not necessary.
- [F26(10A) A licence committee may arrange for any relevant third party premises to be inspected on its behalf and for a report on the inspection to be made to it.]
 - F26(11) An inspection in pursuance of subsection [F27(7), (7A), (8) or (10A)]F27 above may be carried out by a person who is not a member of a licence committee.

Textual Amendments

- F22 S. 9(7A) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 11(2)
- F23 S. 9(8) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 11(3)
- F24 S. 9(9) omitted (25.5.2007 for certain purposes, otherwise 5.7.2007) by virtue of The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 11(4)
- **F25** Words in s. 9(10) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **11(5)**

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- **F26** S. 9(10A) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **11(6)**
- F27 Words in s. 9(11) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 11(7)

Commencement Information

I6 S. 9 wholly in force; s. 9 not in force at Royal Assent see s. 49(2); s. 9(5) in force at 8.7.1991 for certain purposes and s. 9 fully in force at 1.8.1991 by S.I. 1991/1400, art. 2(1)(a)(2)

10 Licensing procedure.

- (1) Regulations may make such provision as appears to the Secretary of State to be necessary or desirable about the proceedings of licence committees and of the Authority on any appeal from such a committee.
- (2) The regulations may in particular include provision—
 - (a) for requiring persons to give evidence or to produce documents, and
 - (b) about the admissibility of evidence.

Commencement Information

I7 S. 10 wholly in force; s. 10 not in force at Royal Assent see s. 49(2); s. 10 partly in force for certain purposes at 8.7.1991 and s. 10 fully in force at 1.8.1991 by S.I. 1991/1400, art. 2(1)(a)(2)

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,
 - [F28(aa) licences under paragraph 1A of that Schedule authorising activities in the course of providing non-medical fertility services,]
 - F28(b) licences under that Schedule authorising the storage of gametes and 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.

Textual Amendments

F28 S. 11(1)(aa) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 12

Commencement Information

I8 S. 11 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Licence conditions

12 General conditions.

[F29(1)] The following shall be conditions of every licence granted under this Act—

- (a) [F30 except to the extent that the activities authorised by the licence fall within paragraph (aa), that those activities]F30 shall be carried on only on the premises to which the licence relates and under the supervision of the person responsible,
- [F31(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,]
 - f31(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) [F32 except in relation to the use of gametes in the course of providing basic partner treatment services or non-medical fertility services,]F32 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 or embryos unless authorised by directions,
 - (f) that, where gametes or 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.

[F33(2) Subsection (3) applies to—

- (a) every licence under paragraph 1 or 1A of Schedule 2, and
- (b) every licence under paragraph 2 of that Schedule, so far as authorising the storage of gametes or embryos 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.^{F33}]

Textual Amendments

- F29 S. 12 renumbered as s. 12(1) (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 13(2)
- **F30** Words in s. 12(1)(a) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **13(3)(a)**
- F31 S. 12(1)(aa) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 13(3)(b)
- **F32** Words in s. 12(1)(c) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **13(3)(c)**

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F33 S. 12(2)(3) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 13(4)

Commencement Information

I9 S. 12 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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 [F34, other than basic partner treatment services,]F34 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 a father), and of any other child who may be affected by the birth.
- (6) A woman shall not be provided with any treatment services involving—
 - (a) the use of any gametes of any person, if that person's consent is required under paragraph 5 of Schedule 3 to this Act for the use in question,
 - (b) the use of any embryo the creation of which was brought about in vitro, or
 - (c) the use of any embryo taken from a woman, if the consent of the woman from whom it was taken is required under paragraph 7 of that Schedule for the use in question,

unless the woman being treated and, where she is being treated together with a man, the man have been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and have been provided with such relevant information as is proper.

- (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

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(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.

Textual Amendments

F34 Words in s. 13(5) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 14

Commencement Information

I10 S. 13 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

$I^{F35}13A$

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.
- (4) Donors of sperm, other than partner-donated sperm, shall be provided with such information as the Authority shall specify in directions for the purpose of securing compliance with the requirements of Part A of the Annex to the first Directive (information to be provided on the donation of reproductive cells).]

Textual Amendments

F35 S. 13A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **15**

14 Conditions of storage licences.

- (1) The following shall be conditions of every licence authorising the storage of gametes or embryos—
 - (a) that gametes of a person or an embryo taken from a woman shall be placed in storage only if received from that person or woman or acquired from a person to whom a licence [F36 or third party agreement]F36 applies and 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 [F36 or third party agreement]F36 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,
 - (c) that no gametes or embryos 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

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- (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 five years as the licence may specify.
- (5) Regulations may provide that subsection (3) or (4) above shall have effect as if for ten years or, as the case may be, five 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.

Textual Amendments

F36 Words in s. 14(1)(a) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **16**

Modifications etc. (not altering text)

- C4 S. 14(3) modified by S.I. 1991/1540, art. 2(1), Sch.
- C5 S. 14(4) applied (with modifications) (1.5.1996) by S.I. 1996/375, reg. 2(2)(3)

Commencement Information

III S. 14 wholly in force; s. 14 not in force at Royal Assent see s. 49(2); s. 14(5) in force for certain purposes at 8.7.1991 and s. 14 fully in force at 1.8.1991 by S.I. 1991/1400, art. 2(1)(a)(2)

[F3714A

Conditions of licences: human application

- (1) This section applies to—
 - (a) every licence under paragraph 1 or 1A of Schedule 2, and
 - (b) every licence under paragraph 2 of that Schedule, so far as authorising storage of gametes or embryos 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.

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(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.]

Textual Amendments

F37 S. 14A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 17

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.

Commencement Information

I12 S. 15 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

IF3815A

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.]

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Textual Amendments

F38 S. 15A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **18**

Grant, revocation and suspension of licences

16 Grant of licence.

- (1) Where application is made to the Authority in a form approved for the purpose by it accompanied by the initial fee, a licence may be granted to any person by a licence committee if the requirements of subsection (2) below are met and any additional fee is paid.
- (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 licence committee is satisfied that the applicant is a suitable person to hold a licence,
 - [F39(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, 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 licence committee 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,
 - in relation to a licence under paragraph 2 of Schedule 2 authorising storage of gametes or embryos not intended for human application or a licence under paragraph 3 of that Schedule, that the licence committee is satisfied that the qualifications and experience of that individual are such as are required for the supervision of the activities,
 - (cb) that the licence committee 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.]
 - that the licence committee is satisfied that the premises in respect of which the licence is to be granted 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.

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- (4) Where the licence committee 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 licence committee 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.
- (6) In subsection (1) above "initial fee" and "additional fee" mean a fee of such amount as may be fixed from time to time by the Authority with the approval of the Secretary of State and the Treasury, and in determining any such amount, the Authority may have regard to the costs of performing all its functions.
- (7) Different fees may be fixed for different circumstances and fees paid under this section are not repayable.

Textual Amendments

F39 S. 16(2)(c)-(cb) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) for s. 16(2)(c) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 19

Commencement Information

II3 S. 16 wholly in force; s. 16 not in force at Royal Assent see s. 49(2); s. 16(1)(6) in force for certain purposes at 8.7.1991 and s. 16 fully in force at 1.8.1991 by s.I. 1991/1400, art. 2(1)(b)(c)(2)

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 and embryos and for the disposal of gametes or embryos that have been allowed to perish,
 - (d) that suitable practices are used in the course of the activities, ^{F40}...
 - (e) that the conditions of the licence are complied with,
 - [F41(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.]
- F41(2) References in this Act to the persons to whom a licence applies are to—
 - (a) the person responsible,

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- (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.
- (3) References below in this Act to the nominal licensee are to a person who holds a licence under which a different person is the person responsible.

Textual Amendments

- **F40** Word in s. 17(1) omitted (25.5.2007 for certain purposes, otherwise 5.7.2007) by virtue of The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **20**
- **F41** S. 17(1)(f)(g) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **20**

Commencement Information

I14 S. 17 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

18 Revocation and variation of licence.

- (1) A licence committee may revoke a licence if it is satisfied—
 - (a) that any information given for the purposes of the application for the grant of the licence was in any material respect false or misleading,
 - (b) that the premises to which the licence relates are no longer suitable for the activities authorised by the licence,
 - [F42(ba) that any premises which are relevant third party premises in relation to the licence are not suitable for the activities entrusted to the third party by the person who holds the licence,]
 - that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17 of this Act or has failed to comply with directions given in connection with any licence, or
 - (d) that there has been any other material change of circumstances since the licence was granted.
- (2) A licence committee may also revoke a licence if—
 - (a) it ceases to be satisfied that the character of the person responsible is such as is required for the supervision of those activities or that the nominal licensee is a suitable person to hold a licence, or
 - (b) the person responsible dies or is convicted of an offence under this Act.
- (3) Where a licence committee has power to revoke a licence under subsection (1) above it may instead vary any terms of the licence.
- (4) A licence committee may, on an application by the person responsible or the nominal licensee, vary or revoke a licence.
- (5) A licence committee may, on an application by the nominal licensee, vary the licence so as to designate another individual in place of the person responsible if—
 - (a) the committee is satisfied that the character, qualifications and experience of the other individual are such as are required for the supervision of the activities

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- authorised by the licence and that the individual will discharge the duty under section 17 of this Act, and
- (b) the application is made with the consent of the other individual.
- (6) Except on an application under subsection (5) above, a licence can only be varied under this section—
 - (a) so far as it relates to the activities authorised by the licence, the manner in which they are conducted or the conditions of the licence, or
 - (b) so as to extend or restrict the premises to which the licence relates.

Textual Amendments

F42 S. 18(1)(ba) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 21

Commencement Information

I15 S. 18 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

19 Procedure for refusal, variation or revocation of licence.

- (1) Where a licence committee proposes to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, the committee shall give notice of the proposal, the reasons for it and the effect of subsection (3) below to the applicant.
- (2) Where a licence committee proposes to vary or revoke a licence, the committee shall give notice of the proposal, the reasons for it and the effect of subsection (3) below to the person responsible and the nominal licensee (but not to any person who has applied for the variation or revocation).
- (3) If, within the period of twenty-eight days beginning with the day on which notice of the proposal is given, any person to whom notice was given under subsection (1) or (2) above gives notice to the committee of a wish to make to the committee representations about the proposal in any way mentioned in subsection (4) below, the committee shall, before making its determination, give the person an opportunity to make representations in that way.
- (4) The representations may be—
 - (a) oral representations made by the person, or another acting on behalf of the person, at a meeting of the committee, and
 - (b) written representations made by the person.

(5) A licence committee shall—

- (a) in the case of a determination to grant a licence, give notice of the determination to the person responsible and the nominal licensee,
- (b) in the case of a determination to refuse a licence, or to refuse to vary a licence so as to designate another individual in place of the person responsible, give such notice to the applicant, and
- (c) in the case of a determination to vary or revoke a licence, give such notice to the person responsible and the nominal licensee.

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(6) A licence committee giving notice of a determination to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, or of a determination to vary or revoke a licence otherwise than on an application by the person responsible or the nominal licensee, shall give in the notice the reasons for its decision.

Commencement Information

I16 S. 19 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

20 Appeal to Authority against determinations of licence committee.

- (1) Where a licence committee determines to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, the applicant may appeal to the Authority if notice has been given to the committee and to the Authority before the end of the period of twenty-eight days beginning with the date on which notice of the committee's determination was served on the applicant.
- (2) Where a licence committee determines to vary or revoke a licence, any person on whom notice of the determination was served (other than a person who applied for the variation or revocation) may appeal to the Authority if notice has been given to the committee and to the Authority before the end of the period of twenty-eight days beginning with the date on which notice of the committee's determination was served.
- (3) An appeal under this section shall be by way of rehearing by the Authority and no member of the Authority who took any part in the proceedings resulting in the determination appealed against shall take any part in the proceedings on appeal.
- (4) On the appeal—
 - (a) the appellant shall be entitled to appear or be represented,
 - (b) the members of the licence committee shall be entitled to appear, or the committee shall be entitled to be represented, and
 - (c) the Authority shall consider any written representations received from the appellant or any member of the committee and may take into account any matter that could be taken into account by a licence committee,

and the Authority may make such determination on the appeal as it thinks fit.

- (5) The Authority shall give notice of its determination to the appellant and, if it is a determination to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible or a determination to vary or revoke a licence, shall include in the notice the reasons for the decision.
- (6) The functions of the Authority on an appeal under this section cannot be discharged by any committee, member or employee of the Authority and, for the purposes of the appeal, the quorum shall not be less than five.

Commencement Information

II7 S. 20 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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21 Appeals to High Court or Court of Session.

Where the Authority determines under section 20 of this Act—

- (a) to refuse a licence or to refuse to vary a licence so as to designate another individual in place of the person responsible, or
- (b) to vary or revoke a licence,

any person on whom notice of the determination was served may appeal to the High Court or, in Scotland, the Court of Session on a point of law.

Commencement Information

I18 S. 21 wholly in force at 1.8.1991, see s. 49(2) and S.I. 1991/1400, art. 2(2)

22 Temporary suspension of licence.

- (1) Where a licence committee—
 - (a) has reasonable grounds to suspect that there are grounds for revoking the licence under section 18 of this Act, 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) Notice under subsection (1) above shall be given to the person responsible or, where the person responsible has died or appears to the licence committee to be unable because of incapacity to discharge the duty under section 17 of this Act, to some other person to whom the licence applies or the nominal licensee and a licence committee may, by a further notice to that person, renew or further renew the notice under subsection (1) above for such further period not exceeding three months as may be specified in the renewal notice.
- (3) While suspended under this section a licence shall be of no effect, but application may be made under section 18(5) of this Act by the nominal licensee to designate another individual as the person responsible.

Commencement Information

I19 S. 22 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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.

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- (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 who is or was the person responsible or the nominal licensee, or
 - (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.
- (6) This section does not apply to directions under section 9(4) of this Act.

Commencement Information

I20 S. 23 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

24 Directions as to particular matters.

- (1) If, in the case of any information about persons for whom treatment services [F43, other than basic partner treatment services, F43 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 [F44 or 1A]F44 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) [F45] In relation to gametes or embryos that are not intended for human application,]F45 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.
- [F46(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 directions given under subsection (4),

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

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- F46(4) Directions may authorise any person to whom a licence applies to receive gametes or embryos from outside the United Kingdom or to send gametes or 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.
- [F47(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.]
 - F47(5) A licence committee may from time to time give such directions as are mentioned in subsection (7) below where a licence has been varied or has ceased to have effect (whether by expiry, suspension, revocation or otherwise).
 - (6) A licence committee proposing to suspend, revoke or vary a licence may give such directions as are mentioned in subsection (7) below.
 - (7) The directions referred to in subsections (5) and (6) above are directions given for the purpose of securing the continued discharge of the duties of the person responsible under the licence concerned ("the old licence"), and such directions may, in particular—
 - (a) require anything kept or information held in pursuance of the old licence to be transferred to the Authority or any other person, or
 - (b) provide for the discharge of the duties in question by any individual, being an individual whose character, qualifications and experience are, in the opinion of the committee, such as are required for the supervision of the activities authorised by the old licence, and authorise those activities to be carried on under the supervision of that individual,

but cannot require any individual to discharge any of those duties unless the individual has consented in writing to do so.

- (8) Directions for the purpose referred to in subsection (7)(a) above shall be given to the person responsible under the old licence or, where that person has died or appears to the licence committee to have become unable because of incapacity to discharge the duties in question, to some other person to whom the old licence applies or applied or to the nominal licensee.
- (9) Directions for the purpose referred to in subsection (7)(b) above shall be given to the individual who under the directions is to discharge the duty.
- (10) Where a person who holds a licence dies, anything done subsequently by an individual which that individual would have been authorised to do if the licence had continued in force shall, until directions are given by virtue of this section, 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(5) of Schedule 2 to this Act, it shall report the

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- 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.
- [F48(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. F48

Textual Amendments

- F43 Words in s. 24(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 22(2)
- **F44** Words in s. 24(2) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **22(3)**
- F45 Words in s. 24(3) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 22(4)
- **F46** S. 24(3A) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **22(5)**
- F47 S. 24(4A) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 22(6)
- F48 S. 24(12)-(14) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, 22(7)

Commencement Information

I21 S. 24 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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 a father), and of other children who may be affected by such births.
- (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.

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- (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) a licence committee 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) a licence committee 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.

Commencement Information

I22 S. 25 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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.

Status

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 [F49] woman's child F49.
- (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.

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Textual Amendments

F49 Words in s. 27(2) substituted (30.12.2005) by Adoption and Children Act 2002 (c. 38), ss. 139, 148, **Sch. 3 para. 77** (with Sch. 4 para. 6-8); S.I. 2005/2213, **art. 2(0)**

Modifications etc. (not altering text)

C6 S. 27(2) modified (1.11.1994) by S.I. 1994/2804, reg. 3, Sch. 2 para. 6

Commencement Information

I23 S. 27 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

Meaning of "father".

(1) [F50] Subject to subsections (5A) to (5I) below, F50 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 [F51man's child]F51.

$I^{F52}(5A)$ 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 artificialinsemination,
- (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 theembryo was brought about

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- 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 maybe) 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 manto be treated for the purpose mentioned in subsection (51) 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 artificialinsemination,
- (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 theembryo 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 thewoman 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 maybe) 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 manto be treated for the purpose mentioned in subsection (51) 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,

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- (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 theother 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 (51) 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 servicesprovided 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 manto be treated for the purpose mentioned in subsection (51) 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 thereshall 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

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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" meansthe Registrar General for England and Wales, the Registrar General of Births, Deaths and Marriages for Scotland or (as the case maybe) 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-birthskept under the Births and Deaths Registration Act 1953 or the Births and Deaths Registration (Northern Ireland) Order 1976 or aregister of births or still-births kept under the Registration of Births, Deaths and Marriages (Scotland) Act 1965.]

F52(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 [F53, subject to subsections (5A) and (5B) above,]F53 to be treated as the father of the child.

- (7) The references in subsection (2) above [F54] and subsections (5A) to (5D) above]F54 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.

Textual Amendments

- **F50** Words in s. 28(1) inserted (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 2(1), {Sch. para. 13)}; S.I. 2003/3095, art. 2
- **F51** Words in s. 28(5)(c) substituted (30.12.2005) by Adoption and Children Act 2002 (c. 38), ss. 139, 148, **Sch. 3 para. 78** (with Sch. 4 paras. 6-8); S.I. 2005/2213, **art. 2(0)**
- **F52** S. 28(5A)-(5I) inserted (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), **s. 1(1)** (with s. 31(1)-(6)); S.I. 2003/3095, **art. 2**
- **F53** Words in s. 28(6)(b) inserted (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 2(1), **Sch. para. 14**; S.I. 2003/3095, **art. 2**

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F54 Words in s. 28(7) inserted (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 2(1), **Sch. para. 15**; S.I. 2003/3095, **art. 2**

Modifications etc. (not altering text)

- C7 S. 28 modified (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 3(5); S.I. 2003/3095, art. 2
- C8 S. 28(5)(c) modified (1.11.1994) by S.I. 1994/2804, reg. 3, Sch. 2 para. 6
- C9 S. 28(5A) modified (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 3(2); S.I. 2003/3095, art. 2
 - S. 28(5A) modified (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 3(6)(a); S.I. 2003/3095, art. 2
- C10 S. 28(5B) modified (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 3(2); S.I. 2003/3095, art. 2
 - S. 28(5B) modified (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 3(6)(a); S.I. 2003/3095, art. 2
- C11 S. 28(5C) modified (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 3(3); S.I. 2003/3095, art. 2
 - S. 28(5C) modified (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 3(6)(b); S.I. 2003/3095, art. 2
- C12 S. 28(5D) modified (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 3(6)(b); S.I. 2003/3095, art. 2

Commencement Information

I24 S. 28 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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.
- [F55(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 (wheneverpassed or made) are to be read accordingly.

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- (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.]
- F55(4) In relation to England and Wales and Northern Ireland, nothing in the provisions of section 27(1) or 28(2) to (4) [F56 or (5A) to (5I)]F56, 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.

Textual Amendments

- F55 S. 29(3A)-(3D) inserted (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 1(2); S.I. 2003/3095, art. 2
- **F56** Words in s. 29(4) inserted (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 2(1), **Sch. para. 16**; S.I. 2003/3095, **art. 2**

Commencement Information

I25 S. 29 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

30 Parental orders in favour of gamete donors.

- (1) The court may make an order providing for a child to be treated in law as the child of the parties to a marriage (referred to in this section as "the husband" and "the wife") if—
 - (a) the child has been carried by a woman other than the wife as the result of the placing in her of an embryo or sperm and eggs or her artificial insemination,
 - (b) the gametes of the husband or the wife, or both, were used to bring about the creation of the embryo, and
 - (c) the conditions in subsections (2) to (7) below are satisfied.
- (2) The husband and the wife must apply for the order within six months of the birth of the child or, in the case of a child born before the coming into force of this Act, within six months of such coming into force.
- (3) At the time of the application and of the making of the order—
 - (a) the child's home must be with the husband and the wife, and
 - (b) the husband or the wife, of both of them, must be domiciled in a part of the United Kingdom or in the Channel Islands or the Isle of Man.

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- (4) At the time of the making of the order both the husband and the wife must have attained the age of eighteen.
- (5) The court must be satisfied that both the father of the child (including a person who is the father by virtue of section 28 of this Act), where he is not the husband, and the woman who carried the child have freely, and with full understanding of what is involved, agreed unconditionally to the making of the order.
- (6) Subsection (5) above does not require the agreement of a person who cannot be found or is incapable of giving agreement and the agreement of the woman who carried the child is ineffective for the purposes of that subsection if given by her less than six weeks after the child's birth.
- (7) The court must be satisfied that no money or other benefit (other than for expenses reasonably incurred) has been given or received by the husband or the wife for or in consideration of—
 - (a) the making of the order,
 - (b) any agreement required by subsection (5) above,
 - (c) the handing over of the child to the husband and the wife, or
 - (d) the making of any arrangements with a view to the making of the order, unless authorised by the court.
- (8) For the purposes of an application under this section—
 - (a) in relation to England and Wales, section 92(7) to (10) of, and Part I of Schedule 11 to, the MI Children Act 1989 (jurisdiction of courts) shall apply for the purposes of this section to determine the meaning of "the court" as they apply for the purposes of that Act and proceedings on the application shall be "family proceedings" for the purposes of that Act,
 - (b) in relation to Scotland, "the court" means the Court of Session or the sheriff court of the sheriffdom within which the child is, and
 - (c) in relation to Northern Ireland, "the court" means the High Court or any county court within whose division the child is.
- (9) Regulations may provide—
 - (a) for any provision of the enactments about adoption to have effect, with such modifications (if any) as may be specified in the regulations, in relation to orders under this section, and applications for such orders, as it has effect in relation to adoption, and applications for adoption orders, and
 - (b) for references in any enactment to adoption, an adopted child or an adoptive relationship to be read (respectively) as references to the effect of an order under this section, a child to whom such an order applies and a relationship arising by virtue of the enactments about adoption, as applied by the regulations, and for similar expressions in connection with adoption to be read accordingly,

and the regulations may include such incidental or supplemental provision as appears to the Secretary of State necessary or desirable in consequence of any provision made by virtue of paragraph (a) or (b) above.

(10) In this section "the enactments about adoption" means the [F57Adoption and Children Act 2002]F57, the M2Adoption (Scotland) Act 1978 and the M3Adoption (Northern Ireland) Order 1987.

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(11) Subsection (1)(a) 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 or her artificial insemination.

Textual Amendments

F57 Words in s. 30(10) substituted (30.12.2005) by Adoption and Children Act 2002 (c. 38), ss. 139, 148, Sch. 3 para. 79 (with Sch. 4 paras. 6-8); S.I. 2005/2213, art 2(o)

Modifications etc. (not altering text)

- C13 S. 30(9): transfer of certain functions (1.7.1999) by S.I. 1999/1750, arts. 1(1)(4), 2, Sch. 1 (with saving in art. 7).
- C14 S. 30(9)(b) amended (1.12.2003) by Human Fertilisation and Embryology (Deceased Fathers) Act 2003 (c. 24), s. 2(1), Sch. para. 17; S.I. 2003/3095, art. 2

Commencement Information

126 S. 30 wholly in force; s. 30 not in force at Royal Assent see s. 49(2); s. 30(9)(10) in force at 5.7.1994 and s. 30(1)-(8)(11) in force at 1.11.1994 by S.I. 1994/1776, art. 2(1)(2)

Marginal Citations

M1 1989 c. 41.

M2 1978 c. 28.

M3 S.I. 1987/2203 (N.I. 22).

Information

31 The Authority's register of information.

- (1) The Authority shall keep a register which shall contain any information obtained by the Authority which falls within subsection (2) below.
- (2) Information falls within this subsection if it relates to—
 - [F58(a) the provision for any identifiable individual of treatment services other than basic partner treatment services,]
- [F59F58(aa) the procurement or distribution, in the course of providing non-medical fertility services for any identifiable individual, of any sperm (other than partner-donated sperm which has not been stored),]
 - the keeping ^{F60}... of the gametes of any identifiable individual or of an embryo taken from any identifiable woman,
 - [F61(ba) the use, otherwise than for the purposes of basic partner treatment services, of gametes of an identifiable individual, or
 - (bb) the use of an embryo taken from any identifiable woman,]
 - F61 or if it shows that any identifiable individual [F62 is a relevant individual] F62.
- (3) A person who has attained the age of eighteen ("the applicant") may by notice to the Authority require the Authority to comply with a request under subsection (4) below, and the Authority shall do so if—
 - (a) the information contained in the register shows that the applicant $[^{F63}{\rm is}\ a$ relevant individual] F63 , and

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- (b) the applicant has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (4) 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 other than a parent of the applicant would or might, but for sections 27 to 29 of this Act, be a parent of the applicant and, if it does show that—
 - (a) giving the applicant so much of that information as relates to the person concerned as the Authority is required by regulations to give (but no other information), or
 - (b) stating whether or not that information shows that, but for sections 27 to 29 of this Act, the applicant, and a person specified in the request as a person whom the applicant proposes to marry, would or might be related.
- (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) A person who has not attained the age of eighteen ("the minor") may by notice to the Authority specifying another person ("the intended spouse") as a person whom the minor proposes to marry require the Authority to comply with a request under subsection (7) below, and the Authority shall do so if—
 - (a) the information contained in the register shows that the minor $[^{F64}$ is a relevant individual $]^{F64}$, and
 - (b) the minor has been given a suitable opportunity to receive proper counselling about the implications of compliance with the request.
- (7) The minor may request the Authority to give the minor notice stating whether or not the information contained in the register shows that, but for sections 27 to 29 of this Act, the minor and the intended spouse would or might be related.
- [F65(8) 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, in the course of providing non-medical fertility services, of any sperm (other than partner-donated sperm which has not been stored). [65]

Textual Amendments

- F58 S. 31(2)(a) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 23(2)(a)
- F59 S. 31(2)(aa) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 23(2)(b)
- **F60** Words in s. 31(2)(b) omitted (25.5.2007 for certain purposes, otherwise 5.7.2007) by virtue of The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 23(2)(c)
- **F61** S. 31(2)(ba)(bb) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **23(2)(d)**
- **F62** Words in s. 31(2) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 23(2)(e)

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- Words in s. 31(3)(a) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 23(3)
- **F64** Words in s. 31(6)(a) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 23(4)
- F65 S. 31(8) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 23(5)

Commencement Information

I27 S. 31 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

[F6631A

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, and
 - (b) every licence under paragraph 1A of Schedule 2.
- (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, if applicable, the nominal licensee, 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.

Textual Amendments

F66 Ss. 31A, 31B inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **24**

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.]

Textual Amendments

F66 Ss. 31A, 31B inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **24**

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32 Information to be provided to Registrar General.

- (1) This section applies where a claim is made before the Registrar General that a man is or is not the father 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 man may be the father of the child by virtue of section 28 of this Act and, if it does, disclose that information.
- (3) In this section and section 33 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.

Commencement Information

I28 S. 32 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

33 Restrictions on disclosure of information.

- (1) No person who is or has been a member or employee of the Authority shall disclose any information mentioned in subsection (2) below which he holds or has held as such a member or employee.
- (2) The information referred to in subsection (1) above is—
 - (a) any information contained or required to be contained in the register kept in pursuance of section 31 of this Act, and
 - (b) any other information obtained by any member or employee of the Authority on terms or in circumstances requiring it to be held in confidence.
- (3) Subsection (1) above does not apply to any disclosure of information mentioned in subsection (2)(a) above made—
 - (a) to a person as a member or employee of the Authority,
 - (b) to a person to whom a licence applies for the purposes of his functions as such,
 - (c) so that no individual to whom the information relates can be identified,
 - (d) in pursuance of an order of a court under section 34 or 35 of this Act,
 - (e) to the Registrar General in pursuance of a request under section 32 of this Act, or
 - (f) in accordance with section 31 of this Act.
- (4) Subsection (1) above does not apply to any disclosure of information mentioned in subsection (2)(b) above—
 - (a) made to a person as a member or employee of the Authority,
 - (b) made with the consent of the person or persons whose confidence would otherwise be protected, or
 - (c) which has been lawfully made available to the public before the disclosure is made.
- (5) No person who is or has been a person to whom a licence applies [F67, no person who is or has been a person to whom a third party agreement applies,]F67 and no person

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to whom directions have been given shall disclose any information falling within section 31(2) of this Act which he holds or has held as such a person.

- (6) Subsection (5) above does not apply to any disclosure of information made—
 - (a) to a person as a member or employee of the Authority,
 - (b) to a person to whom a licence applies for the purposes of his functions as such,
 - [F68(ba) to a person to whom a third party agreement applies for the purposes of his functions under the third party agreement,]
 - so far as it identifies a person who, but for sections 27 to 29 of this Act, would or might be a parent of a person who instituted proceedings under section 1A of the M4Congenital Disabilities (Civil Liability) Act 1976, but only for the purpose of defending such proceedings, or instituting connected proceedings for compensation against that parent,
 - (d) so that no individual to whom the information relates can be identified, F69...
 - (e) in pursuance of directions given by virtue of section 24(5) or (6) of this Act,
 - [F70(f) necessarily—
 - (i) for any purpose preliminary to proceedings, or
 - (ii) for the purposes of, or in connection with, any proceedings,
 - (g) for the purpose of establishing, in any proceedings relating to an application for an order under subsection (1) of section 30 of this Act, whether the condition specified in paragraph (a) or (b) of that subsection is met, [F71 or]
 - (h) under section 3 of the M5 Access to Health Records Act 1990 (right of access to health records), [F72 or]]
 - [F72(i) under Article 5 of the Access to Health Records (Northern Ireland) Order 1993 (right of access to health records).]
- [F73(6A) Paragraph (f) of subsection (6) above, so far as relating to disclosure for the purposes of, or in connection with, any proceedings, does not apply—
 - (a) to disclosure of 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 to this Act, for the purposes of treatment services in consequence of which an identifiable individual was, or may have been, born, 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.
 - (6B) In the case of information relating to the provision of treatment services for any identifiable individual—
 - (a) where one individual is identifiable, subsection (5) above does not apply to disclosure with the consent of that individual;
 - (b) where both a woman and a man treated together with her are identifiable, subsection (5) above does not apply—
 - (i) to disclosure with the consent of them both, or
 - (ii) if disclosure is made for the purpose of disclosing information about the provision of treatment services for one of them, to disclosure with the consent of that individual.
 - (6C) For the purposes of subsection (6B) above, consent must be to disclosure to a specific person, except where disclosure is to a person who needs to know—

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- (a) in connection with the provision of treatment services, or any other description of medical, surgical or obstetric services, for the individual giving the consent,
- (b) in connection with the carrying out of an audit of clinical practice, or
- (c) in connection with the auditing of accounts.
- (6D) For the purposes of subsection (6B) above, 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.
- (6E) In the case of information which relates to the provision of treatment services for any identifiable individual, subsection (5) above does not apply to disclosure in an emergency, that is to say, to disclosure made—
 - (a) 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 with whose consent the information could be disclosed under subsection (6B) above, and
 - (b) in circumstances where it is not reasonably practicable to obtain that individual's consent.
- (6F) In the case of information which shows that any identifiable individual was, or may have been, born in consequence of treatment services, subsection (5) above does not apply to any disclosure which is necessarily incidental to disclosure under subsection (6B) or (6E) above.
- (6G) Regulations may provide for additional exceptions from subsection (5) above, but no exception may be made under this subsection—
 - (a) for disclosure of a kind mentioned in paragraph (a) or (b) of subsection (6A) above, or
 - (b) for disclosure, in circumstances in which section 32 of this Act applies, of information having the tendency mentioned in subsection (2) of that section.]
 - (7) This section does not apply to the disclosure to any individual of information which—
 - (a) falls within section 31(2) of this Act by virtue of [F74 paragraphs (a) to (bb)]F74 of that subsection, and
 - (b) relates only to that individual or, in the case of an individual treated together with another, only to that individual and that other.

F75(8)	_	_	_	_	_		_	_	_	_	_	_	_	_	_	_	_		_		

Textual Amendments

- **F67** Words in s. 33(5) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **25(2)**
- F68 S. 33(6)(ba) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 25(3)
- **F69** Word in s. 33(6)(d) repealed (16.7.1992) by Human Fertilisation and Embryology (Disclosure of Information) Act 1992 (c. 54), s. 1(1)(2)(5).
- F70 S. 33(6)(f)-(g) inserted (16.7.1992) by Human Fertilisation and Embryology (Disclosure of Information) Act 1992 (c. 54), s. 1(1)(2)(5).
 S. 33(6)(h) inserted (E.W.S.) (16.7.1992) by Human Fertilisation and Embryology (Disclosure of Information) Act 1992 (c. 54), s. 1(1)(2)(5).
- F71 Word in s. 33(6)(g) repealed (N.I.) (30.5.1994) by S.I. 1993/1250, art. 13; S.R. 1994/151, art. 2(1)
- F72 Word and s. 33(6)(i) inserted (N.I.) (30.5.1994) by S.I. 1993/1250, art. 13; S.R. 1994/151, art. 2(1)

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- F73 S. 33(6A)-(6G) inserted (16.7.1992) by Human Fertilisation and Embryology (Disclosure of Information) Act 1992 (c. 54), s. 1(1)(3)(5).
- F74 Words in s. 33(7) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 25(4)
- F75 S. 33(8) repealed (1.3.2000) by 1998 c. 29, s. 74(2), Sch. 16 Pt. I; S.I. 2000/183, art. 2(1)

Commencement Information

129 S. 33 wholly in force; s. 33 wholly in force at 1.8.1991 see s. 49(2), S.I. 1991/2165 and 1991/1400, art. 2(2)

Marginal Citations

M4 1976 c. 28.

M5 1990 c. 23.

34 Disclosure in interests of justice.

- (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 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)(b) 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.

Commencement Information

I30 S. 34 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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

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- sections 27 to 29 of this Act, 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 sections 27 to 29 of this Act, 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.
- (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.".

Commencement Information

I31 S. 35 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

Surrogacy

36 Amendment of Surrogacy Arrangements Act 1985.

(1) After section 1 of the M6Surrogacy Arrangements Act 1985 there is inserted—

"1A Surrogacy arrangements unenforceable.

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.

Marginal Citations

M6 1985 c. 49.

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Abortion

37 Amendment of law relating to termination of pregnancy.

- (1) For paragraphs (a) and (b) of section 1(1) of the M7Abortion 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 M8Infant 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".

Commencement Information

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

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.

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Commencement Information
133 S. 38 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)
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Enforcement

39 Powers of members and employees of Authority.

- (1) Any member or employee of the Authority entering and inspecting premises to which a licence relates [^{F76}, or relevant third party premises,]^{F76} may—
 - (a) take possession of anything which he has reasonable grounds to believe may be required—
 - (i) for the purpose of the functions of the Authority relating to the grant, variation, suspension and revocation of licences, F77...
 - [F78(ia) for the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction, or]
 - F78(ii) for the purpose of being used in evidence in any proceedings for an offence under this Act,

and retain it for so long as it may be required for the purpose in question, and

- (b) for the purpose in question, take such steps as appear to be necessary for preserving any such thing or preventing interference with it, including requiring any person having the power to do so to give such assistance as may reasonably be required.
- (2) In subsection (1) above—
 - (a) the references to things include information recorded in any form, and
 - (b) the reference to taking possession of anything includes, in the case of information recorded otherwise than in legible form, requiring any person having the power to do so to produce a copy of the information in legible form and taking possession of the copy.

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(3) Nothing in this Act makes it unlawful for a member or employee of the Authority to keep any embryo or gametes in pursuance of that person's functions as such.

Textual Amendments

- F76 Words in s. 39(1) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 26(a)
- F77 Word in s. 39(1)(a)(i) omitted (25.5.2007 for certain purposes, otherwise 5.7.2007) by virtue of The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 26(b)(i)
- F78 S. 39(1)(a)(ia) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 26(b)(ii)

Commencement Information

I34 S. 39 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

40 Power to enter premises.

- (1) A justice of the peace (including, in Scotland, a sheriff) may issue a warrant under this section if satisfied by the evidence on oath of a member or employee of the Authority that there are reasonable grounds for suspecting that an offence under this Act is being, or has been, committed on any premises.
- (2) A warrant under this section shall authorise any named member or employee of the Authority (who must, if so required, produce a document identifying himself), together with any constables—
 - (a) to enter the premises specified in the warrant, using such force as is reasonably necessary for the purpose, and
 - (b) to search the premises and—
 - (i) take possession of anything which he has reasonable grounds to believe may be required to be used in evidence in any proceedings for an offence under this Act, or
 - (ii) take such steps as appear to be necessary for preserving any such thing or preventing interference with it, including requiring any person having the power to do so to give such assistance as may reasonably be required.
- (3) A warrant under this section shall continue in force until the end of the period of one month beginning with the day on which it is issued.
- (4) Anything of which possession is taken under this section may be retained—
 - (a) for a period of six months, or
 - (b) if within that period proceedings to which the thing is relevant are commenced against any person for an offence under this Act, until the conclusion of those proceedings.
- (5) In this section—
 - (a) the references to things include information recorded in any form, and
 - (b) the reference in subsection (2)(b)(i) above to taking possession of anything includes, in the case of information recorded otherwise than in legible form, requiring any person having the power to do so to produce a copy of the

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

information in legible form [F⁷⁹, or in a form from which it can readily be produced in visible and legible form] and taking possession of the copy.

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Textual Amendments
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F79 Words in s. 40(5)(b) inserted (1.4.2003) by 2001 c. 16, ss. 70, 138(2), Sch. 2 Pt. 2 para. 16(1)(2)(e); S.I. 2003/708, art. 2(k)

Modifications etc. (not altering text)

- C15 S. 40(2) extended (1.4.2003) by 2001 c. 16, ss. 50, 52-54, 68, 138(2), Sch. 1 Pt. 1 para. 52; S.I. 2003/708, art. 2(j)
- C16 S. 40(4) applied (1.4.2003) by 2001 c. 16, ss. 57(1)(k)(4), 138(2); S.I. 2003/708, art. 2(a)

Offences

41 Offences.

- (1) A person who—
 - (a) contravenes section 3(2) [^{F80}, 3A] or 4(1)(c) 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) [F81 or (1A)]F81 of this Act, otherwise than by doing something which, by virtue of section 3(3) of this Act, cannot be authorised by a licence,
 - (b) keeps F82 ... any gametes in contravention of section 4(1)(a) F82 ... of this Act,
 - I^{F83} (ba) uses any gametes in contravention of section 4(1)(b),
 - ⁶⁸³(c) contravenes section 4(3) of this Act, or
 - (d) fails to comply with any directions given by virtue of section 24(7)(a) of this Act,

is guilty of an offence.

I^{F84}(2A) A person who contravenes section 3(1B) or 4(1A) is guilty of an offence.

F84(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 [^{F85}, other than an offence to which subsection (4B) applies,]^{F85} 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.

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[F86(4A) Subsection (4B) applies to—

- (a) an offence under subsection (2)(ba) or (d) or (3) committed in the course of providing basic partner treatment services or non-medical fertility services, or
- (b) an offence under subsection (2A).
- (4B) A person guilty of an offence to which this subsection applies 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 three months or a fine not exceeding the statutory maximum or both.]
- F86(5) A person who discloses any information in contravention of section 33 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.
 - (6) A person who—
 - (a) fails to comply with a requirement made by virtue of section 39(1)(b) or (2) (b) or 40(2)(b)(ii) or (5)(b) of this Act, or
 - (b) intentionally obstructs the exercise of any rights conferred by a warrant issued under section 40 of this Act,

is guilty of an offence.

- (7) A person who without reasonable excuse fails to comply with a requirement imposed by regulations made by virtue of section 10(2)(a) of this Act is guilty of an offence.
- (8) Where a person to whom a licence applies or the nominal licensee gives or receives any money or other benefit, not authorised by directions, in respect of any supply of gametes or embryos, he is guilty of an offence.
- (9) A person guilty of an offence under subsection (6), (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 4(1) of this Act, 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 by virtue of section 24(9) of this Act, and
 - (ii) that the defendant was authorised by virtue of the licence 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 [F87] or third party agreement] applied or to whom directions had been given, and

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(b) that he took all such steps as were reasonable and exercised all due diligence to avoid committing the offence.

Textual Amendments

- **F80** Words in s. 41(1)(a) inserted (10.4.1995) by 1994 c. 33, s. 156(3); S.I. 1995/721, art. 2, Sch.
- **F81** Words in s. 41(2)(a) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **27(2)**
- F82 Words in s. 41(2)(b) omitted (25.5.2007 for certain purposes, otherwise 5.7.2007) by virtue of The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 27(3)
- F83 S. 41(2)(ba) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 27(4)
- F84 S. 41(2A) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 27(5)
- F85 Words in s. 41(4) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 27(6)
- F86 S. 41(4A)(4B) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 27(7)
- F87 Words in s. 41(11)(a) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 27(8)

Commencement Information

I35 S. 41 wholly in force; s. 41 not in force at Royal Assent see s. 49(2); s. 41(3)(4) in force 8.7.1991 and the remaining provisions in force 1.8.1991 see S.I. 1990/2165 and S.I. 1991/1400, art. 2(1)(d)(e)(2)

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.

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Commencement Information

S. 43 wholly in force, s. 43 not in force at Royal Assent see s. 49(2), s. 43(1) in force for certain purposes at 8.7.1991; and s. 43 fully in force at 1.8.1991 see S.I. 1991/1400, art. 2(1)(f)(2)

44 Civil liability to child with disability.

(1) After section 1 of the M9Congenital 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."
- (2) 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".

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Commencement Information

I37 S. 44 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

Marginal Citations

M9 1976 c. 28.

45 Regulations.

- (1) The Secretary of State may make regulations for any purpose for which regulations may be made under this Act.
- (2) The power to make regulations shall be exercisable by statutory instrument.
- (3) Regulations may make different provision for different cases.
- (4) The Secretary of State shall not make regulations by virtue of section 3(3)(c), 4(2) or (3), 30, 31(4)(a), [F8833(6G),] or 43 of this Act or paragraph 1(1)(g) or 3 of Schedule 2 to this Act unless a draft has been laid before and approved by resolution of each House of Parliament.
- (5) A statutory instrument containing regulations 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.

Textual Amendments

F88 Words in s. 45(4) inserted (16.7.1992) by Human Fertilisation and Embryology (Disclosure of Information) Act 1992 (c. 54), s. 2(2).

Commencement Information

I38 S. 45 fully in force at 8.7.1991 see s. 49(2) and S.I. 1991/1400, art. 2(1)(g)

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.

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- (4) For the purposes of this section and section 7 of the M10 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.

Commencement Information

I39 S. 46 fully in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

Marginal Citations

M10 1978 c. 30.

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.

Activities governed by this Act	Section 4(5)
Authority	Section 2(1)
[F89Basic partner treatment services	Section 2(1) ^{F89}]
Carry, in relation to a child	Section 2(3)
[F90Competent authority	Section 2(1) ^{F90}]
Directions	Section 2(1)
[F91Distribution, in relation to gametes or embryos intended for human application	Section 2(1) ^{F91}]
Embryo	Section 1
[F92First Directive	Section 1A ^{F92}]
Gametes, eggs or sperm	Section 1
[F93Human application	Section 2(1) ^{F93}]
Keeping, in relation to embryos or gametes	Section 2(2)
Licence	Section 2(1)
Licence committee	Section 9(1)
Nominal licensee	Section 17(3)

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Section 2(1) ^{F94}]
Section $1(5)^{F95}$]
Section 17(1)
Section 17(2)
Section 2A(3) ^{F96}]
Section 2(1) ^{F97}]
Section 2(1) ^{F98}]
Section 2A(2) ^{F99}]
Section 1A ^{F100}]
Section 2(1) ^{F101}]
Section $2(1)^{F102}$]
Section 14(3) to (5)
[F103 Section 2(1)F103]
Section 1A ^{F104}]
Section 2A(2) ^{F105}]
Section 2A(1) ^{F106}]
Section 2(1) ^{F107}]
Section 2(1)

Textual Amendments

- F89 S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 28(2)(b)
- **F90** S. 47: table entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **28(2)(b)**
- F91 S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 28(2)(b)
- F92 S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 28(2)(b)
- F93 S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 28(2)(b)
- F94 S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 28(2)(b)
- F95 S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 28(2)(b)
- **F96** S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **28(2)(b)**
- F97 S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 28(2)(b)

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- F98 S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 28(2)(b)
- F99 S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 28(2)(b)
- **F100** S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **28(2)(b)**
- **F101** S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **28(2)(b)**
- **F102** S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **28(2)(b)**
- **F103** S. 47 Table: words in entry substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **28(2)(a)**
- **F104** S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **28(2)(b)**
- **F105** S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **28(2)(b)**
- **F106** S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **28(2)(b)**
- **F107** S. 47 Table: entry inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **28(2)(b)**

Commencement Information

I40 S. 47 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

48 Northern Ireland.

(1)	This A	Act (except	t [^{F108}	sectio	ns 33	(6)(h)	and]	37)	extend	ls to]	Northe	ern l	Ireland
$^{9}(2)$)													

Textual Amendments

F108 Words in s. 48(1) substituted (16.7.1992) by Human Fertilisation and Embryology (Disclosure of Information) Act 1992 (c. 54), s. 2(4).

F109 S. 48(2) repealed (2.12.1999) by 1998 c. 47, s. 100(2), Sch. 15; S.I. 1999/3209, art. 2, Sch.

Commencement Information

I41 S. 48 wholly in force at 1.11.1994; s. 48 not in force at Royal Assent see s. 49(2); s. 48(1) in force for specified purposes at 1.4.1991, 8.7.1991 and 1.8.1991 by S.I. 1991/1400, art. 2(1)(2); s. 48(2) in force at 1.8.1991 by S.I. 1991/1400, art. 2(1)(2); s. 48(1) in force for specified purposes at 5.7.1994 and 1.11.1994 by S.I. 1994/1776, art. 2(1)(2)

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.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (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 MII 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.

Subordinate Legislation Made

P1 S. 49(2)(6): power exercised by S.Is: 1990/2165, 1991/480, 1991/1400, 1991/1781, 1994/1776

Marginal Citations

M11 1987 c. 42.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

SCHEDULES

SCHEDULE 1

Section 5.

THE AUTHORITY: SUPPLEMENTARY PROVISIONS

Status and capacity

- 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.
- 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

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 M12Medical 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).

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Marginal Citations

M12 1983 c. 54.

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 reappointment (whether or not in the same capacity).
 - (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
 - (b) has become bankrupt or made an arrangement with his creditors, or, in Scotland, has had his estate sequestrated or has granted a trust deed for or entered into an arrangement with his creditors, or
 - (c) is unable or unfit to discharge the functions of a member,

the Secretary of State may declare his office as a member of the Authority vacant, and notify the declaration in such manner as he thinks fit; and thereupon the office shall become vacant.

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

In Part II of Schedule 1 to the M13 House of Commons Disqualification Act 1975 and in Part II of Schedule 1 to the M14 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".

Marginal Citations

M13 1975 c. 24. **M14** 1975 c. 25.

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.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(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) 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 or any licence committee with respect to the licence, and if he does so the deliberation or decision shall be of no effect.
- The validity of any proceedings of the Authority, or of any committee or subcommittee, shall not be affected by any vacancy among the members or by any defect in the appointment of a member.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Instruments

- 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.
- 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

The Authority shall be subject to investigation by the Parliamentary Commissioner and accordingly, in Schedule 2 to the M15 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".

Marginal Citations

M15 1967 c. 13.

SCHEDULE 2

Section 11 etc.

ACTIVITIES FOR WHICH LICENCES MAY BE GRANTED

Commencement Information

I42 Schedule 2 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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,
 - [F110(b) procuring, keeping, testing, processing or distributing embryos,
 - (c) procuring, testing, processing, distributing or using gametes]
 - [FIII] [FIII] ther] FIII practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose,
 - (e) placing any 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 as may be specified in, or determined in accordance with, regulations.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (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 genetic structure of any cell while it forms part of an embryo.
- (5) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

Textual Amendments

- F110 Sch. 2 para. 1(1)(b)(c) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 29(a)(i)
- F111 Word in Sch. 2 para. 1(1)(d) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 29(a)(ii)

Commencement Information

I43 Schedule 2 para. 1 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

I^{F112}Licences for non-medical fertility services

Textual Amendments

- **F112** Sch. 2 para. 1A and cross-heading inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs. 1, **29(b)**
- 1A (1) A licence under this paragraph may authorise any of the following in the course of providing non-medical fertility services—
 - (a) procuring sperm, and
 - (b) distributing sperm.
 - (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.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (2) Subject to the provisions of this Act, a licence authorising such storage 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.

Commencement Information

144 Schedule 2 para. 2 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400 art. 2(2)

Licences for research

- 3 (1) A licence under this paragraph may authorise any of the following—
 - (a) bringing about the creation of embryosin 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 cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of—
 - (a) promoting advances in the treatment of infertility,
 - (b) increasing knowledge about the causes of congenital disease,
 - (c) increasing knowledge about the causes of miscarriages,
 - (d) developing more effective techniques of contraception, or
 - (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation,

or for such other purposes as may be specified in regulations.

- (3) Purposes may only be so specified with a view to the authorisation of projects of research which increase knowledge about the creation and development of embryos, or about disease, or enable such knowledge to be applied.
- (4) A licence under this paragraph cannot authorise altering the genetic structure of any cell while it forms part of an embryo, except in such circumstances (if any) as may be specified in or determined in pursuance of regulations.
- (5) 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, not later than the two cell stage.
- (6) No licence under this paragraph shall be granted unless the Authority is satisfied that any proposed use of embryos is necessary for the purposes of the research.
- (7) 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.
- (8) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1) or (5) above in such manner as may be so specified.
- (9) A licence under this paragraph shall be granted for such period not exceeding three years as may be specified in the licence.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Commencement Information

I45 Schedule 2 para. 3 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

General

- 4 [F113(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.]
 - F113(2) A licence cannot—
 - (a) F114.....
 - (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
 - [F115(d) apply to premises of the person who holds the licence in different places. F115]

Textual Amendments

- **F113** Sch. 2 para. 4(1)(1A) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) for Sch. 2 para. 4(1) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 29(c)
- F114 Sch. 2 para. 4(2)(a) omitted (25.5.2007 for certain purposes, otherwise 5.7.2007) by virtue of The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 29(d)
- F115 Sch. 2 para. 4(2)(d) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, 29(e)

Commencement Information

146 Schedule 2 para 4 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

SCHEDULE 3

Section 12 etc.

CONSENTS TO USE OF GAMETES OR EMBRYOS

Commencement Information

I47 Schedule 3 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Consent

A consent under this Schedule must be given in writing and, in this Schedule, "effective consent" means a consent under this Schedule which has not been withdrawn.

Commencement Information

148 Schedule 3 para. 1 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

- 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, or
 - (c) use for the purposes of any project of research,

and may specify conditions subject to which the embryo may be so used.

- (2) A consent to the storage of any gametes or any embryo must—
 - (a) specify the maximum period of storage (if less than the statutory storage period), and
 - (b) state what is to be done with the gametes or embryo if the person who gave the consent dies or is unable because of incapacity to vary the terms of the consent or to revoke it,

and may specify conditions subject to which the gametes or embryo may remain in storage.

- (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
 - (b) in the case of a person providing gametes, to the use or storage of any embryo whose creation may be brought about using those gametes,

and in the paragraph (b) case 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 particular embryo or particular embryos.

Commencement Information

149 Schedule 3 para. 2 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

(2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4 below.

Commencement Information

I50 Schedule 3 para. 3 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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 or embryo to which the consent is relevant.
 - (2) 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, or
 - (b) for the purposes of any project of research.

Commencement Information

I51 Schedule 3 para. 4 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

Use of gametes for treatment of others

- 5 (1) A person's gametes must not be used for the purposes of treatment 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.

Commencement Information

152 Schedule 3 para. 5 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

In vitro fertilisation and subsequent use of embryo

- 6 (1) A person's gametes must not be used to bring about the creation of any embryoin *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 being used for one or more of the purposes mentioned in paragraph 2(1) 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 person whose gametes were used to bring about the creation of the embryo to the use for one or more of the purposes mentioned in paragraph 2(1) above of the embryo.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

- (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 person whose gametes were used to bring about the creation of the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.
- (4) Any consent required by this paragraph is in addition to any consent that may be required by paragraph 5 above.

Commencement Information

I53 Schedule 3 para. 6 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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) This paragraph does not apply to the use, for the purpose of providing a woman with treatment services, of an embryo taken from her.

Commencement Information

I54 Schedule 3 para. 7 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 29(2)

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 person whose gametes were used to bring about the creation of the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.
 - (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.

Commencement Information

I55 Schedule 3 para. 8 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

[F116SCHEDULE 3A

Section 14A

SUPPLEMENTARY LICENCE CONDITIONS: HUMAN APPLICATION

Textual Amendments

F116 Sch. 3A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007 (S.I. 2007/1522), regs 1, **30**

Traceability and coding system

- 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

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

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

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(requirements for the procurement of human tissues and cells) of the second Directive.

Selection criteria and laboratory tests required for donors of reproductive cells

- 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.
- 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.
- 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.

Relevant provisions of the second Directive

1. Donation and procurement procedures

Consent and donor identification (record of consent, method Annex IV, point 1.1 of identification, donor interview)

Donor evaluation: other than partner-donated sperm and Annex IV, point 1.2 partner-created embryos and autologous donors (assessment of donor's medical and behavioural information)

Procurement procedures for gametes and embryos Annex IV, point 1.3 (requirements relating to procurement procedures and instruments)

Donor documentation (record of donor and the procurement) Annex IV, point 1.4

Packaging (requirements as to packaging and shipping Annex IV, point 1.5 containers)

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Status: Point in time view as at 25/05/2007.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Labelling of the procured gametes and embryos (minimum Annex IV, point 1.6 labelling requirements)

Labelling of the shipping container (minimum labelling Annex IV, point 1.7 requirements)

2. Reception of tissues and cells at the tissue establishment

Verification upon arrival (procedures for verification and Annex IV, points 2.1 requirement for quarantine until verification) to 2.3

Registration of data (other than in respect of partner-donated Annex IV, point 2.4 sperm and partner-created embryos)

Registration of data (partner-donated sperm and partner- Annex IV, point 2.5 created embryos)

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

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 Annex I, Part A organisational structure, management systems, and third party agreements)

Personnel (number, competence, responsibilities and Annex I, Part B training)

Equipment and materials (appropriate for use, validation, Annex I, Part C maintenance, and specifications)

Facilities and premises (suitability, environment, storage, and Annex I, Part D maintenance)

Documentation and records (standard operating procedures, Annex I, Part E document control, record reliability)

Quality review (quality management system, investigations, Annex I, Part F corrective action, and reviews)

Requirements for holding a licence for gametes and embryo preparation processes

- 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.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Relevant
provisions of
the third
Directive

Reception of gametes and embryos at the tissue Annex II, Part A establishment

Processing of gametes and embryos (validation, Annex II, Part B documentation and evaluation of critical procedures)

Storage and release of gametes and embryos (criteria Annex II, Part C to be complied with, including standard operating procedure)

Distribution and recall of gametes and embryos Annex II, Part D (criteria to be complied with, including procedures to be adopted)

Final labelling of gametes and embryo containers for Annex II, Part E distribution (information to be shown on container label or in accompanying documentation)

External labelling of the shipping container Annex II, Part F (information to be shown on label on shipping container)

Interpretation of this Schedule

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 4

Section 49

MINOR AND CONSEQUENTIAL AMENDMENTS

Commencement Information

Schedule 4 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

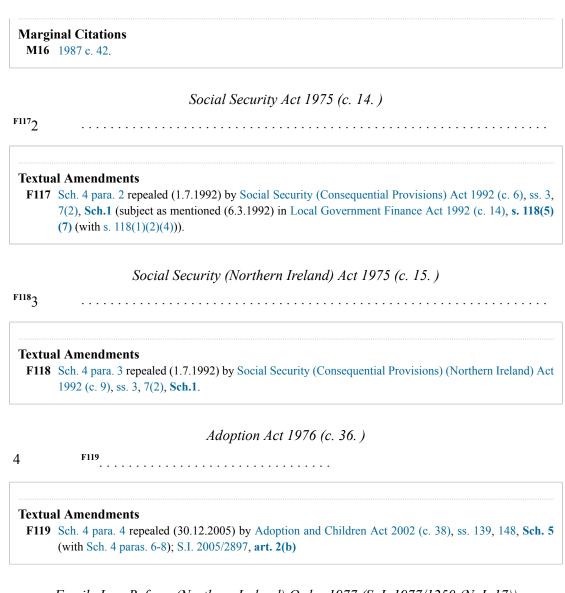
Family Law Reform Act 1969 (c. 46.)

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 M16Family Law Reform Act 1987 and to sections 27 to 29 of the Human Fertilisation and Embryology Act 1990".

Commencement Information

I57 Schedule 4 para. 1 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)



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

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".

Commencement Information

I58 Schedule 4 para. 5 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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

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".

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Commencement Information

I59 Schedule 4 para. 6 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

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

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".

Commencement Information

I60 Schedule 4 para. 7 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, art. 2(2)

Human Organ Transplants Act 1989 (c. 31.)

8 F120

Textual Amendments

F120 Sch. 4 para. 8 repealed (1.9.2006) by Human Tissue Act 2004 (c. 30), ss. 57, 60, **Sch. 7 Pt. 1**; S.I. 2006/1997, **art. 3(2)** (subject to arts. 4, 7, 8) (as that S.I is amended by S.I. 2006/2169, art. 2)

Human Organ Transplants (Northern Ireland) Order 1989 (S.I. 1989/2408 (N.I. 21)

9 F121

Textual Amendments

F121 Sch. 4 para. 9 repealed (1.9.2006) by Human Tissue Act 2004 (c. 30), ss. 57, 60, **Sch. 7 Pt. 1**; S.I. 2006/1997, **art. 3(2)** (subject to arts. 4, 7, 8) (as that S.I is amended by S.I. 2006/2169, art. 2)

Status:

Point in time view as at 25/05/2007.

Changes to legislation:

Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 05 May 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.