

Status: Point in time view as at 28/09/2009.

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SCHEDULES

SCHEDULE 1

Section 5.

THE AUTHORITY: SUPPLEMENTARY PROVISIONS

Status and capacity

- 1 The Authority shall not be regarded as the servant or agent of the Crown, or as enjoying any status, privilege or immunity of the Crown; and its property shall not be regarded as property of, or property held on behalf of, the Crown.
- 2 The Authority shall have power to do anything which is calculated to facilitate the discharge of its functions, or is incidental or conducive to their discharge, except the power to borrow money.

Expenses

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

Appointment of members

- 4 (1) All the members of the Authority (including the chairman and deputy chairman who shall be appointed as such) shall be appointed by the Secretary of State.
(2) In making appointments the Secretary of State shall have regard to the desirability of ensuring that the proceedings of the Authority, and the discharge of its functions, are informed by the views of both men and women.
(3) The following persons are disqualified for being appointed as chairman or deputy chairman of the Authority—
 - (a) any person who is, or has been, a medical practitioner registered under the ^{M1}Medical Act 1983 (whether fully, provisionally or with limited registration), or under any repealed enactment from which a provision of that Act is derived,
 - (b) any person who is, or has been, concerned with keeping or using gametes or embryos outside the body, and
 - (c) any person who is, or has been, directly concerned with commissioning or funding any research involving such keeping or use, or who has actively participated in any decision to do so.
- (4) The Secretary of State shall secure that at least one-third but fewer than half of the other members of the Authority fall within sub-paragraph (3)(a), (b) or (c) above, and that at least one member falls within each of paragraphs (a) and (b).

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Marginal Citations

M1 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 re-appointment (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

- 6 In Part II of Schedule 1 to the ^{M2}House of Commons Disqualification Act 1975 and in Part II of Schedule 1 to the ^{M3}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

M2 1975 c. 24.

M3 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.

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

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Instruments

- 12 The fixing of the seal of the Authority shall be authenticated by the signature of the chairman or deputy chairman of the Authority or some other member of the Authority authorised by the Authority to act for that purpose.
- 13 A document purporting to be duly executed under the seal of the Authority, or to be signed on the Authority’s behalf, shall be received in evidence and shall be deemed to be so executed or signed unless the contrary is proved.

Investigation by Parliamentary Commissioner

- 14 The Authority shall be subject to investigation by the Parliamentary Commissioner and accordingly, in Schedule 2 to the ^{M4}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

M4 1967 c. 13.

[^{F1}Application of Statutory Instruments Act 1946

Textual Amendments

F1 Sch. 1 para. 15 and cross-heading inserted (6.4.2009) by [Human Fertilisation and Embryology Act 2008](#) (c. 22), s. 68(2), [Sch. 7 para. 15\(c\)](#); S.I. 2009/479, art. 5(g)(h) (with art. 7Sch.)

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

SCHEDULE 2

Section 11 etc.

ACTIVITIES FOR WHICH LICENCES MAY BE GRANTED

Commencement Information

II 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*,
 - [^{F2}(b) procuring, keeping, testing, processing or distributing embryos,
 - (c) procuring, testing, processing, distributing or using gametes]

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- ^{F2}(d) [^{F3}other]^{F3} 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.
- (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

- F2** 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)**
- F3** 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

- I2** Schedule 2 para. 1 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400](#), **art. 2(2)**

^{F4}Licences for non-medical fertility services

Textual Amendments

- F4** 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

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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.
- (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

I3 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 embryos *in vitro*, and
 - (b) keeping or using embryos,
- for the purposes of a project of research specified in the licence.
- (2) A licence under this paragraph 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.

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- (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.

Commencement Information

I4 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 ^{F5}(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.]
- ^{F5}(2) A licence cannot—
- (a) ^{F6}
 - (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
 - ^{F7}(d) apply to premises of the person who holds the licence in different places.]^{F7}

Textual Amendments

- F5** 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\(c\)](#)
- F6** 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\(d\)](#)
- F7** 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

I5 Schedule 2 para 4 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400, art. 2\(2\)](#)

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SCHEDULE 3

Section 12 etc.

CONSENTS TO USE OF GAMETES OR EMBRYOS

Commencement Information

I6 Schedule 3 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400, art. 2\(2\)](#)

Consent

- 1 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

I7 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

I8 Schedule 3 para. 2 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400, art. 2\(2\)](#)

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Procedure for giving consent

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

Commencement Information

I9 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

I10 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

I11 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 embryo *in vitro* unless there is an effective consent by that person to any embryo the creation of which may be brought about with the use of those gametes being used for one or more of the purposes mentioned in paragraph 2(1) above.

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- (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.
- (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

I12 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

I13 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

I14 Schedule 3 para. 8 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400, art. 2\(2\)](#)

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[^{F8}SCHEDULE 3ZA

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

Textual Amendments

F8 Sch. 3ZA inserted (6.4.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), Sch. 4; S.I. 2009/479, art. 4(b) (with art. 7Sch.)

PART 1

KINDS OF TREATMENT IN RELATION TO WHICH COUNSELLING MUST BE OFFERED

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

PART 2

EVENTS IN CONNECTION WITH WHICH COUNSELLING MUST BE OFFERED

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

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[^{F9}SCHEDULE 3A

Section 14A

SUPPLEMENTARY LICENCE CONDITIONS: HUMAN APPLICATION

Textual Amendments

- F9** 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

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

Serious adverse events and serious adverse reactions

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

Third party agreements and termination of licensed activities

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

Requirements for procurement of gametes and embryos

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

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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

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

Donation and procurement procedures and reception at the tissue establishment

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

***Relevant
provisions of the
second Directive***

1. Donation and procurement procedures

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

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

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

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

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

Status: Point in time view as at 28/09/2009.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (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 requirement for quarantine until verification) 2.1 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

- 10 Licence conditions shall require compliance with the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

Relevant provisions of the third Directive

Organisation and management (requirements as to 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

- 11 In respect of gametes and embryos preparation processes, licence conditions shall require compliance with—
- (a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and
 - (b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

Status: Point in time view as at 28/09/2009.

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	<i>Relevant provisions of the third Directive</i>
Reception of gametes and embryos at the tissue establishment	Annex II, Part A
Processing of gametes and embryos (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of gametes and embryos (criteria to be complied with, including standard operating procedure)	Annex II, Part C
Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of gametes and embryo containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F

Interpretation of this Schedule

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

SCHEDULE 4

Section 49.

MINOR AND CONSEQUENTIAL AMENDMENTS

Commencement Information

I15 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.)

- 1 In section 25 of the Family Law Reform Act 1969 (interpretation), at the end of the definition of “excluded” there is added “ to section 27 of the ^{M5}Family Law Reform Act 1987 and to sections 27 to 29 of the Human Fertilisation and Embryology Act 1990 ”.

Commencement Information

I16 Schedule 4 para. 1 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400, art. 2\(2\)](#)

Status: Point in time view as at 28/09/2009.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Marginal Citations

M5 1987 c. 42.

Social Security Act 1975 (c. 14.)

F10₂

Textual Amendments

F10 Sch. 4 para. 2 repealed (1.7.1992) by [Social Security \(Consequential Provisions\) Act 1992 \(c. 6\)](#), ss. 3, 7(2), [Sch.1](#) (subject as mentioned (6.3.1992) in [Local Government Finance Act 1992 \(c. 14\)](#), [s. 118\(5\)\(7\)](#) (with [s. 118\(1\)\(2\)\(4\)](#))).

Social Security (Northern Ireland) Act 1975 (c. 15.)

F11₃

Textual Amendments

F11 Sch. 4 para. 3 repealed (1.7.1992) by [Social Security \(Consequential Provisions\) \(Northern Ireland\) Act 1992 \(c. 9\)](#), ss. 3, 7(2), [Sch.1](#).

Adoption Act 1976 (c. 36.)

4

F12

Textual Amendments

F12 Sch. 4 para. 4 repealed (30.12.2005) by [Adoption and Children Act 2002 \(c. 38\)](#), ss. 139, 148, [Sch. 5](#) (with [Sch. 4 paras. 6-8](#)); [S.I. 2005/2897](#), [art. 2\(b\)](#)

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

5

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

Commencement Information

I17 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.)

F13₆

Status: Point in time view as at 28/09/2009.

Changes to legislation: Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details)

Textual Amendments

- F13** Sch. 4 para. 6 repealed (S.) (28.9.2009) by [Adoption and Children \(Scotland\) Act 2007 \(asp 4\)](#), s. 121(2), [sch. 3](#); S.S.I. 2009/267, arts. 1(2), 2 (with arts. 3-21) (as amended (7.5.2012) by S.S.I. 2012/99, art. 2)

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

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

Commencement Information

- I18** 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 **F14**

Textual Amendments

- F14** 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 **F15**

Textual Amendments

- F15** 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 28/09/2009.

Changes to legislation:

Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 26 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.