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registered under the [M1]Medical Act 1983 (whether fully, provisionally or with limited registration), or under any repealed enactment from which a provision of that Act is derived,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).

Marginal Citations

M1 1983 c. 54.

[F1 4A (1) A person ("P") is disqualified for being appointed as chairman, deputy chairman, or as any other member of the Authority if—

(a) P is the subject of a bankruptcy restrictions order or interim order,

(b) a bankruptcy order has been made against P by a court in Northern Ireland, P's estate has been sequestered by a court in Scotland, or under the law of Northern Ireland or Scotland, P has made a composition or arrangement with, or granted a trust deed for, P's creditors, or

(c) in the last five years P has been convicted in the United Kingdom, the Channel Islands or the Isle of Man of an offence and has had a qualifying sentence passed on P.

(2) Where P is disqualified under sub-paragraph (1)(b) because a bankruptcy order has been made against P or P's estate has been sequestered, the disqualification ceases—

(a) on P obtaining a discharge, or

(b) if the bankruptcy order is annulled or the sequestration of P's estate is recalled or reduced, on the date of that event.

(3) Where P is disqualified under sub-paragraph (1)(b) because of P having made a composition or arrangement with, or granted a trust deed for, P's creditors, the disqualification ceases—

(a) at the end of the period of five years beginning with the date on which the terms of the deed of composition or arrangement or trust deed are fulfilled, or

(b) if, before then, P pays P's debts in full, on the date on which the payment is completed.

(4) For the purposes of sub-paragraph (1)(c), the date of conviction is to be taken to be the ordinary date on which the period allowed for making an appeal or application expires or, if an appeal or application is made, the date on which the appeal or application is finally disposed of or abandoned or fails by reason of its non-prosecution.

(5) In sub-paragraph (1)(c), the reference to a qualifying sentence is to a sentence of imprisonment for a period of not less than three months (whether suspended or not) without the option of a fine.**]**

Textual Amendments

F1 Sch. 1 para. 4A inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 1 para. 2**; S.I. 2009/2232, art. 2(u)

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).

[F2(4A) A person holding office as chairman, deputy chairman or other member of the Authority is to cease to hold that office if the person becomes disqualified for appointment to it.**]**

(5) If the Secretary of State is satisfied that a member of the Authority—

(a) has been absent from meetings of the Authority for six consecutive months or longer without the permission of the Authority, or

F3(b) . . . . . .

(c) is unable or unfit to discharge the **[**F4person's functions as chairman, deputy chairman or other member**]**,

the Secretary of State may **[**F5remove the member from office as chairman, deputy chairman or other member**]**.

Textual Amendments

F2 Sch. 1 para. 5(4A) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 1 para. 3(a)**; S.I. 2009/2232, art. 2(u)

F3 Sch. 1 para. 5(5)(b) repealed (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), Sch. 1 para. 3(b)(i), **Sch. 8 Pt. 1**; S.I. 2009/2232, art. 2(u)

F4 Words in Sch. 1 para. 5(5)(c) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 1 para. 3(b)(ii)**; S.I. 2009/2232, art. 2(u)

F5 Words in Sch. 1 para. 5(5) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 1 para. 3(b)(iii)**; S.I. 2009/2232, art. 2(u)

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

6 In Part II of Schedule 1 to the M2House of Commons Disqualification Act 1975 and in Part II of Schedule 1 to the M3Northern 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.

(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) **[**F6Subject to any provision of this Act, the**]** Authority may regulate its own proceedings, and make such arrangements as it thinks appropriate for the discharge of its functions.

(2) The Authority may pay to the members of any committee or sub-committee such fees and allowances as the Secretary of State may, with the consent of the Treasury, determine.

Textual Amendments

F6 Words in Sch. 1 para. 9(1) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 7 para. 15(a)**; S.I. 2009/2232, art. 2(y)

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 [F7]... with respect to the licence, and if he does so the deliberation or decision shall be of no effect.

Textual Amendments

F7 Words in Sch. 1 para. 10(3) repealed (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), Sch. 7 para. 15(b), **Sch. 8 Pt. 1**; S.I. 2009/2232, art. 2(y)

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

Instruments

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

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

Investigation by Parliamentary Commissioner

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

[F8Application of Statutory Instruments Act 1946

Textual Amendments

F8 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

I1 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*,

[F9(b) procuring, keeping, testing, processing or distributing embryos,

(c) procuring, testing, processing, distributing or using gametes**]**

[F10(ca) using embryos for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques,**]**

(d) **[**F11other**]** practices designed to secure that embryos are in a suitable condition to be placed in a woman F12... ,

(e) placing any **[**F13permitted 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**[**F14, apart from practices falling within section 4A(2),**]** as may be specified in, or determined in accordance with, regulations.

(2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such manner as may be so specified.

(3) A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services.

[F15(4) A licence under this paragraph cannot authorise altering the nuclear or mitochondrial DNA of a cell while it forms part of an embryo, except for the purpose of creating something that will by virtue of regulations under section 3ZA(5) be a permitted embryo.**]**

[F16(4A) A licence under this paragraph cannot authorise the use of embryos for the purpose mentioned in sub-paragraph (1)(ca) unless the Authority is satisfied that the proposed use of embryos is necessary for that purpose.**]**

(5) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

[F17(6) In this paragraph, references to a permitted embryo are to be read in accordance with section 3ZA.**]**

Textual Amendments

F9 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)**

F10 Sch. 2 para. 1(1)(ca) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 2(2)(a)**; S.I. 2009/2232, art. 2(v)

F11 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)**

F12 Words in Sch. 2 para. 1(1)(d) repealed (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), Sch. 2 para. 2(2)(b), **Sch. 8 Pt. 1**; S.I. 2009/2232, art. 2(v)

F13 Words in Sch. 2 para. 1(1)(e) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 2(2)(c)**; S.I. 2009/2232, art. 2(v)

F14 Words in Sch. 2 para. 1(1)(g) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 2(2)(d)**; S.I. 2009/2232, art. 2(v)

F15 Sch. 2 para. 1(4) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 2(3)**; S.I. 2009/2232, art. 2(v)

F16 Sch. 2 para. 1(4A) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 2(4)**; S.I. 2009/2232, art. 2(v)

F17 Sch. 2 para. 1(6) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 2(5)**; S.I. 2009/2232, art. 2(v)

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)**

[F18 Embryo testing

Textual Amendments

F18 Sch. 2 paras. 1ZA-1ZC and cross-headings inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 3**; S.I. 2009/2232, art. 2(v)

1ZA (1) A licence under paragraph 1 cannot authorise the testing of an embryo, except for one or more of the following purposes—

(a) establishing whether the embryo has a gene, chromosome or mitochondrion abnormality that may affect its capacity to result in a live birth,

(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,

(c) in a case where there is a particular risk that any resulting child will have or develop—

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

(ii) a gender-related serious illness, or

(iii) any other gender-related serious medical condition,

establishing the sex of the embryo,

(d) in a case where a person ("the sibling") who is the child of the persons whose gametes are used to bring about the creation of the embryo (or of either of those persons) suffers from a serious medical condition which could be treated by umbilical cord blood stem cells, bone marrow or other tissue of

any resulting child, establishing whether the tissue of any resulting child would be compatible with that of the sibling, and

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

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

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

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

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

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

(a) it affects only one sex, or

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

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

Sex selection

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

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

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

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

(b) a gender-related serious illness, or

(c) any other gender-related serious medical condition.

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

(a) it affects only one sex, or

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

Power to amend paragraphs 1ZA and 1ZB

1ZC (1) Regulations may make any amendment of paragraph 1ZA (embryo testing).

(2) Regulations under this paragraph which amend paragraph 1ZA may make any amendment of sub-paragraphs (2) to (4) of paragraph 1ZB (sex selection) which appears to the Secretary of State to be necessary or expedient in consequence of the amendment of paragraph 1ZA.

(3) Regulations under this paragraph may not enable the authorisation of—

(a) the testing of embryos for the purpose of establishing their sex, or

(b) other practices falling within paragraph 1ZB(1),

except on grounds relating to the health of any resulting child.

(4) For the purposes of this paragraph, "amend" includes add to and repeal, and references to "amendment" are to be read accordingly.**]**

[F19Licences for non-medical fertility services

Textual Amendments

F19 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.

[F20(1A) A licence under this paragraph cannot authorise the procurement or distribution of sperm to which there has been applied any process designed to secure that any resulting child will be of one sex rather than the other.**]**

(2) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence and may authorise the performance of any of the activities referred to in sub-paragraph (1) above in such manner as may be so specified.

(3) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.**]**

Textual Amendments

F20 Sch. 2 para. 1A(1A) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 4**; S.I. 2009/2232, art. 2(v)

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.

[F21(1A) A licence under this paragraph or paragraph 3 may authorise the storage of human admixed embryos (whether or not the licence also authorises the storage of gametes or embryos or both).**]**

(2) Subject to the provisions of this Act, a licence authorising such storage **[**F22as is mentioned in sub-paragraph (1) or (1A)**]** may be granted subject to such conditions as may be specified in the licence and may authorise storage in such manner as may be so specified.

(3) A licence under this paragraph shall be granted for such period not exceeding five years as may be specified in the licence.

Textual Amendments

F21 Sch. 2 para. 2(1A) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 5(a)**; S.I. 2009/2232, art. 2(v)

F22 Words in Sch. 2 para. 2(2) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 5(b)**; S.I. 2009/2232, art. 2(v)

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)

[F23 Licences for research

Textual Amendments

F23 Sch. 2 paras. 3, 3A and cross-headings substituted for Sch. 2 para. 3 (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 2 para. 6**; S.I. 2009/2232, art. 2(v)

3 (1) A licence under this paragraph may authorise any of the following—

(a) bringing about the creation of embryos *in vitro*, and

(b) keeping or using embryos,

for the purposes of a project of research specified in the licence.

(2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.

(3) A licence under this paragraph may authorise any of the following—

(a) bringing about the creation of human admixed embryos *in vitro*, and

(b) keeping or using human admixed embryos,

for the purposes of a project of research specified in the licence.

(4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).

(5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.

(6) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence.

(7) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.

(8) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.

(9) This paragraph has effect subject to paragraph 3A.

Purposes for which activities may be licensed under paragraph 3

3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority—

(a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) ("the principal purposes"),

(b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or

(c) to be necessary or desirable for such other purposes as may be specified in regulations.

(2) The principal purposes are—

(a) increasing knowledge about serious disease or other serious medical conditions,

(b) developing treatments for serious disease or other serious medical conditions,

(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

(d) promoting advances in the treatment of infertility,

(e) increasing knowledge about the causes of miscarriage,

(f) developing more effective techniques of contraception,

(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or

(h) increasing knowledge about the development of embryos.**]**

General

4 **[**F24(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.**]**

F24(2) A licence cannot—

(a) F25 . . . . . .

(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

[F26(d) apply to premises of the person who holds the licence in different places.**]**F26

Textual Amendments

F24 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)**

F25 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)**

F26 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

I4 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 [F27OR STORAGE OF GAMETES, EMBRYOS OR HUMAN ADMIXED EMBRYOS ETC]

Textual Amendments

F27 Words in Sch. 3 heading substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 2**; S.I. 2009/2232, art. 2(w)

Commencement Information

I5 Schedule 3 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, **art. 2(2)**

Consent

[F28] (1) A consent under this Schedule, and any notice under paragraph 4 varying or withdrawing a consent under this Schedule, must be in writing and, subject to sub-paragraph (2), must be signed by the person giving it.

(2) A consent under this Schedule by a person who is unable to sign because of illness, injury or physical disability (a "person unable to sign"), and any notice under paragraph 4 by a person unable to sign varying or withdrawing a consent under this Schedule, is to be taken to comply with the requirement of sub-paragraph (1) as to signature if it is signed at the direction of the person unable to sign, in the presence of the person unable to sign and in the presence of at least one witness who attests the signature.

(3) In this Schedule "effective consent" means a consent under this Schedule which has not been withdrawn.]

Textual Amendments

F28 Sch. 3 para. 1 substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 3**; S.I. 2009/2232, art. 2(w)

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,

[[F29](ba) use for the purpose of training persons in embryo biopsy, embryo storage or other embryological techniques, or**]**

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

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

[[F30](1A) A consent to the use of any human admixed embryo must specify use for the purposes of any project of research and may specify conditions subject to which the human admixed embryo may be so used.**]**

[[F31](2) A consent to the storage of any gametes, any embryo or any human admixed embryo must—

(a) specify the maximum period of storage (if less than the statutory storage period),

(b) except in a case falling within paragraph (c), state what is to be done with the gametes, embryo or human admixed embryo if the person who gave the consent dies or is unable, because the person lacks capacity to do so, to vary the terms of the consent or to withdraw it, and

(c) where the consent is given by virtue of paragraph 8(2A) or 13(2), state what is to be done with the embryo or human admixed embryo if the person to whom the consent relates dies,

and may (in any case) specify conditions subject to which the gametes, embryo or human admixed embryo may remain in storage.

(2A) A consent to the use of a person's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo is to be taken unless otherwise stated to include consent to the use of the cells after the person's death.

(2B) In relation to Scotland, the reference in sub-paragraph (2)(b) to the person lacking capacity is to be read as a reference to the person—

(a) lacking capacity within the meaning of the Age of Legal Capacity (Scotland) Act 1991, or

(b) being incapable within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000.**]**

(3) A consent under this Schedule must provide for such other matters as the Authority may specify in directions.

[[F32](4) A consent under this Schedule may apply—

(a) to the use or storage of a particular embryo or human admixed embryo, or

(b) in the case of a person providing gametes or human cells, to the use or storage of—

(i) any embryo or human admixed embryo whose creation may be brought about using those gametes or those cells, and

(ii) any embryo or human admixed embryo whose creation may be brought about using such an embryo or human admixed embryo.

(5) In the case of a consent falling within sub-paragraph (4)(b), the terms of the consent may be varied, or the consent may be withdrawn, in accordance with this Schedule either generally or in relation to—

(a) a particular embryo or particular embryos, or

(b) a particular human admixed embryo or particular human admixed embryos.**]**

Textual Amendments

F29 Sch. 3 para. 2(1)(ba) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 4(2)**; S.I. 2009/2232, art. 2(w)

F30 Sch. 3 para. 2(1A) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 4(3)**; S.I. 2009/2232, art. 2(w)

F31 Sch. 3 para. 2(2)-(2B) substituted for Sch. 3 para. 2(2) (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 4(4)**; S.I. 2009/2232, art. 2(w)

F32 Sch. 3 para. 2(4)(5) substituted for Sch. 3 para. 2(4) (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 4(5)**; S.I. 2009/2232, art. 2(w)

Commencement Information

I6 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.

(2) Before a person gives consent under this Schedule he must be informed of the effect of paragraph 4 **[**F33and, if relevant, paragraph 4A**]** below.

Textual Amendments

F33 Words in Sch. 3 para. 3(2) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 5**; S.I. 2009/2232, art. 2(w)

Commencement Information

I7 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**[**F34, human cells, embryo or human admixed embryo**]** to which the consent is relevant.

(2) **[**F35Subject to sub-paragraph (3), the**]** terms of any consent to the use of any embryo cannot be varied, and such consent cannot be withdrawn, once the embryo has been used—

(a) in providing treatment services,

[F36(aa) in training persons in embryo biopsy, embryo storage or other embryological techniques, or**]**

(b) for the purposes of any project of research.

[F37(3) Where the terms of any consent to the use of an embryo ("embryo A") include consent to the use of an embryo or human admixed embryo whose creation may be brought about *in vitro* using embryo A, that consent to the use of that subsequent embryo or human admixed embryo cannot be varied or withdrawn once embryo A has been used for one or more of the purposes mentioned in sub-paragraph (2)(a) or (b).

(4) Subject to sub-paragraph (5), the terms of any consent to the use of any human admixed embryo cannot be varied, and such consent cannot be withdrawn, once the human admixed embryo has been used for the purposes of any project of research.

(5) Where the terms of any consent to the use of a human admixed embryo ("human admixed embryo A") include consent to the use of a human admixed embryo or embryo whose creation may be brought about *in vitro* using human admixed embryo A, that consent to the use of that subsequent human admixed embryo or embryo cannot be varied or withdrawn once human admixed embryo A has been used for the purposes of any project of research.**]**

Textual Amendments

F34 Words in Sch. 3 para. 4(1) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 6(2)**; S.I. 2009/2232, art. 2(w)

F35 Words in Sch. 3 para. 4(2) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 6(3)(a)**; S.I. 2009/2232, art. 2(w)

F36 Sch. 3 para. 4(2)(aa) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 6(3)(b)**; S.I. 2009/2232, art. 2(w)

F37 Sch. 3 para. 4(3)-(5) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 6(4)**; S.I. 2009/2232, art. 2(w)

Commencement Information

I8 Schedule 3 para. 4 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, **art. 2(2)**

[F38 4A (1) This paragraph applies where—

(a) a permitted embryo, the creation of which was brought about *in vitro*, is in storage,

(b) it was created for use in providing treatment services,

(c) before it is used in providing treatment services, one of the persons whose gametes were used to bring about its creation ("P") gives the person keeping the embryo notice withdrawing P's consent to the storage of the embryo, and

(d) the embryo was not to be used in providing treatment services to P alone.

(2) The person keeping the embryo must as soon as possible take all reasonable steps to notify each interested person in relation to the embryo of P's withdrawal of consent.

(3) For the purposes of sub-paragraph (2), a person is an interested person in relation to an embryo if the embryo was to be used in providing treatment services to that person.

(4) Storage of the embryo remains lawful until—

(a) the end of the period of 12 months beginning with the day on which the notice mentioned in sub-paragraph (1) was received from P, or

(b) if, before the end of that period, the person keeping the embryo receives a notice from each person notified of P's withdrawal under sub-paragraph (2) stating that the person consents to the destruction of the embryo, the time at which the last of those notices is received.

(5) The reference in sub-paragraph (1)(a) to a permitted embryo is to be read in accordance with section 3ZA.**]**

Textual Amendments

F38 Sch. 3 para. 4A inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 7**; S.I. 2009/2232, art. 2(w)

Use of gametes for treatment of others

5 (1) A person's gametes must not be used for the purposes of treatment services **[**F39or non-medical fertility services**]** unless there is an effective consent by that person to their being so used and they are used in accordance with the terms of the consent.

(2) A person's gametes must not be received for use for those purposes unless there is an effective consent by that person to their being so used.

(3) This paragraph does not apply to the use of a person's gametes for the purpose of that person, or that person and another together, receiving treatment services.

Textual Amendments

F39 Words in Sch. 3 para. 5 inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 8**; S.I. 2009/2232, art. 2(w)

Commencement Information

I9 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 **[**F40or human cells**]** must not be used to bring about the creation of any embryo*in vitro* unless there is an effective consent by that person to any embryo**[**F41,**]** the creation of which may be brought about with the use of those gametes **[**F42or human cells,**]** being used for one or more of the purposes mentioned in **[**F43paragraph 2(1)(a), (b) and (c)**]** above.

(2) An embryo the creation of which was brought about *in vitro* must not be received by any person unless there is an effective consent by **[**F44each relevant person in relation to**]** the embryo to the use for one or more of the purposes mentioned in **[**F45paragraph 2(1)(a), (b), (ba) and (c)**]** above of the embryo.

(3) An embryo the creation of which was brought about *in vitro* must not be used for any purpose unless there is an effective consent by each **[**F46relevant person in relation

to**]** the embryo to the use for that purpose of the embryo and the embryo is used in accordance with those consents.

[F47(3A) If the Authority is satisfied that the parental consent conditions in paragraph 15 are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years ("C"), the Authority may in the licence authorise the application of sub-paragraph (3B) in relation to C.

(3B) Where the licence authorises the application of this sub-paragraph, the effective consent of a person having parental responsibility for C—

(a) to the use of C's human cells to bring about the creation of an embryo *in vitro* for use for the purposes of a project of research, or

(b) to the use for those purposes of an embryo in relation to which C is a relevant person by reason only of the use of C's human cells,

is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.

(3C) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (3B) ceases to apply in relation to C.

(3D) Sub-paragraphs (1) to (3) have effect subject to paragraphs 16 and 20.

(3E) For the purposes of sub-paragraphs (2), (3) and (3B), each of the following is a relevant person in relation to an embryo the creation of which was brought about *in vitro* ("embryo A")—

(a) each person whose gametes or human cells were used to bring about the creation of embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A.**]**

(4) Any consent required by this paragraph is in addition to any consent that may be required by paragraph 5 above.

Textual Amendments

F40 Words in Sch. 3 para. 6(1) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 9(2)(a)**; S.I. 2009/2232, art. 2(w)

F41 Comma in Sch. 3 para. 6(1) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 9(2)(b)**; S.I. 2009/2232, art. 2(w)

F42 Words in Sch. 3 para. 6(1) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 9(2)(c)**; S.I. 2009/2232, art. 2(w)

F43 Words in Sch. 3 para. 6(1) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 9(2)(d)**; S.I. 2009/2232, art. 2(w)

F44 Words in Sch. 3 para. 6(2) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 9(3)(a)**; S.I. 2009/2232, art. 2(w)

F45 Words in Sch. 3 para. 6(2) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 9(3)(b)**; S.I. 2009/2232, art. 2(w)
F46 Words in Sch. 3 para. 6(3) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 9(4)**; S.I. 2009/2232, art. 2(w)
F47 Sch. 3 para. 6(3A)-(3E) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 9(5)**; S.I. 2009/2232, art. 2(w)

Commencement Information
I10 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) **[**F48Sub-paragraphs (1) and (2) do**]** not apply to the use, for the purpose of providing a woman with treatment services, of an embryo taken from her.

[F49(4) An embryo taken from a woman must not be used to bring about the creation of any embryo *in vitro* or any human admixed embryo *in vitro*.**]**

Textual Amendments
F48 Words in Sch. 3 para. 7(3) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 10(2)**; S.I. 2009/2232, art. 2(w)
F49 Sch. 3 para. 7(4) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 10(3)**; S.I. 2009/2232, art. 2(w)

Commencement Information
I11 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 **[**F50relevant person in relation to**]** the embryo, to the storage of the embryo and the embryo is stored in accordance with those consents.

[F51(2A) Where a licence authorises the application of paragraph 6(3B) in relation to a person who has not attained the age of 18 years ("C"), the effective consent of a person having parental responsibility for C to the storage of an embryo in relation to which C is a relevant person by reason only of the use of C's human cells is to be treated for the purposes of sub-paragraph (2) as the effective consent of C.

(2B) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraph (2) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2A) ceases to apply in relation to C.

(2C) For the purposes of sub-paragraphs (2) and (2A), each of the following is a relevant person in relation to an embryo the creation of which was brought about *in vitro* ("embryo A")—

(a) each person whose gametes or human cells were used to bring about the creation of embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any other embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any human admixed embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of embryo A.**]**

(3) An embryo taken from a woman must not be kept in storage unless there is an effective consent by her to its storage and it is stored in accordance with the consent.

[F52(4) Sub-paragraph (1) has effect subject to paragraphs 9 and 10; and sub-paragraph (2) has effect subject to paragraphs 4A(4), 16 and 20.**]**

Textual Amendments

F50 Words in Sch. 3 para. 8(2) substituted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 11(2)**; S.I. 2009/2232, art. 2(w)

F51 Sch. 3 para. 8(2A)-(2C) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 11(3)**; S.I. 2009/2232, art. 2(w)

F52 Sch. 3 para. 8(4) inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 11(4)**; S.I. 2009/2232, art. 2(w)

Commencement Information

I12 Schedule 3 para. 8 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, **art. 2(2)**

[F53Cases where consent not required for storage

Textual Amendments

F53 Sch. 3 paras. 9-11 and cross-heading inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 12**; S.I. 2009/2232, art. 2(w)

9 (1) The gametes of a person ("C") may be kept in storage without C's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by C before C attains the age of 18 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that C is expected to undergo medical treatment and that in the opinion of the registered medical practitioner—

(a) the treatment is likely to cause a significant impairment of C's fertility, and

(b) the storage of the gametes is in C's best interests.

(4) Condition C is that, at the time when the gametes are first stored, either—

(a) C has not attained the age of 16 years and is not competent to deal with the issue of consent to the storage of the gametes, or

(b) C has attained that age but, although not lacking capacity to consent to the storage of the gametes, is not competent to deal with the issue of consent to their storage.

(5) Condition D is that C has not, since becoming competent to deal with the issue of consent to the storage of the gametes—

(a) given consent under this Schedule to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that C does not wish them to continue to be stored.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications—

(a) for sub-paragraph (4), substitute—

"(4) Condition C is that, at the time when the gametes are first stored, C does not have capacity (within the meaning of section 2(4) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the storage of the gametes.", and

(b) in sub-paragraph (5), for "becoming competent to deal with the issue of consent to the storage of the gametes" substitute " acquiring such capacity ".

10 (1) The gametes of a person ("P") may be kept in storage without P's consent if the following conditions are met.

(2) Condition A is that the gametes are lawfully taken from or provided by P after P has attained the age of 16 years.

(3) Condition B is that, before the gametes are first stored, a registered medical practitioner certifies in writing that P is expected to undergo medical treatment and that in the opinion of the registered medical practitioner—

(a) the treatment is likely to cause a significant impairment of P's fertility,

(b) P lacks capacity to consent to the storage of the gametes,

(c) P is likely at some time to have that capacity, and

(d) the storage of the gametes is in P's best interests.

(4) Condition C is that, at the time when the gametes are first stored, P lacks capacity to consent to their storage.

(5) Condition D is that P has not subsequently, at a time when P has capacity to give a consent under this Schedule—

(a) given consent to the storage of the gametes, or

(b) given written notice to the person keeping the gametes that P does not wish them to continue to be stored.

(6) In relation to Scotland—

(a) references in sub-paragraphs (3) and (4) to P lacking capacity to consent are to be read as references to P being incapable, within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000, of giving such consent,

(b) the references in sub-paragraphs (3) and (5) to P having capacity are to be read as references to P not being so incapable, and

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

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

[F54Creation, use and storage of human admixed embryos

Textual Amendments

F54 Sch. 3 paras. 12-14 and cross-heading inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 13**; S.I. 2009/2232, art. 2(w)

12 (1) A person's gametes or human cells must not be used to bring about the creation of any human admixed embryo *in vitro* unless there is an effective consent by that person to any human admixed embryo, the creation of which may be brought about with the use of those gametes or human cells, being used for the purposes of any project of research.

(2) A human admixed embryo the creation of which was brought about *in vitro* must not be received by any person unless there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for the purposes of any project of research.

(3) A human admixed embryo the creation of which was brought about *in vitro* must not be used for the purposes of a project of research unless—

(a) there is an effective consent by each relevant person in relation to the human admixed embryo to the use of the human admixed embryo for that purpose, and

(b) the human admixed embryo is used in accordance with those consents.

(4) If the Authority is satisfied that the parental consent conditions in paragraph 15 are met in relation to the proposed use under a licence of the human cells of a person who has not attained the age of 18 years ("C"), the Authority may in the licence authorise the application of sub-paragraph (5) in relation to C.

(5) Where the licence authorises the application of this sub-paragraph, the effective consent of a person having parental responsibility for C—

(a) to the use of C's human cells to bring about the creation of a human admixed embryo *in vitro* for use for the purposes of a project of research, or

(b) to the use for those purposes of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C's human cells,

is to be treated for the purposes of sub-paragraphs (1) to (3) as the effective consent of C.

(6) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraphs (1) to (3) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (5) ceases to apply in relation to C.

(7) Sub-paragraphs (1) to (3) have effect subject to paragraphs 16 and 20.

13 (1) A human admixed embryo the creation of which was brought about *in vitro* must not be kept in storage unless—

(a) there is an effective consent by each relevant person in relation to the human admixed embryo to the storage of the human admixed embryo, and

(b) the human admixed embryo is stored in accordance with those consents.

(2) Where a licence authorises the application of paragraph 12(5) in relation to a person who has not attained the age of 18 years ("C"), the effective consent of a person having parental responsibility for C to the storage of a human admixed embryo in relation to which C is a relevant person by reason only of the use of C's human cells is to be treated for the purposes of sub-paragraph (1) as the effective consent of C.

(3) If C attains the age of 18 years or the condition in paragraph 15(3) ceases to be met in relation to C, paragraph 4 has effect in relation to C as if any effective consent previously given under sub-paragraph (1) by a person having parental responsibility for C had been given by C but, subject to that, sub-paragraph (2) ceases to apply in relation to C.

(4) Sub-paragraph (1) has effect subject to paragraphs 16 and 20.

14 For the purposes of paragraphs 12 and 13, each of the following is a relevant person in relation to a human admixed embryo the creation of which was brought about *in vitro* ("human admixed embryo A")—

(a) each person whose gametes or human cells were used to bring about the creation of human admixed embryo A,

(b) each person whose gametes or human cells were used to bring about the creation of any embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of human admixed embryo A, and

(c) each person whose gametes or human cells were used to bring about the creation of any other human admixed embryo, the creation of which was brought about *in vitro*, which was used to bring about the creation of human admixed embryo A.**]**

[F55 Parental consent conditions

Textual Amendments

F55 Sch. 3 paras. 15-21 and cross-headings inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 14**; S.I. 2009/2232, art. 2(w)

15 (1) In relation to a person who has not attained the age of 18 years ("C"), the parental consent conditions referred to in paragraphs 6(3A) and 12(4) are as follows.

(2) Condition A is that C suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.

(3) Condition B is that either—

(a) C is not competent to deal with the issue of consent to the use of C's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research, or

(b) C has attained the age of 16 years but lacks capacity to consent to such use of C's human cells.

(4) Condition C is that any embryo or human admixed embryo to be created *in vitro* is to be used for the purposes of a project of research which is intended to increase knowledge about—

(a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or

(b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.

(5) Condition D is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation *in vitro* of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who—

(a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project, or

(b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.

(6) In relation to Scotland, sub-paragraphs (1) to (5) are to be read with the following modifications—

(a) for sub-paragraph (3) substitute—

"(3) Condition B is that C does not have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to consent to the use of C's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research.",

(b) in sub-paragraph (5)(a), for "have capacity to consent" substitute " are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent ", and

(c) in sub-paragraph (5)(b), for "are competent to deal with the issue of" substitute " have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to ".

Adults lacking capacity: exemption relating to use of human cells etc.

16 (1) If, in relation to the proposed use under a licence of the human cells of a person who has attained the age of 18 years ("P"), the Authority is satisfied—

(a) that the conditions in paragraph 17 are met,

(b) that paragraphs (1) to (4) of paragraph 18 have been complied with, and

(c) that the condition in paragraph 18(5) is met,

the Authority may in the licence authorise the application of this paragraph in relation to P.

(2) Where a licence authorises the application of this paragraph, this Schedule does not require the consent of P—

(a) to the use (whether during P's life or after P's death) of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research,

(b) to the storage or the use for those purposes (whether during P's life or after P's death) of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of P's human cells.

(3) This paragraph has effect subject to paragraph 19.

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

17 (1) The conditions referred to in paragraph 16(1)(a) are as follows.

(2) Condition A is that P suffers from, or is likely to develop, a serious disease, a serious physical or mental disability or any other serious medical condition.

(3) Condition B is that P lacks capacity to consent to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research.

(4) Condition C is that the person responsible under the licence has no reason to believe that P had refused such consent at a time when P had that capacity.

(5) Condition D is that it appears unlikely that P will at some time have that capacity.

(6) Condition E is that any embryo or human admixed embryo to be created *in vitro* is to be used for the purposes of a project of research which is intended to increase knowledge about—

(a) the disease, disability or medical condition mentioned in sub-paragraph (2) or any similar disease, disability or medical condition, or

(b) the treatment of, or care of persons affected by, that disease, disability or medical condition or any similar disease, disability or medical condition.

(7) Condition F is that there are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the only human cells that can be used to bring about the creation *in vitro* of embryos or human admixed embryos for use for the purposes of the project are the human cells of persons who—

(a) have attained the age of 18 years and have capacity to consent to the use of their human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project, or

(b) have not attained that age but are competent to deal with the issue of consent to such use of their human cells.

(8) In this paragraph and paragraph 18 references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.

(9) In relation to Scotland—

(a) references in sub-paragraphs (3) to (5) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being,

incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent, and

(b) sub-paragraph (7) is to be read with the following modifications—

(i) in paragraph (a), for "have capacity to consent" substitute " are not incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving consent ", and

(ii) in paragraph (b), for "are competent to deal with the issue of" substitute " have capacity (within the meaning of section 2(4ZB) of the Age of Legal Capacity (Scotland) Act 1991) to ".

Consulting carers etc. in case of adult lacking capacity

18 (1) This paragraph applies in relation to a person who has attained the age of 18 years ("P") where the person responsible under the licence ("R") wishes to use P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research, in a case where P lacks capacity to consent to their use.

(2) R must take reasonable steps to identify a person who—

(a) otherwise than in a professional capacity or for remuneration, is engaged in caring for P or is interested in P's welfare, and

(b) is prepared to be consulted by R under this paragraph of this Schedule.

(3) If R is unable to identify such a person R must nominate a person who—

(a) is prepared to be consulted by R under this paragraph of this Schedule, but

(b) has no connection with the project.

(4) R must provide the person identified under sub-paragraph (2) or nominated under sub-paragraph (3) ("F") with information about the proposed use of human cells to bring about the creation *in vitro* of embryos or human admixed embryos for use for the purposes of the project and ask F what, in F's opinion, P's wishes and feelings about the use of P's human cells for that purpose would be likely to be if P had capacity in relation to the matter.

(5) The condition referred to in paragraph 16(1)(c) is that, on being consulted, F has not advised R that in F's opinion P's wishes and feelings would be likely to lead P to decline to consent to the use of P's human cells for that purpose.

(6) In relation to Scotland, the references in sub-paragraphs (1) and (4) to P lacking, or having, capacity to consent are to be read respectively as references to P being, or not being, incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

Effect of acquiring capacity

19 (1) Paragraph 16 does not apply to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo if, at a time before the human cells are used for that purpose, P—

(a) has capacity to consent to their use, and

(b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.

(2) Paragraph 16 does not apply to the storage or use of an embryo or human admixed embryo whose creation *in vitro* was brought about with the use of P's human cells if, at a time before the embryo or human admixed embryo is used for the purposes of the project of research, P—

(a) has capacity to consent to the storage or use, and

(b) gives written notice to the person keeping the human cells that P does not wish them to be used for that purpose.

(3) In relation to Scotland, the references in sub-paragraphs (1)(a) and (2)(a) to P having capacity to consent are to be read as references to P not being incapable (within the meaning of section 1(6) of the Adults with Incapacity (Scotland) Act 2000) of giving such consent.

Use of cells or cell lines in existence before relevant commencement date

20 (1) Where a licence authorises the application of this paragraph in relation to qualifying cells, this Schedule does not require the consent of a person ("P")—

(a) to the use of qualifying cells of P to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of a project of research, or

(b) to the storage or the use for those purposes of an embryo or human admixed embryo in relation to which P is a relevant person by reason only of the use of qualifying cells of P.

(2) "Qualifying cells" are human cells which—

(a) were lawfully stored for research purposes immediately before the commencement date, or

(b) are derived from human cells which were lawfully stored for those purposes at that time.

(3) The "commencement date" is the date on which paragraph 9(2)(a) of Schedule 3 to the Human Fertilisation and Embryology Act 2008 (requirement for consent to use of human cells to create an embryo) comes into force.

Conditions for grant of exemption in paragraph 20

21 (1) A licence may not authorise the application of paragraph 20 unless the Authority is satisfied—

(a) that there are reasonable grounds for believing that scientific research will be adversely affected to a significant extent if the only human cells that can be used to bring about the creation *in vitro* of embryos or human admixed embryos for use for the purposes of the project of research are—

(i) human cells in respect of which there is an effective consent to their use to bring about the creation *in vitro* of embryos or human admixed embryos for use for those purposes, or

(ii) human cells which by virtue of paragraph 16 can be used without such consent, and

(b) that any of the following conditions is met in relation to each of the persons whose human cells are qualifying cells which are to be used for the purposes of the project of research.

(2) Condition A is that—

(a) it is not reasonably possible for the person responsible under the licence ("R") to identify the person falling within sub-paragraph (1)(b) ("P"), and

(b) where any information that relates to P (without identifying P or enabling P to be identified) is available to R, that information does not suggest that P would have objected to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project.

(3) Condition B is that—

(a) the person falling within sub-paragraph (1)(b) ("P") is dead or the person responsible under the licence ("R") believes on reasonable grounds that P is dead,

(b) the information relating to P that is available to R does not suggest that P would have objected to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project, and

(c) a person who stood in a qualifying relationship to P immediately before P died (or is believed to have died) has given consent in writing to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project.

(4) Condition C is that—

(a) the person responsible under the licence ("R") has taken all reasonable steps to contact—

(i) the person falling within sub-paragraph (1)(b) ("P"), or

(ii) in a case where P is dead or R believes on reasonable grounds that P is dead, persons who could give consent for the purposes of sub-paragraph (3)(c),

but has been unable to do so, and

(b) the information relating to P that is available to R does not suggest that P would have objected to the use of P's human cells to bring about the creation *in vitro* of an embryo or human admixed embryo for use for the purposes of the project.

(5) The HTA consent provisions apply in relation to consent for the purposes of sub-paragraph (3)(c) as they apply in relation to consent for the purposes of section 3(6)(c) of the Human Tissue Act 2004; and for the purposes of this sub-paragraph the HTA consent provisions are to be treated as if they extended to Scotland.

(6) In sub-paragraph (5) "the HTA consent provisions" means subsections (4), (5), (6), (7) and (8)(a) and (b) of section 27 of the Human Tissue Act 2004.

(7) In this paragraph references to the person responsible under the licence are to be read, in a case where an application for a licence is being made, as references to the person who is to be the person responsible.

(8) Paragraphs 1 to 4 of this Schedule do not apply in relation to a consent given for the purposes of sub-paragraph (3)(c).**]**

[F56 Interpretation

Textual Amendments

F56 Sch. 3 para. 22 and cross-heading inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 3 para. 15**; S.I. 2009/2232, art. 2(w)

22 (1) In this Schedule references to human cells are to human cells which are not—

(a) cells of the female or male germ line, or

(b) cells of an embryo.

(2) References in this Schedule to an embryo or a human admixed embryo which was used to bring about the creation of an embryo ("embryo A") or a human admixed embryo ("human admixed embryo A") include an embryo or, as the case may be, a human admixed embryo which was used to bring about the creation of—

(a) an embryo or human admixed embryo which was used to bring about the creation of embryo A or human admixed embryo A, and

(b) the predecessor of that embryo or human admixed embryo mentioned in paragraph (a), and

(c) the predecessor of that predecessor, and so on.

(3) References in this Schedule to an embryo or a human admixed embryo whose creation may be brought about using an embryo or a human admixed embryo are to be read in accordance with sub-paragraph (2).

(4) References in this Schedule (however expressed) to the use of human cells to bring about the creation of an embryo or a human admixed embryo include the use of human cells to alter the embryo or, as the case may be, the human admixed embryo.

(5) References in this Schedule to parental responsibility are—

(a) in relation to England and Wales, to be read in accordance with the Children Act 1989,

(b) in relation to Northern Ireland, to be read in accordance with the Children (Northern Ireland) Order 1995, and

(c) in relation to Scotland, to be read as references to parental responsibilities and parental rights within the meaning of the Children (Scotland) Act 1995.

(6) References in this Schedule to capacity are, in relation to England and Wales, to be read in accordance with the Mental Capacity Act 2005.

(7) References in this Schedule to the age of 18 years are, in relation to Scotland, to be read as references to the age of 16 years.**]**

[F57SCHEDULE 3ZA

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

Textual Amendments

F57 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.**]**

[F58SCHEDULE 3A

Section 14A

SUPPLEMENTARY LICENCE CONDITIONS: HUMAN APPLICATION

Textual Amendments

F58 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

(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

Labelling of the procured gametes and embryos (minimum labelling requirements)	Annex IV, point 1.6
Labelling of the shipping container (minimum labelling requirements)	Annex IV, point 1.7
2. Reception of tissues and cells at the tissue establishment	
Verification upon arrival (procedures for verification and requirement for quarantine until verification)	Annex IV, points 2.1 to 2.3
Registration of data (other than in respect of partner-donated sperm and partner-created embryos)	Annex IV, point 2.4
Registration of data (partner-donated sperm and partner-created embryos)	Annex IV, point 2.5

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

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

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

Requirements for holding a licence for gametes and embryo preparation processes

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

(a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and

(b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

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

[F59SCHEDULE 3B

INSPECTION, ENTRY, SEARCH AND SEIZURE

Textual Amendments

F59 Sch. 3B inserted (1.10.2009) by Human Fertilisation and Embryology Act 2008 (c. 22), s. 68(2), **Sch. 5**; S.I. 2009/2232, art. 2(x)

Inspection of statutory records

1 (1) A duly authorised person may require a person to produce for inspection any records which the person is required to keep by, or by virtue of, this Act.

(2) Where records which a person is so required to keep are stored in any electronic form, the power under sub-paragraph (1) includes power to require the records to be made available for inspection—

(a) in a visible and legible form, or

(b) in a form from which they can be readily produced in a visible and legible form.

(3) A duly authorised person may inspect and take copies of any records produced for inspection in pursuance of a requirement under this paragraph.

Arranging inspections

2 (1) Where a person—

(a) makes an enquiry to the Authority which concerns the making of a relevant application by that person, or

(b) has made a relevant application to the Authority which the Authority has not yet considered,

the Authority may arrange for a duly authorised person to inspect any of the premises mentioned in sub-paragraph (3).

(2) For the purposes of sub-paragraph (1) a "relevant application" means—

(a) an application for authorisation for a person to carry on an activity governed by this Act which the person is not then authorised to carry on, or

(b) an application for authorisation for a person to carry on any such activity on premises where the person is not then authorised to carry it on.

(3) The premises referred to in sub-paragraph (1) are—

(a) the premises where any activity referred to in sub-paragraph (2) is to be carried on;

(b) any premises that will be relevant third party premises for the purposes of any application.

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

Entry and inspection of premises

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

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

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

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

Entry and search in connection with suspected offence

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

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

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

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

(2) The conditions referred to are—

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

(b) that the premises are unoccupied;

(c) that the occupier is temporarily absent;

(d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this paragraph shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) In relation to Scotland—

(a) any reference in sub-paragraph (1) to a justice of the peace includes a reference to a sheriff, and

(b) the reference in that sub-paragraph to "on sworn information" is to be read as a reference to "by evidence on oath".

Execution of warrants

6 (1) Entry and search under a warrant under paragraph 5 is unlawful if any of sub-paragraphs (2) to (4) and (6) is not complied with.

(2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—

(a) produce the warrant to the occupier, and

(b) give the occupier—

(i) a copy of the warrant, and

(ii) an appropriate statement.

(4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—

(a) produce the warrant to that other person,

(b) give that other person—

(i) a copy of the warrant, and

(ii) an appropriate statement, and

(c) leave a copy of the warrant in a prominent place on the premises.

(5) In sub-paragraphs (3)(b)(ii) and (4)(b)(ii), the references to an appropriate statement are to a statement in writing containing such information relating to the powers of the person executing the warrant and the rights and obligations of the person to whom the statement is given as may be prescribed by regulations made by the Secretary of State.

(6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

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

Seizure in the course of inspection or search

7 (1) A duly authorised person entering and inspecting premises under paragraph 3 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for—

(a) the purposes of the Authority's functions relating to the grant, revocation, variation or suspension of licences, or

(b) the purpose of taking appropriate control measures in the event of a serious adverse event or serious adverse reaction.

(2) A duly authorised person entering or searching premises under a warrant under paragraph 5 may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under this Act.

(3) Where a person has power under sub-paragraph (1) or (2) to seize anything, that person may take such steps as appear to be necessary for preserving that thing or preventing interference with it.

(4) The power under sub-paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.

(5) Where by virtue of sub-paragraph (1) or (2) a person ("P") seizes anything, P shall leave on the premises from which the thing was seized a statement giving particulars of what P has seized and stating that P has seized it.

Supplementary provision

8 (1) Power under this Schedule to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.

(2) Power under this Schedule to inspect or search any premises includes, in particular—

(a) power to inspect any equipment found on the premises,

(b) power to inspect and take copies of any records found on the premises, and

(c) in the case of premises to which a licence relates or premises which are relevant third party premises in relation to a licence, power to observe the carrying-on of the licensed activity on the premises.

(3) Any power under this Schedule to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

9 (1) A person's right to exercise a power under this Schedule is subject to production of evidence of the person's entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having inspected premises in pursuance of arrangements made under paragraph 2 or after having exercised a power under this Schedule to inspect or search premises, the duly authorised person shall—

(a) prepare a written report of the inspection, or as the case may be, the inspection and search, and

(b) if requested to do so by the appropriate person, give the appropriate person a copy of the report.

(3) In sub-paragraph (2), the "appropriate person" means—

(a) in relation to premises to which a licence relates, the person responsible, or

(b) in relation to any other premises, the occupier.

Enforcement

10 A person who—

(a) fails without reasonable excuse to comply with a requirement under paragraph 1(1) or 8(3), or

(b) intentionally obstructs the exercise of any right under this Schedule,

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

Interpretation

11 In this Schedule—

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

(b) "licensed activity", in relation to a licence, means the activity which the licence authorises to be carried on.**]**

SCHEDULE 4

Section 49.

MINOR AND CONSEQUENTIAL AMENDMENTS

Commencement Information

I13 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

I14 Schedule 4 para. 1 wholly in force at 1.8.1991 see s. 49(2) and S.I. 1991/1400, **art. 2(2)**

Marginal Citations

M5 1987 c. 42.

Social Security Act 1975 (c. 14.)

F60 2 . . . . . .

Textual Amendments

F60 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.)

F61 3 . . . . . .

Textual Amendments

F61 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 F62 . . . . . .

Textual Amendments

F62 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

I15 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.)

F63 6 . . . . . .

Textual Amendments

F63 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

I16 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 F64 . . . . . .

Textual Amendments

F64 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 F65 . . . . . .

Textual Amendments

F65 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 01/10/2009.

Changes to legislation:
Human Fertilisation and Embryology Act 1990 is up to date with all changes known to be in force on or before 20 October 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.