



Human Fertilisation and Embryology Act 1990

1990 CHAPTER 37

Grant, revocation and suspension of licences

16 Grant of licence.

[^{F1}(1) The Authority may on application grant a licence to any person if the requirements of subsection (2) below are met.]

(2) The requirements mentioned in subsection (1) above are—

- (a) that the application is for a licence designating an individual as the person under whose supervision the activities to be authorised by the licence are to be carried on,
- (b) that either that individual is the applicant or—
 - (i) the application is made with the consent of that individual, and
 - (ii) the [^{F2}Authority] is satisfied that the applicant is a suitable person to hold a licence,

[^{F3}(c) in relation to a licence under paragraph 1 or 1A of Schedule 2 or a licence under paragraph 2 of that Schedule authorising the storage of gametes or embryos intended for human application [^{F4} or a licence under paragraph 3 of that Schedule authorising activities in connection with the derivation from embryos of stem cells that are intended for human application], that the individual—

- (i) possesses a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences, awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or is otherwise considered by the [^{F2}Authority] to be suitably qualified on the basis of academic qualifications in the field of nursing, and
- (ii) has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence,

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- (ca) in relation to a licence under paragraph 2 of Schedule 2 authorising storage of gametes^{F5}, embryos or human admixed embryos] not intended for human application or a licence under paragraph 3 of that Schedule [^{F6}authorising activities otherwise than in connection with the derivation from embryos of stem cells that are intended for human application], that the [^{F2}Authority] is satisfied that the qualifications and experience of that individual are such as are required for the supervision of the activities,
 - (cb) that the [^{F2}Authority] is satisfied that the character of that individual is such as is required for the supervision of the activities and that the individual will discharge the duty under section 17 of this Act.]
 - ^{F3}(d) that the [^{F2}Authority] is satisfied that the premises in respect of which the licence is to be granted [^{F7}and any premises which will be relevant third party premises] are suitable for the activities, and
 - (e) that all the other requirements of this Act in relation to the granting of the licence are satisfied.
- (3) The grant of a licence to any person may be by way of renewal of a licence granted to that person, whether on the same or different terms.
- (4) Where the [^{F8}Authority] is of the opinion that the information provided in the application is insufficient to enable it to determine the application, it need not consider the application until the applicant has provided it with such further information as it may require him to provide.
- (5) The [^{F9}Authority] shall not grant a licence unless a copy of the conditions to be imposed by the licence has been shown to, and acknowledged in writing by, the applicant and (where different) the person under whose supervision the activities are to be carried on.

- ^{F10}(6)
- ^{F10}(7)

Textual Amendments

- F1** S. 16(1) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 16(2), 68(2)**; S.I. 2009/2232, art. 2(f)
- F2** Word in s. 16(2) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 16(3)(a), 68(2)**; S.I. 2009/2232, art. 2(f)
- F3** S. 16(2)(c)-(cb) substituted (25.5.2007 for certain purposes, otherwise 5.7.2007) for s. 16(2)(c) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), regs. 1, 19
- F4** Words in s. 16(2)(c) inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 16(3)(b), 68(2)**; S.I. 2009/2232, art. 2(f)
- F5** Words in s. 16(2)(ca) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 16(3)(c)(i), 68(2)**; S.I. 2009/2232, art. 2(f)
- F6** Words in s. 16(2)(ca) inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 16(3)(c)(ii), 68(2)**; S.I. 2009/2232, art. 2(f)
- F7** Words in s. 16(2)(d) inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 16(3)(d), 68(2)**; S.I. 2009/2232, art. 2(f)
- F8** Word in s. 16(4) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 16(4), 68(2)**; S.I. 2009/2232, art. 2(f)
- F9** Word in s. 16(5) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), **ss. 16(5), 68(2)**; S.I. 2009/2232, art. 2(f)

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F10 S. 16(6)(7) repealed (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. 16(6), 68(2), [Sch. 8 Pt. 1](#); S.I. 2009/2232, art. 2(f)

Commencement Information

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

17 The person responsible.

(1) It shall be the duty of the individual under whose supervision the activities authorised by a licence are carried on (referred to in this Act as the “person responsible”) to secure—

- (a) that the other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence,
- (b) that proper equipment is used,
- (c) that proper arrangements are made for the keeping of gametes^{F11}, embryos and human admixed embryos] and for the disposal of gametes^{F12}, embryos or human admixed embryos] that have been allowed to perish,
- (d) that suitable practices are used in the course of the activities,^{F13} ...
- (e) that the conditions of the licence are complied with,
- ^{F14}(f) that conditions of third party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with, and
- (g) that the Authority is notified and provided with a report analysing the cause and the ensuing outcome of any serious adverse event or serious adverse reaction.]

(2) References in this Act to the persons to whom a licence applies are to—

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

^{F15}(3)

Textual Amendments

F11 Words in s. 17(1)(c) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 17\(2\)\(a\)](#), 68(2); S.I. 2009/2232, art. 2(f)

F12 Words in s. 17(1)(c) substituted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 17\(2\)\(b\)](#), 68(2); S.I. 2009/2232, art. 2(f)

F13 Word in s. 17(1) omitted (25.5.2007 for certain purposes, otherwise 5.7.2007) by virtue of [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), regs. 1, 20

F14 S. 17(1)(f)(g) inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), regs. 1, 20

F15 S. 17(3) repealed (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. 17(3), 68(2), [Sch. 8 Pt. 1](#); S.I. 2009/2232, art. 2(f)

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Commencement Information

I2 S. 17 wholly in force at 1.8.1991 see s. 49(2) and [S.I. 1991/1400, art. 2\(2\)](#)

[^{F16}18 Revocation of licence

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

Textual Amendments

F16 Ss. 18, 18A substituted for s. 18 (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 18, 68\(2\)](#); [S.I. 2009/2232, art. 2\(f\)](#)

18A Variation of licence

- (1) The Authority may on application by the holder of the licence vary the licence so as to substitute another person for the person responsible if—
 - (a) the application is made with the consent of that other person, and
 - (b) the Authority is satisfied that the other person is a suitable person to supervise the licensed activity.
- (2) The Authority may vary a licence on application by—
 - (a) the person responsible, or
 - (b) the holder of the licence (if different).
- (3) The Authority may vary a licence without an application under subsection (2) if it has the power to revoke the licence under section 18(2).

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

Textual Amendments

F16 Ss. 18, 18A substituted for s. 18 (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), ss. 18, 68(2); S.I. 2009/2232, art. 2(f)

[^{F17}19 Procedure in relation to licensing decisions

- (1) Before making a decision—
 - (a) to refuse an application for the grant, revocation or variation of a licence, or
 - (b) to grant an application for a licence subject to a condition imposed under paragraph 1(2), 1A(2), 2(2) or 3(6) of Schedule 2,the Authority shall give the applicant notice of the proposed decision and of the reasons for it.
- (2) Before making a decision under section 18(2) or 18A(3) or (5) the Authority shall give notice of the proposed decision and of the reasons for it to—
 - (a) the person responsible, and
 - (b) the holder of the licence (if different).
- (3) Where an application has been made under section 18A(2) to vary a licence, but the Authority considers it appropriate to vary the licence otherwise than in accordance with the application, before so varying the licence the Authority shall give notice of its proposed decision and of the reasons for it to—
 - (a) the person responsible, and
 - (b) the holder of the licence (if different).
- (4) A person to whom notice is given under subsection (1), (2) or (3) has the right to require the Authority to give him an opportunity to make representations of one of the following kinds about the proposed decision, namely—
 - (a) oral representations by him, or a person acting on his behalf;
 - (b) written representations by him.
- (5) The right under subsection (4) is exercisable by giving the Authority notice of the exercise of the right before the end of the period of 28 days beginning with the day on which the notice under subsection (1), (2) or (3) was given.
- (6) The Authority may by regulations make such additional provision about procedure in relation to the carrying out of functions under sections 18 and 18A and this section as it thinks fit.

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Textual Amendments

F17 Ss. 19-19B substituted for s. 19 (6.4.2009 for specified purposes, 1.10.2009 for remaining purposes) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 19](#), [68\(2\)](#); [S.I. 2009/479](#), [art. 5\(b\)\(h\)](#) (with [art. 7 Sch.](#)); [S.I. 2009/2232](#), [art. 2\(g\)](#)

19A Notification of licensing decisions

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

Textual Amendments

F17 Ss. 19-19B substituted for s. 19 (6.4.2009 for specified purposes, 1.10.2009 for remaining purposes) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 19](#), [68\(2\)](#); [S.I. 2009/479](#), [art. 5\(b\)\(h\)](#) (with [art. 7 Sch.](#)); [S.I. 2009/2232](#), [art. 2\(g\)](#)

19B Applications under this Act

- (1) Directions may make provision about—
 - (a) the form and content of applications under this Act, and
 - (b) the information to be supplied with such an application.

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- (2) The Secretary of State may by regulations make other provision about applications under this Act.
- (3) Such regulations may, in particular, make provision about procedure in relation to the determination of applications under this Act and may, in particular, include—
 - (a) provision for requiring persons to give evidence or to produce documents;
 - (b) provision about the admissibility of evidence.]

Textual Amendments

F17 Ss. 19-19B substituted for s. 19 (6.4.2009 for specified purposes, 1.10.2009 for remaining purposes) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 19](#), 68(2); [S.I. 2009/479](#), [art. 5\(b\)\(h\)](#) (with [art. 7 Sch.](#)); [S.I. 2009/2232](#), [art. 2\(g\)](#)

[^{F18}19C Power to suspend licence

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

Textual Amendments

F18 S. 19C inserted (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 20](#), 68(2); [S.I. 2009/2232](#), [art. 2\(h\)](#)

[^{F19}20 Right to reconsideration of licensing decisions

- (1) If an application for the grant, revocation or variation of a licence is refused, the applicant may require the Authority to reconsider the decision.
- (2) Where the Authority decides to vary or revoke a licence, any person to whom notice of the decision was required to be given (other than a person who applied for the variation or revocation) may require the Authority to reconsider the decision.

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- (3) The right under subsections (1) and (2) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 28 days beginning with the day on which notice of the decision concerned was given under section 19A.
- (4) If the Authority decides —
 - (a) to suspend a licence under section 19C(1), or
 - (b) to continue the suspension of a licence under section 19C(2),
 any person to whom notice of the decision was required to be given may require the Authority to reconsider the decision.
- (5) The right under subsection (4) is exercisable by giving the Authority notice of exercise of the right before the end of the period of 14 days beginning with the day on which notice of the decision concerned was given under section 19C.
- (6) The giving of any notice to the Authority in accordance with subsection (5) shall not affect the continuation in force of the suspension of the licence in respect of which that notice was given.
- (7) Subsections (1), (2) and (4) do not apply to a decision on reconsideration.

Textual Amendments

F19 Ss. 20-21 substituted for ss. 20 21 (6.4.2009 for specified purposes, 1.10.2009 for remaining purposes) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 21, 68\(2\)](#); [S.I. 2009/479](#), [art. 3](#) (with [art. 7 Sch.](#)); [S.I. 2009/2232](#), [art. 2\(i\)](#)

20A Appeals committee

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

Textual Amendments

F19 Ss. 20-21 substituted for ss. 20 21 (6.4.2009 for specified purposes, 1.10.2009 for remaining purposes) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 21, 68\(2\)](#); [S.I. 2009/479](#), [art. 3](#) (with [art. 7 Sch.](#)); [S.I. 2009/2232](#), [art. 2\(i\)](#)

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20B Procedure on reconsideration

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

Textual Amendments

F19 Ss. 20-21 substituted for ss. 20 21 (6.4.2009 for specified purposes, 1.10.2009 for remaining purposes) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 21, 68\(2\)](#); [S.I. 2009/479](#), [art. 3](#) (with [art. 7 Sch.](#)); [S.I. 2009/2232](#), [art. 2\(i\)](#)

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21 Appeal on a point of law

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

Textual Amendments

F19 Ss. 20-21 substituted for ss. 20 21 (6.4.2009 for specified purposes, 1.10.2009 for remaining purposes) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [ss. 21, 68\(2\)](#); [S.I. 2009/479](#), [art. 3](#) (with [art. 7 Sch.](#)); [S.I. 2009/2232](#), [art. 2\(i\)](#)

^{F20}22 Temporary suspension of licence.

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Textual Amendments

F20 S. 22 repealed (1.10.2009) by [Human Fertilisation and Embryology Act 2008 \(c. 22\)](#), [s. 68\(2\)](#), [Sch. 7 para. 8](#), [Sch. 8 Pt. 1](#); [S.I. 2009/2232](#), [art. 2\(y\)](#)

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