Draft Regulations laid before Parliament under section 45(4) of the Human Fertilisation and Embryology Act 1990, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2009 No. 000

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology (Appeals) Regulations 2009

Made - - - -	*2009*
Coming into force	
Regulations 4 to 6, and 2 so far as it relates to them	*2009*
Remainder	*1st October 2009*

The Secretary of State for Health makes these Regulations in exercise of the powers conferred by sections 20A(3), 20B(2) and 45(1), (3) and (3A) of the Human Fertilisation and Embryology Act 1990(**1**).

A draft of this instrument has been approved by a resolution of each House of Parliament pursuant to section 45 of that Act.

PART 1

General

Citation and commencement

1.—(1) These Regulations may be cited as the Human Fertilisation and Embryology (Appeals) Regulations 2009 and subject to paragraph (2) shall come into force on 1st October 2009.

(2) Regulations 4 to 6, and regulation 2 so far as it relates to them, shall come into force on the day after that on which these Regulations are made.

Interpretation

2. In these Regulations—

(**1**) 1990 c. 37. Sections 20A and 20B were inserted by section 21 of the Human Fertilisation and Embryology Act 2008 c. 22 ("the 2008 Act"). Section 45(3) was substituted by section 30(4) of the 2008 Act.

"the 1991 Regulations" means the Human Fertilisation and Embryology Authority (Licence Committee and Appeals) Regulations 1991(**2**);

"the Act" means the Human Fertilisation and Embryology Act 1990;

"adviser" means an adviser appointed by the Authority in accordance with regulation 10;

"an appeal" means the reconsideration of a licensing decision;

"the appellant" means the person requiring the Authority to reconsider a licensing decision in accordance with section 20(1), (2) or (4) of the Act (right to reconsideration of licensing decisions)(**3**);

"the Chair" means the Chair of the Committee;

"the Committee" means an appeals committee as defined by section 20A(2) of the Act (appeals committee);

"the Deputy Chair" means the Deputy Chair of the Committee;

"hearing" means proceedings of the Committee which the parties to the proceedings may attend or at which they may be represented;

"legally qualified" means holding at least a ten year general qualification (within the meaning of section 71(3)(c) of the Courts and Legal Services Act 1990(**4**) (qualification for judicial and certain other appointments)) or being an advocate or solicitor in Scotland of at least ten years standing;

"licence holder" means a person granted a licence by the Authority under section 16 of the Act (grant of licences)(**5**);

"notice of exercise of right" means the notice referred to in section 20(3) or (5) of the Act (right to reconsideration of licensing decisions);

"notice of hearing" means a notice complying with the requirements of regulation 18;

"parties" means the Authority and the appellant (or where appropriate, the Authority's or the appellant's representatives);

"person responsible under a licence" has the meaning given by section 17(1) of the Act (the person responsible)(**6**);

"person with a professional interest" means a person who is—

(a) a registered medical practitioner,

(b) concerned with keeping or using gametes or embryos outside the body, or

(c) directly concerned with commissioning or funding any research involving such keeping or use, or who has actively participated in any decision to do so;

"private deliberations" means meetings of the Committee held in the presence of any adviser and any person acting as secretary to the Committee, but excluding everyone else;

"the presenter" means the representative of the Authority presenting the case at a hearing (and includes employees of the Authority); and

"witness" means a person giving oral evidence at a hearing, and includes an appellant giving oral evidence.

(**2**) S.I. No.1991/1889.
(**3**) Section 20 was substituted by section 21 of the 2008 Act.
(**4**) 1990 c. 41.
(**5**) Section 16 was amended by section 16 of the 2008 Act.
(**6**) Section 17(1) was amended by section 17 of the 2008 Act.

General

3. Subject to the provisions of the Act and of these Regulations, the Committee may regulate its own proceedings.

PART 2

The Committee

Composition of the Committee

4.—(1) Except where provided for in paragraph (2), the Committee shall have seven members appointed by the Authority including a Chair and Deputy Chair.

(2) Subject to paragraph (3) the Authority may appoint an additional member or members to the Committee for the purposes of a particular case where in the opinion of the Chair it is necessary or desirable to do so.

(3) The majority of members of the Committee must not be persons appointed under paragraph (2).

(4) A person must not be appointed as a member of the Committee if that person is—

(a) a current employee or member of the Authority;

(b) a former employee or member of the Authority;

(c) fulfilling, or has fulfilled, any function of the Authority pursuant to arrangements under section 8B (agency arrangements and provision of services) or 8C (contracting out functions of the Authority) of the Act(**7**);

(d) a licence holder; or

(e) a person responsible under a licence.

(5) The Chair and Deputy Chair must be legally qualified.

(6) The majority of members of the Committee must not be persons with a professional interest.

(7) The Committee may continue to act even if there is a temporary vacancy amongst its members.

Terms of office of members

5.—(1) Members of the Committee shall not serve more than two consecutive terms in office.

(2) Each term of office shall be for three years.

(3) Paragraphs (1) and (2) shall not apply to a member appointed under paragraph (2) of regulation 4 who shall hold office until the case is determined by the Committee and the notice of decision is provided under regulation 29.

(4) A member of the Committee may at any time resign office by notifying the Authority in writing.

Suspension and removal of Committee members

6.—(1) The Authority shall remove from the Committee any member who, in the Authority's opinion—

(a) has seriously or persistently failed to meet the standards of performance, conduct or attendance required of a member of the Committee in the ordinary course of duties;

(**7**) Sections 8B and 8C were inserted into the Act by section 8 of the 2008 Act.

(b) is unable to perform duties because of ill health;

(c) has improperly disclosed confidential information obtained in the course of membership of the Committee;

(d) has brought the Authority into disrepute;

(e) should no longer continue to be a member of the Committee in the public interest;

(f) has otherwise ceased to be an appropriate person (for example, by reason of misconduct or criminal conviction); or

(g) falls within any of the categories set out in regulation 4(4)(a) to (e).

(2) The Authority may suspend a member of the Committee while investigations are being undertaken as to whether that person is suitable to remain as a member.

(3) The Authority shall afford any member of the Committee who is under investigation the opportunity to make written and oral representations before reaching a decision on whether that person should be removed from the Committee.

(4) The procedure for the suspension or dismissal of a member of the Committee shall otherwise be determined by the Authority.

Quorum and voting

7.—(1) Subject to paragraph (2) the quorum for any hearing of the Committee to determine an appeal or meeting, apart from a case management meeting, is three and must include—

(a) the Chair or Deputy Chair; and

(b) at least one member who is a person with a professional interest.

(2) The Committee, when determining an appeal, may not consist of an even number of members.

(3) A member who has not been present throughout a hearing of an appeal may not take part in the determination of the appeal and will not count towards the quorum (or for the purpose of paragraph (2)).

(4) Decisions of the Committee shall be taken by a simple majority of the members.

(5) A member of the Committee may not abstain from voting.

Validity

8. The validity of any proceedings of the Committee shall not be affected by any defect in the appointment of a Committee member.

Annual Report

9.—(1) The Chair shall ensure that an annual written report on the activities of the Committee is prepared for—

(a) the period beginning the 1st October 2009 and ending on 31st March 2011; and

(b) each succeeding period of 12 months ending with 31st March.

(2) The Chair shall ensure that the annual report under paragraph (1) is provided to the Authority as soon as is practicable after the end of the relevant period.

PART 3

Advisers to the Committee

Appointment of advisers to the Committee

10. The Authority may make arrangements to appoint one or more advisers to the Committee as it deems appropriate from time to time.

Functions of advisers

11.—(1) At the request of the Chair an adviser may attend any meeting of the Committee or any hearing before the Committee.

(2) The function of an adviser shall be to—

(a) advise the Committee on any areas within the adviser's expertise; and

(b) intervene to advise the Committee on an issue where it appears that without an intervention there is the possibility of an error being made.

(3) At the request of the Chair, an adviser who is present at a meeting or hearing referred to in paragraph (1) may be present during the private deliberations of the Committee, but the adviser shall not participate in the decision making of the Committee (and is not entitled to vote).

Requirement to give or repeat advice in public

12.—(1) Subject to paragraph (2), any advice tendered by an adviser at a hearing shall be tendered in the presence of each of the parties in attendance at the hearing.

(2) Where the Committee has begun to deliberate on its decision and needs to obtain advice in the course of its deliberations, an adviser may tender advice to the Committee notwithstanding the absence of the parties.

(3) Where the advice is tendered in the absence of the parties in accordance with paragraph (2)—

(a) the adviser shall repeat the advice tendered to the Committee before the parties in attendance at the hearing; and

(b) the parties in attendance at the hearing shall be provided with reasonable opportunity to comment on the advice given by the adviser, before the Committee makes its decision on the issue under consideration.

Requirement to keep records of advice and interventions

13.—(1) The Chair shall ensure that a written record is kept of any advice tendered to the Committee by an adviser.

(2) The Chair shall ensure that a written record is kept of any interventions made by an adviser during the private deliberations of the Committee.

(3) The Chair shall ensure that a copy of any advice tendered by an adviser to the Committee is sent to the parties to the proceedings.

Advice of an adviser not accepted by the Committee

14. Where any advice tendered by an adviser to the Committee is not accepted by the Committee —

(a) if the advice is tendered at a hearing before the Committee, the Chair shall announce the reasons for not accepting the advice tendered;