*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

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

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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(**a**).

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—

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

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(**a**) 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.
(**b**) S.I. No.1991/1889.

"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)(**a**);

"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(**b**) (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)(**c**);

"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)(**d**);

"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.

## General

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

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(**a**) Section 20 was substituted by section 21 of the 2008 Act.
(**b**) 1990 c. 41.
(**c**) Section 16 was amended by section 16 of the 2008 Act.
(**d**) Section 17(1) was amended by section 17 of the 2008 Act.

# 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(**a**);

(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;

(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;

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

(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;

(b) the Chair shall ensure that a written record is kept of the advice tendered, and the reasons why the Committee did not accept that advice; and

(c) a copy of the record of the advice tendered and the reasons why the Committee did not accept that advice shall be sent to the parties.

**Questioning of witnesses by advisers**

**15.** An adviser advising the Committee in accordance with these Regulations may, with the permission of the Chair, question any witness appearing before the Committee.

# PART 4

## Procedure on reconsideration

**Notice of exercise of right and accompanying documents**

**16.**—(1) Where a person wishes to make an appeal, the person must provide to the Authority the information and documents specified in paragraph (2) at the same time as service of the notice of exercise of right.

(2) The information and documents that must be provided are—

(a) the full name, address and telephone number of the appellant;

(b) the appellant's licence number (where applicable);

(c) whether or not the appellant intends to be represented at any hearing and if so, the full name, address and telephone number of any representative and whether the Committee should send replies or notices concerning the appeal to the representative rather than the appellant;

(d) a copy of the original decision to be reconsidered;

(e) the grounds on which the appellant requires the Committee to reconsider the decision;

(f) a copy of the material submitted by the appellant to the Authority prior to the decision which is the subject of reconsideration;

(g) a copy of new material not submitted by the appellant to the Authority which the appellant wishes the Committee to consider;

(h) a skeleton argument;

(i) whether the appellant intends to call any witnesses and if so the names and occupations of those witnesses;

(j) whether the appellant wishes the reconsideration to be considered on the papers or at a hearing; and

(k) in a case where a hearing is requested, whether the appellant would like a case management meeting and the issues to be considered at such a meeting.

(3) The Authority must provide to the Committee any notice of exercise of right received by the Authority and the information and documents provided with that notice pursuant to paragraphs (1) and (2) within 7 days beginning with the date of receipt.

(4) An appellant may withdraw a notice of exercise of right by written notice to the Chair at any time prior to the first day of the hearing, or the first day the Committee considers the case on the papers, as applicable.

**Action following receipt of notice of exercise of right and accompanying documents**

**17.**—(1) Following receipt of the notice of exercise of right and the information and documents specified in regulation 16(2) the Committee must—

(a) acknowledge receipt of the notice of exercise of right and accompanying information and documents to the appellant or, where appropriate, the appellant's representative within 7 days beginning with the date of receipt of the notice;

(b) require the Authority to provide to the Committee within 21 days of receipt by the Authority of the notice of exercise of right and the information and documents specified in regulation 16(2) copies of any documents the Authority intends to rely on in relation to the reconsideration; and

(c) provide to the appellant or, where appropriate, the appellant's representative copies of any papers received under sub-paragraph (b) within 7 days of receipt from the Authority.

(2) In a case where the appellant has requested a hearing, or the Committee considers that a hearing is necessary the Chair shall ensure that a notice of hearing is sent to the parties within 28 days beginning with the date of receipt of the notice of exercise of right.

(3) In a case where the appellant has requested that the case be considered on the papers and the Committee considers this appropriate the Chair must ensure that the parties are—

(a) informed of the date on which the Committee will reconsider the decision; and

(b) required to submit any written submissions no later than 14 days before the date on which the Committee is to meet.

**Notice of Hearing**

**18.** The notice of hearing shall—

(a) state the date, time and venue of the hearing;

(b) inform the appellant of the right to attend and to be represented or accompanied at the hearing in accordance with regulation 26(2) and (3);

(c) inform the appellant that the Committee may proceed with the hearing in the appellant's absence;

(d) inform the appellant of the provisions relating to—

(i) evidence set out in regulation 21,

(ii) procedure at hearings set out in regulation 25, and

(iii) witnesses' evidence set out in regulation 27;

(e) require the parties to inform the Committee, within 14 days beginning with the day of receipt of the notice of hearing, whether the parties intend to—

(i) attend the hearing,

(ii) be represented at the hearing, and if so, by whom, and

(iii) seek to call any witnesses at the hearing, and if so, whom.

**Case management meetings**

**19.**—(1) Where a hearing is to be held, a case management meeting may be convened by the Chair or at the request of one (or both) of the parties with the Chair's approval.

(2) Where a case management meeting is to be convened the Chair shall ensure that the parties are given reasonable notice of the meeting.

(3) At a case management meeting the Chair may—

(a) if satisfied that case management directions are necessary for the just and expeditious management of the case, issue such directions; and

(b) give preliminary rulings on questions of law and admissibility of evidence.

(4) Subject to paragraphs (1) to (3) the Chair may regulate any case management meeting as the Chair considers appropriate.

**Multiple reconsideration**

**20.** The Committee may consider and determine together two or more requests made by the same person to reconsider a licensing decision in accordance with section 20 of the Act (right to reconsideration of licensing decisions), where it is satisfied that it would be appropriate to do so.

**Evidence**

**21.**—(1) All questions of admissibility of evidence and law before the Committee shall be decided by the Chair.

(2) Subject only to the requirements of relevance and fairness, and with the permission of the Chair, the Committee may receive–

(a) any documentary or physical evidence; and

(b) where a hearing is held, any oral evidence,

whether or not such evidence would be admissible in any civil proceedings in that part of the United Kingdom where the hearing before the Committee is taking place.

(3) Where a party wishes to adduce written evidence from a witness other than a letter of testimonial, the Committee shall only receive such evidence if the statement—

(a) contains an attestation, in a format acceptable to the Committee, that the statement is true; and

(b) is signed by the person making it.

(4) Where an appellant has been convicted of a criminal offence in the British Isles (and has not successfully appealed against the conviction), a copy of the certificate of conviction certified by a competent officer of the court (or in Scotland, an extract conviction) shall be admissible as conclusive proof of that conviction and the findings of fact on which it was based.

(5) The only evidence that may be adduced by the appellant in rebuttal of a conviction certified or extracted in accordance with paragraph (3) is evidence for the purpose that the appellant is not the person referred to in the certificate or extract.

(6) A formal notification of a determination about an appellant's fitness to practice made by a body responsible under any enactment for the regulation of a health or social care profession (in the United Kingdom or elsewhere), and signed by an officer authorised by that body to sign such a notification, shall be sufficient evidence, unless the contrary is proved, of any facts found proved by that body.

(7) Written evidence which has not been submitted by either party in accordance with regulations 16 and 17 and this regulation, shall only be considered by the Committee if, in the opinion of the Chair, there are exceptional circumstances.

**Power to require witnesses and documents**

**22.**—(1) Subject to paragraph (3), the Committee may by notice require any person ("P") in the United Kingdom to produce any documents in P's custody or control which the Committee considers relevant to the proceedings before it and P must do so.

(2) Subject to paragraph (3), the Committee may by notice require any person except the appellant to attend as a witness at a hearing of an appeal at such time and place as may be specified in the notice.

(3) A person shall not be required in obedience to a notice under paragraph (1) or (2) to attend and give evidence or to produce any document unless—

(a) that person has been given at least 7 days notice of the hearing or, if less than 7 days, has accepted such notice by informing the Committee; and

(b) except in the case of the appellant, confirmation has been provided that reasonable and necessary travel and subsistence expenses will be paid by the Authority.

(4) The Committee may, on an application by a person to whom it is addressed, set aside or vary a notice under paragraph (1).

(5) A person shall not be compelled to give any evidence or produce any document or other material that they could not be compelled to give or produce on a trial of any action in a civil court of law in that part of the United Kingdom where the hearing before the Committee is to take place.

(6) Each notice under paragraph (1)—

(a) must contain a statement to the effect that the person to whom it is addressed may apply to the Committee to vary or set aside the notice; and

(b) must refer to the fact that under section 41(7) (offences) of the Act a person who without reasonable excuse fails to comply with the requirement of that section is guilty of an

offence and is liable on summary conviction for a term of imprisonment not exceeding six months or a fine not exceeding level five on the standard scale or both.

**Burden and standard of proof**

**23.**—(1) The appellant shall bear the burden of establishing to the Committee that the decision of the Authority being reconsidered should be overturned.

(2) Where facts are in dispute, the Committee shall consider whether they have been established in accordance with the civil standard of proof.

**Reconsideration on the papers**

**24.**—(1) The Committee may reconsider a decision on the papers following receipt of a notice of exercise of right and the information and documents specified in regulation 16(2), unless the appellant has requested a hearing.

(2) Written evidence which has not been submitted by either party in accordance with regulations 16, 17 and 21 shall only be considered by the Committee if, in the opinion of the Chair, there are exceptional circumstances.

(3) Before making its decision the Committee may obtain advice from an adviser.

(4) The Chair shall ensure that a written record (in addition to that required by regulation 13(1) and (2)) is kept of—

(a) any rulings on questions of law or admissibility made by the Chair;

(b) the decision of the Committee; and

(c) the reasons for the Committee's decision.

**Procedure at hearings**

**25.**—(1) The order of proceedings at the hearing shall be as follows—

(a) the Chair shall declare the meeting open;

(b) where the appellant is not present or represented at the hearing, if the Chair is satisfied that all reasonable efforts have been made to provide the appellant with the notice of hearing, having consulted the Committee, the Chair may—

(i) proceed with the hearing in the absence of the appellant, or

(ii) adjourn the hearing and issue appropriate directions;

(c) the presenter shall make an opening statement outlining the facts of the case;

(d) the appellant or, where appropriate, the appellant's representative may—

(i) adduce evidence, and

(ii) call witnesses, subject to regulations 22(3) and 27 (provided that the Chair is satisfied that the witness is in a position to provide the relevant testimony);

(e) the presenter may—

(i) adduce evidence in rebuttal of the position of the appellant and in support of the position of the Authority, and

(ii) call witnesses, subject to regulations 22(3) and 27 (provided that the Chair is satisfied that the witness is in a position to provide the relevant testimony);

(f) the appellant or, where appropriate, the appellant's representative may make a closing statement; and

(g) the Committee shall hold private deliberations and shall then announce its decision in the presence of the parties (where present), together with the reasons for its decision.

(2) The Chair may refuse to allow a witness to give oral evidence, or to give evidence on a particular matter, if in the opinion of the Chair all or part of the evidence that the witness is to

provide, or is to provide on that matter, should have been disclosed to the party not calling the witness at an earlier stage in the proceedings.

**Representation**

**26.**—(1) The presenter shall be a person who is—

(a) a barrister, advocate or solicitor; or

(b) an employee of the Authority,

or both.

(2) The appellant may be represented by a person who is—

(a) a barrister, advocate or solicitor; or

(b) a representative from the appellant's defence organisation or trade union,

or both.

(3) Where the appellant is not represented, a supporter may accompany and advise the appellant, but the supporter must not be—

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

(b) a witness at the hearing.

(4) A supporter under paragraph (3) shall only be entitled to address the Committee with the permission of the Chair.

(5) The presenter, the appellant and the appellant's representative shall be entitled to attend any hearing of the Committee of which notice is given in accordance with regulation 18 or a case management meeting under regulation 19, and to be heard by the Committee at that hearing.

**Witness evidence**

**27.**—(1) A witness shall be required to take an oath, or to affirm, before giving oral evidence.

(2) The Chair has the power to administer an oath to, or take the affirmation of, any person who gives oral evidence to the Committee.

(3) A party may not call a person to be a witness unless the party has provided to the other party concerned a written statement of evidence to be given by the witness at least 7 days before the hearing, unless the Chair determines otherwise.

(4) The Committee may, upon the application of the party calling a witness, direct that any details which may identify that witness shall not be revealed in public.

(5) A witness—

(a) shall first be examined by the party calling them;

(b) may be cross examined;

(c) may then be re-examined by the party calling them; and

(d) may then be questioned by the Committee through the Chair.

(6) The parties may then question a witness on matters arising out of the Committee's questions, with the party calling the witness being given the last opportunity to do so (as between the parties).

(7) Any further questioning of a witness shall be at the discretion of the Chair.

(8) Except in the case of an expert witness, the appellant, or where appropriate, the appellant's representative, a witness shall not be allowed to attend the proceedings until after the witness has completed giving evidence and been formally released by the Chair.

**Postponement and adjournments**

**28.**—(1) The Chair may, following the Chair's own motion, or upon the application of a party, postpone any meeting or hearing of which notice has been given under these Regulations before such meeting or hearing begins.

(2) The Chair may, following the Chair's own motion, or upon the application of a party, adjourn the proceedings at any stage, provided that—

(a) no injustice is caused to the parties; and

(b) the decision to adjourn is made after hearing representations from the parties (where present).

(3) In considering whether or not to grant an application for postponement or adjournment, the Chair shall, amongst other matters, have regard to—

(a) the public interest in the expeditious disposal of the case;

(b) the potential inconvenience caused to a party or any witnesses to be called by that party;

(c) the conduct of the party seeking the postponement or adjournment; and

(d) fairness to the parties.

(4) Where the proceedings have been postponed or adjourned, the Chair shall ensure, as soon as practicable that the parties are notified of the date, time and venue of the postponed or resumed meeting or hearing.

**Decision of the Committee**

**29.**—(1) No later than 7 days after the date on which the Committee has made its decision, the Chair shall ensure that—

(a) a written notice of the Committee's decision; and

(b) a statement of reasons for the Committee's decision,

are provided to the parties, and to any other person whom the Committee considers, in the public interest, ought to be informed of the Committee's decision.

(2) The written notice provided to the appellant shall be accompanied by a record of any rulings on questions of law or admissibility of evidence made by the Chair.

**Notes and transcripts of hearings**

**30.**—(1) Subject to paragraph (3), the Chair shall ensure that all hearings are recorded in writing or electronic form.

(2) Any party to the proceedings shall, on application to the Committee, be furnished with a transcript of the record of any part of the hearing at which the appellant was entitled to be present.

(3) The private deliberations of the Committee shall not be recorded.

**Powers and functions of the Chair**

**31.** Any power or function conferred by these Regulations on the Chair may be exercised or discharged by the Deputy Chair.

**Revocation and saving**

**32.**—(1) Subject to paragraph (2), the 1991 Regulations are revoked.

(2) The 1991 Regulations shall continue to have effect for the purposes of paragraphs 9 (transitional and saving provisions relating to procedure for refusal, variation or revocation of licence) and 10 (transitional provisions relating to reconsideration of licensing decisions) of

Schedule 3 to the Human Fertilisation and Embryology (Consequential Amendments and Transitional and Saving Provisions) Order 2009(**a**).

Signed by authority of the Secretary of State for Health

*Name*
Minister of State
Date Department of Health

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations are made under sections 20A and 20B of the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008) and make provision for an appeals committee ("the Committee") to reconsider licensing decisions made by the Authority.

Part 1 deals with preliminary matters, including commencement and interpretation (regulations 1 to 3).

Part 2 sets out the constitution of the Committee. Regulation 4 provides that the Committee must consist of seven members, although additional members can be appointed for particular cases. Certain people are excluded from being appointed as members, including former or current employees of the Authority. Regulations 5 and 6 make provision about the term of office of members and the procedure for suspension and removal, where necessary. Regulation 7 provides for simple majority voting and a quorum of three. Regulation 8 makes provision preventing the validity of proceedings being questioned by reason of defective appointments. Regulation 9 requires the Committee to prepare an annual report on its activities for the Authority.

Part 3 makes provision relating to advisers to the Committee. Regulation 10 enables the Authority to appoint advisers and regulation 11 sets out the functions of those advisers, including advising the Committee at both public hearings and private deliberations. Regulations 12 to 14 set out requirements relating to the manner in which advice is to be tendered and recorded, and relating to the announcement and recording of decisions not to accept advice from advisers. Advisers are also given the power, with the permission of the chair of the Committee, to question witnesses under regulation 15.

Part 4 makes provision in relation to procedure for appeals. Regulation 16 requires the person wishing to appeal to provide information and documents, including the grounds of appeal, at the same time as serving the notice of exercise of right under section 20 of the 1990 Act. Regulation 17 requires the Authority to provide documents that will be relied on in relation to the appeal and provides for exchange of documents between the parties. Unless the appellant has requested that the case be considered on the papers the Committee must send the parties a notice of hearing, in the form set out under regulation 18 within 28 days, beginning with the date of receipt of the notice of exercise of right.

Regulations 19 and 20 make provision to enable case management meetings and for the Committee to consider and determine two or more appeal requests together from the same appellant, where appropriate.

Regulations 21 and 22 make detailed provision relating to the submission of evidence and the power of the Committee to require witnesses and documents. Regulation 23 makes provision relating to the burden and standard of proof to be applied (the civil standard). Regulation 24 gives the Committee the power to reconsider a decision on the papers unless an appellant has requested a hearing.

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(**a**) S.I. No.2009/[ ]

Regulations 25 to 28 set out the procedure for hearings including the calling of witnesses. Provision is made to ensure that both the appellant and the Authority are represented and to enable postponement and adjournment of the hearing where necessary.

Regulation 29 requires the Committee to give written notice of its decision within 7 days to the parties and any other person who ought to be informed in the public interest. Regulation 30 makes provision in relation to the recording of notes and the availability of transcripts. Regulation 31 provides that any power conferred on the Chair of the Committee by the regulations can be exercised by the Deputy Chair.

Regulation 32 revokes regulations made under the 1990 Act prior to its amendment by the 2008 Act and makes saving provision for the purposes of the Human Fertilisation and Embryology (Consequential Amendments and Transitional and Saving Provisions) Order (S.I.2009/[ ]).

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# HUMAN FERTILISATION AND EMBRYOLOGY

## The Human Fertilisation and Embryology (Appeals) Regulations 2009

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