STATUTORY INSTRUMENTS

2009 No. 1397

HUMAN FERTILISATION AND EMBRYOLOGY

The Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009

Made - - - -	*29th May 2009*
Coming into force - -	*1st October 2009*

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The Human Fertilisation and Embryology Authority makes these Regulations in exercise of powers conferred by sections 19(6); 45(3) and (3A) of the Human Fertilisation and Embryology Act 1990(**a**).

PART 1

General

Citation and commencement

1. These Regulations may be cited as the Human Fertilisation and Embryology Authority (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 and shall come into force on 1st October 2009.

Interpretation

2.—(1) In these Regulations—

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

"the Act" means the Human Fertilisation and Embryology Act 1990(**c**) ;

"case officer" means the person representing the Authority in matters prior to any hearing (and may be the same person as the presenter);

"committee" means the Licence Committee;

"chair" means the 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;

"Licence Committee" means the committee established under section 9A (2) of the Act, to which the Authority has delegated its functions under sections 18(2); 18A (3) and (5); and considering representations made under section 19(4) of the Act;

"notice of exercise of right" means the notice referred to in section 19(5) of the Act;

"notice of hearing" means a notice complying with the requirements of Regulation 6;

"person concerned" means a person who has the right to make representations to the Authority in accordance with section 19(4) of the Act or a licence holder in respect of whose licence a recommendation has been made that the licence be suspended;

"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;

"parties" means the Authority and the person concerned (or, where appropriate, the representatives of the Authority and the person concerned);

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

"secretary" means the secretary to the committee.

(2) For the purposes of these Regulations—

(**a**) 1990 c.37 section 19(6) was substituted by section 19 of the Human Fertilisation and Embryology Act 2008. c.22 ("the 2008 Act"). Sections 45(3) and (3A) were substituted by section 30(4) of the 2008 Act.
(**b**) S.I. No. 1991/1889.
(**c**) 1990 c.37 as amended by the Human Fertilisation and Embryology Act 2008 c.22.

(a) a hearing of the committee, other than when it is deliberating in private, is considered to be "in private" if it is held in the presence of—

(i) the parties and any person representing a party (where present),

(ii) the person acting as secretary,

(iii) any witness giving evidence,

(iv) any legal, clinical, scientific or specialist adviser,

(v) any person responsible for the recording of the proceedings, or

(vi) any other person whose presence is deemed necessary by the chair,

but excluding everyone else; and

(b) the private deliberations of the committee are considered to be "in private" if they are held in the presence of —

(i) the person acting as secretary, or

(ii) any legal, clinical, scientific or specialist adviser,

but excluding everyone else.

PART 2

Procedure of Committee

Consideration of representations made under section 19(4) of the Act

3.—(1) Representations received from the person concerned shall be considered by the committee.

(2) When considering representations received from the person concerned, the committee —

(a) shall—

(i) sit with either 3 or 5 members, including the chair or deputy chair,

(ii) sit with a majority of members who are not persons with a professional interest,

(iii) participate in the decision making equally (and no member shall abstain from voting on any issue where a vote is required),

(iv) take decisions by simple majority (and the chair shall not have a casting vote),

(v) sit with a legal adviser,

(vi) be assisted by a secretary (provided that the secretary is not a member of the Authority or person acting as secretary to the Appeal Committee); and

(b) may sit with a clinical, scientific or specialist adviser where the chair considers it desirable to do so.

(3) No member of the committee shall consider representations received from the person concerned, if that member has a conflict of interest in relation to that case.

(4) The legal, clinical, scientific or specialist advisers referred to in paragraph (2) above—

(a) shall advise the committee on any areas within the adviser's expertise;

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

(c) at the request of the chair, may be present during the private deliberations of the committee but shall not participate in the decision making of the committee (and are not entitled to vote);

(d) subject to sub-paragraph (e), shall tender any advice at a hearing in the presence of each of the parties in attendance at that hearing;

(e) where at a hearing the committee has begun to deliberate on its decision and needs to obtain advice in the course of its deliberations, may tender advice to the committee notwithstanding the absence of the parties; and

(f) where advice has been tendered in accordance with sub-paragraph (e), shall repeat the advice before the parties in attendance at the hearing.

(5) 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 refused to accept that advice; and

(c) a copy of the record of the advice tendered and the reasons why the committee refused to accept that advice shall be sent to the parties.

(6) The secretary shall—

(a) not participate in the decision making of the committee (and is not entitled to vote); and

(b) keep a record of —

(i) the committee's decision and of the reasons for such decision,

(ii) any advice tendered by the legal, clinical, scientific or specialist advisers (or any interventions made by them when they are present during the private deliberations of the committee); and

(iii) any declarations of interest (or potential conflicts of interest) made by a member during the proceedings.

(7) Subject to the Act and these Regulations, the committee may regulate its own proceedings.

Notice of exercise of right and accompanying documents

4.—(1) Where a person wishes to require the Authority to give him an opportunity to make representations, 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 required by section 19(5) of the Act.

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

(a) the full name and correspondence address of the person concerned;

(b) a daytime telephone number at which the person concerned can be contacted;

(c) the licence number of the person concerned (where applicable);

(d) a statement as to whether or not the person concerned is to be represented in the course of the proceedings, and if so, the contact details of any representative;

(e) any written representations that the person concerned wishes to make to the committee;

(f) copies of all material on which the person concerned intends to rely in the course of the proceedings before the committee;

(g) a skeleton argument setting out the submissions that the person concerned wishes to make to the committee;

(h) a statement as to whether the person concerned wishes to rely on any witness evidence, and if so, the names and occupations of such witnesses;

(i) a statement as to whether the person concerned wishes the matter to be considered on the papers or at a hearing; and

(j) in a case where the person concerned wishes a hearing to be held, a statement as to whether he wishes a case management meeting to be convened, and if so, the issues that the person concerned wishes to be considered at that meeting.

(3) At a case management meeting, the chair may—

(a) extend the time for delivery of the skeleton argument and any additional material necessary to determine the appeal; and

(b) allow the person concerned to amend the details regarding representation.

(4) A person concerned may withdraw his notice of exercise of right at any time prior to the first day of the hearing, or the first day that the committee considers the case on the papers, as applicable, by written notice to the Chair.

(5) Where a person concerned has not fully provided the information and documents set out in paragraph (2), the committee shall not be required to consider his representations.

Action following receipt of notice of exercise of right

5.—(1) The Authority shall provide to the secretary any notice of exercise of right received by the Authority and the information and documents provided with that notice pursuant to regulations 4(1) and (2) within 7 days beginning with the date of receipt of the notice.

(2) Following receipt of the notice of exercise of right from the Authority, the secretary shall—

(a) acknowledge receipt of the notice of exercise of right and any accompanying material submitted by the person concerned within 7 days beginning with the date of receipt of the notice;

(b) (where not already provided) provide copies of the notice of exercise of right and any accompanying material to a case officer within 7 days beginning with the date of receipt of the notice;

(c) require the case officer to provide him with copies of all documents on which the Authority intends to rely on in the proceedings before the committee within 21 days of receipt of papers by the case officer under sub-paragraph (b);

(d) send copies of any documents provided by the case officer under paragraph (c) to the person concerned or (where applicable) the representative of the person concerned within 7 days of receipt from the case officer;

(e) as soon as possible, serve notice on the parties of the date on which the committee will consider the matter (which, in the case of a hearing, unless the parties agree otherwise, shall be no less than 28 days after the date on which the secretary serves the notice of hearing);

(f) where the person concerned has stated that he wishes the committee to consider the matter at a hearing, send a notice of hearing to the parties, which shall be in the format described in Regulation 6; and

(g) require the parties to submit any further written submissions no later than 14 days before the date of the hearing or the date on which the committee is to meet.

Notice of hearing

6. The notice of hearing shall—

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

(b) inform the person concerned of his right to attend and to be represented or accompanied at the hearing in accordance with Regulation 14;

(c) inform the person concerned that the committee may proceed with the hearing in his absence;

(d) inform the person concerned of the provisions relating to—

(i) evidence set out in Regulation 9 ,

(ii) procedure at hearings set out in Regulation 13, and

(iii) witness evidence set out in Regulations 13(4) and 15(2); and

(e) require the person concerned to inform the secretary, within 14 days of service of the Notice of Hearing, whether he intends 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

7.—(1) Where a hearing is to be held, a case management meeting may be convened by the chair of his own motion or at the request of one or both of the parties.

(2) Where a case management meeting is to be convened, the secretary shall give the parties such notice of it as is reasonable (in the opinion of the chair) in all the circumstances of the case.

(3) The format of the case management meeting, the procedure to be followed and the persons required to attend that meeting shall be determined by the chair, in consultation with the parties.

(4) Case management meetings shall be held in private.

(5) At a case management meeting, the chair may issue such directions as he considers necessary for the just and expeditious management of the case.

Multiple representations

8. After obtaining the advice of the legal adviser, the committee may consider and determine together two or more representations made under section 19(4) of the Act by the same person concerned, or by different persons concerned, where it is satisfied that it would be fair and appropriate to do so.

Evidence

9.—(1) All questions of admissibility of evidence and law before the committee shall be decided by the committee, after obtaining the advice of the legal adviser.

(2) Upon obtaining the advice of the legal adviser, and subject only to the requirements of relevance and fairness, the committee may receive—

(a) subject to paragraph (3), any documentary or physical evidence; and

(b) subject to regulations 13(2)(d) and (e), 13(4), and 15(2), where a hearing is held, any oral evidence,

whether or not such evidence would be admissible in civil proceedings in that part of the United Kingdom where the meeting or hearing is to take 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 document—

(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 a person concerned has been convicted of a criminal offence in the British Islands (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 which may be adduced by the person concerned in rebuttal of a conviction certified or extracted in accordance with paragraph (4) is evidence for the purpose of proving that he is not the person referred to in the certificate or extract.

(6) A formal notification of a determination about a person concerned's fitness to practise 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 regulatory body.

(7) The chair shall only allow a party to adduce written evidence at a hearing which has not been submitted in accordance with this regulation in exceptional circumstances which could not reasonably have been foreseen at the time of the service of the notice of exercise of right or of any case management meeting.

Power to summons witnesses and require production of documents

10.—(1) Subject to paragraph (3) and regulation 15(1), the committee may by summons require any person (P) in the United Kingdom to attend as a witness at a hearing before it at such time and place as may be specified in the summons and P must do so.

(2) Subject to paragraph (4) the committee may by summons require any person including the person concerned (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.

(3) P shall not be required in obedience to any summons issued in accordance with paragraph (1) to attend and give evidence or to produce any document unless—

(a) he has been given at least 7 days notice of the hearing or, if less than 7 days, he has informed the committee that he accepts such notice as he has been given, and

(b) he has been provided with confirmation that his reasonable and necessary travel and subsistence expenses will be paid by the Authority.

(4) P shall not be compelled to give any evidence or produce any document or other material that he could not be compelled to give or produce on a trial of any action in a civil court of law in that part of Great Britain in which the proceedings before the committee are to take place.

(5) Each summons under paragraph (1) and (2) above must—

(a) 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 summons; and

(b) refer to the fact that by virtue of section 41(7) of the Act a person who without reasonable excuse fails to comply with the requirement of that paragraph is guilty of an offence and is liable on summary conviction to imprisonment for a term not exceeding six months or a fine not exceeding level five on the standard scale or both.

Burden and standard of proof

11.—(1) The Authority shall bear the burden of establishing that a licence should be revoked, varied (otherwise than on an application) or that a licence should be suspended.

(2) The person concerned shall bear the burden of establishing that a licence should not be refused.

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

Consideration on the papers

12.—(1) The committee shall determine a matter referred to it on the papers unless the person concerned has requested a hearing when providing notice of his exercise of right.

(2) No later than 7 days before the meeting, the secretary shall provide the committee with an agenda and the documents relevant to the proceedings before the committee.

(3) Before making its decision, in addition to considering the material submitted by the parties, the committee may obtain advice from a legal, clinical, scientific or specialist adviser.

(4) Before making its decision, the committee may adjourn and require the person concerned and the Authority to provide further information or documents.

(5) Before making its decision, the committee may adjourn and require—

(a) an inspection to be made by employees of the Authority of any premises where the licensed activity is or is to be carried out;

(b) an inspection to be made by employees of the Authority of any premises that are or will be relevant third party premises; and

(c) a report to be presented to it of any inspection made in accordance with sub-paragraphs (a) and (b).

(6) The secretary shall record—

(a) any advice tendered by a legal, clinical, scientific or specialist adviser (where present);

(b) any rulings on questions of law or admissibility made by the chair;

(c) the decision of the committee; and

(d) the reasons for the committee's decision.

Procedure at hearings

13.—(1) No later than 7 days before the hearing, the secretary shall provide the committee with an agenda and the documents relevant to the proceedings before the committee.

(2) The order of proceedings at the hearing shall be as follows—

(a) the chair shall declare the hearing open;

(b) where the person concerned is not present or represented at the hearing, the chair—

(i) shall require the secretary to adduce evidence that all reasonable efforts have been made to serve the notice of hearing on the person concerned, and

(ii) having consulted the committee, may—

(aa) if he is satisfied that the notice of hearing has been duly served, proceed with the hearing in the absence of the person concerned, or

(bb) adjourn the hearing and issue appropriate directions;

(c) the presenter shall make an opening statement, outlining what he considers to be the relevant circumstances of the case;

(d) the person concerned may adduce evidence, and may call witnesses (provided that the chair is satisfied that the witness is in a position to provide relevant testimony and subject to paragraph (4));

(e) the presenter may adduce evidence in rebuttal of the position of the person concerned and in support of the position of the Authority, and may call witnesses (provided that the chair is satisfied that the witness is in a position to provide relevant testimony and subject to paragraph (4));

(f) the person concerned may make a closing statement;

(g) before making its decision, the committee may—

(i) seek advice from a legal, clinical, scientific or specialist adviser (provided that the parties are provided with an opportunity to comment on such advice before the committee makes its decision),

(ii) adjourn and require a party to provide further information or documents,

(iii) adjourn and require an inspection to be made by employees of the Authority of any premises where licensed activity is or is to be carried out,

(iv) adjourn and require an inspection to be made by employees of the Authority of any premises that are or will be relevant third party premises, and

(v) adjourn and require a report to be presented to it of any inspection made in accordance with (iii) and (iv) above;

(h) the committee shall deliberate in private and shall then announce its decision in the presence of the parties (where present), together with the reasons for its decision.

(3) The conduct of the hearing shall otherwise be at the discretion of the chair, who may (amongst other matters) invite the parties to make additional submissions to those outlined in paragraph (2).

(4) The chair may refuse to allow a witness to give oral evidence, or to give evidence on a particular matter, if he is satisfied that 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.

(5) Subject to paragraph (6), hearings shall be held in public.

(6) After consulting with the legal adviser, the chair may require some or all of the hearing to be held in private, where he is satisfied that an interest of a party in maintaining privacy outweighs the public interest in holding the hearing or part of it in public.

(7) The chair may require any member of the public attending the hearing to be excluded from the hearing, where he considers that the continued presence of that person may disrupt the proceedings before the committee.

Representation and entitlement to be heard

14.—(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 person concerned may be represented by a person who is—

(a) a barrister, advocate or solicitor; or

(b) a representative from his or its defence organisation or his trade union,

or both.

(3) Where the person concerned is not represented, he may be accompanied and advised by a supporter, but the supporter—

(a) shall not be—

(i) a member or employee of the Authority, or

(ii) a witness at the hearing; and

(b) shall only be entitled to address the committee with the permission of the chair.

(4) The presenter and the person concerned or his representative shall be entitled to attend any hearing before the committee of which notice is given in accordance with Regulation 6, and to be heard by the committee at that hearing.

Witness evidence

15.—(1) The Authority may not compel the person concerned to be a witness.

(2) A party may not call a person to be a witness unless that party has provided to the other party a written statement of evidence provided by the witness at least 7 days before the hearing (which meets the requirements of Regulation 9(3)), unless the chair determines otherwise.

(3) The committee may, upon the application of the party calling the witness, direct that any details which may identify that witness should not be revealed in public.

(4) Witnesses—

(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;

(d) may then be questioned by the committee through the chair, and with the leave of the chair, by a legal, clinical, scientific or specialist adviser.

(5) The parties may then question the witnesses 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).

(6) Any further questioning of witnesses shall be at the discretion of the chair.

(7) Except for expert witnesses and the person concerned, witnesses shall not be allowed to attend the proceedings until after they have completed giving their evidence and been formally released by the chair.

Postponements and adjournments

16.—(1) The chair may, of his 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, of his 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 a request for postponement or adjournment, the chair shall, amongst other matters, have regard to—

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

(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 secretary shall, as soon as practicable, notify the parties of the date, time and venue of the postponed or resumed meeting or hearing.

Decision of the committee

17.—(1) The committee shall provide the notice referred to in section 19A (2) to (5) of the Act, in writing, together with a statement of its reasons for the decision, no later than 7 days after the date on which it has made its decision.

(2) The committee may serve notice of its decision, and the statement of its reasons for that decision, on any other person whom it considers, in the public interest, ought to be informed of the committee's decision.

(3) When serving the notice referred to in section 19A of the Act, the committee shall at the same time serve a written record of—

(a) any advice tendered by a legal, clinical, scientific or specialist adviser;

(b) any rulings on admissibility of evidence made by the committee.

Notes and transcripts of hearings

18.—(1) Subject to paragraph (3), the Authority shall arrange for all hearings to be recorded in writing or electronic form.

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

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

Report of committee's activities

19. The chair shall prepare an annual written report to the Authority detailing the activities of the committee.

Made by the Authority this 29th day of May 2009

Lisa Jardine
Chair,
29th May 2009 Human Fertilisation and Embryology Authority

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made under Sections 19(6) and 45(3) and (3A) of the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008).

The Regulations set out set out the procedure to be followed when a person wishes to make representations against certain decisions made by the Human Fertilisation and Embryology Authority.

Part 1 deals with preliminary matters, including commencement and interpretation (regulations 1 and 2).

Part 2 sets out the procedure for consideration of representations.

Regulation 3 provides that representations are to be considered by a Licence Committee of the Human Fertilisation Authority. This regulations sets out details of the quorum and voting procedure to be followed by the Committee, and provides for the Committee to be assisted by advisers and a secretary. This regulation further specifies the roles of the advisers and of the secretary.

Regulation 4 specifies the information and documents to be provided to the Authority at the same time that the person wishing to make representations serves the notice of exercise of right that is required by the Act.

Regulation 5 sets out the actions that need to be taken by the respective parties after service of the notice of exercise of right, and the required time limits for such actions. Regulation 6 sets out the information that must be contained in a notice of hearing (including information relating to the right to be represented and the procedure to be followed at a hearing) that is to be served on the person wishing to make representations, where that person has requested that a hearing be held.

Regulation 7 makes provision for case management meetings to be held, in order to ensure that hearings proceed smoothly and that effective use of time is made at the hearing. Regulation 8 provides for multiple representations to be considered by the same committee, where the committee are satisfied that it is fair and appropriate to do so.

Regulation 9 sets out detailed requirements relating to the evidence that the committee can consider. Regulation 10 provides for a power to summons witnesses (other than the person making representations) and to require production of documents. Regulation 11 sets out the burden and standard of proof to be considered by the committee.

Regulation 12 and 13 set out the respective procedures to be followed by the committee when it is considering representations on the papers, and when it is considering representations at a hearing.

Regulation 14 makes provision for representation and the entitlement of the person making representations to be heard before the committee and regulation 15 makes provision for witness evidence. Regulations 16-19 deal with administrative matters such as adjournments, format of decision notices, transcripts of hearings, and a requirement for the committee to provide an annual report of its activities to the Human Fertilisation and Embryology Authority.

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