

# Human Fertilisation and Embryology Authority

## Standing Orders and Annexes

Approved 7 December 2011

Standing Orders and Annexes to be reviewed by Authority annually

## Version control

Reviewed and approved by Authority [9 December 2009](#)

Amendments approved by Authority on [20 January 2010](#) and [12 May 2010](#)

Typographical corrections made 04 August 2010

Reviewed and amendments approved by Authority via written resolution (issued 12 November 2010) and decision noted at Authority meeting [8 December 2010](#).

Reviewed and amended in light of new Equalities Legislation and approved by Authority on [23 March 2011](#).

Reviewed, amended and approved by Authority [7 December 2011](#)

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## Foreword<sup>1</sup>

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1. The Human Fertilisation and Embryology Authority (“the Authority”) is an executive Non-departmental Public Body sponsored by the Department of Health. The Authority is a body corporate, established by section 5 of the Human Fertilisation and Embryology Act 1990 (as amended) (“the Act”). In accordance with Schedule 1 to that Act, the Chair and members of the Authority are appointed by the Secretary of State for Health.
2. The Authority is committed to adopting best practice in corporate governance. These Standing Orders form part of the corporate governance framework with which the Authority must comply, and which includes:
  - (a) the Act;
  - (b) Regulations issued by the Secretary of State for Health which govern the operation of some of the Authority’s Committees;
  - (c) the management statement agreed between the Authority and the Department of Health;
  - (d) Standing Financial Instructions adopted by the Authority; and
  - (e) Financial procedures for procurement and payment of goods and services, budget management and travel and subsistence.
3. As a public body, the Authority is also required to comply with the Human Rights Act 1998; applicable legislation including that relating to equalities, freedom of information, environment information and data protection; and with relevant government policies on information assurance and data security. In addition, the Authority is expected to comply with the Statutory Code of Practice for Regulators (the Regulators Compliance Code).
4. These Standing Orders are based on the ‘Guidance on Codes of Practice for Board Members of Public Bodies’, issued by the Cabinet Office in January 1997 as a model for corporate governance in the public sector. The purpose of the Guidance is to secure the public service values of impartiality, integrity, objectivity, openness and accountability, and to ensure that value for money is optimised.
5. These Standing Orders primarily govern the procedures of the Authority sitting as a board of members, and the committees established by the Authority.
6. In the conduct of operational activities, members and employees of the Authority are also expected to comply with policies approved by the Authority (refer list in 3.2.1).

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<sup>1</sup> This Foreword is not part of the Standing Orders

7. Employees of the Authority are, in addition, expected to comply with the requirements set out in the Employee Handbook.

# Human Fertilisation and Embryology Authority

## Standing Orders

Approved 7 December 2011

## Section 1: Use of standing orders

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### 1.1 Power to Make Standing Orders

1.1.1 These Standing Orders are made in accordance with the powers of the Authority:

- a) under paragraph 9 of Schedule 1 to the Act, to regulate its own proceedings and to make such arrangements as it considers appropriate for the discharge of its functions; and
- b) under section 9A of the Act, to establish committees and to delegate functions to committees, members and staff.

1.1.2 These Standing Orders shall govern the proceedings of the Authority and its Committees and working groups.

### 1.2 Commencement

1.2.1 These Standing Orders were adopted by the Authority at its public meeting on 9 December 2009, and first came into force on 1 January 2010.

### 1.3 Variation and amendment of Standing Orders

1.3.1 These Standing Orders shall be amended only if:

- a notice of motion has been given; and
- no fewer than half the total Members vote in favour of amendment; and
- at least two-thirds of the Members are present; and
- the variation proposed does not contravene a statutory provision or a direction made by the Secretary of State.

### 1.4 Standing Orders to be given to Members and Officers

1.4.1 It shall be the duty of the Chief Executive to ensure that:

- a) existing members and officers and all new appointees are provided with a copy of these Standing Orders and informed of their obligation to comply with these Standing Orders; and
- b) a copy of these Standing Orders is published on the Authority's website.

### 1.5 Non-compliance with Standing Orders

1.5.1 All members, officers and staff shall have a duty to disclose any non-compliance with these Standing Orders to the Chair of the Authority or Chief Executive.

1.5.2 If for any reason these Standing Orders are not complied with, full details of the non-compliance and any justification for non-compliance shall be reported to the next formal meeting of the Authority for action or ratification.

## 1.6 Review of Standing Orders

1.6.1 These Standing Orders shall be reviewed at least annually by the Authority. The scope or extent of such a review can be agreed in advance by the Chair, with input from the Executive and Chairs of Committees, where relevant.

## Section 2: Interpretation

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### 2.1 Role of Chair of the Authority

2.1.1 The Chair of the Authority shall be the final authority on the interpretation of these Standing Orders.

### 2.2 Definition of Terms

2.2.1 The following terms are used in these standing orders:

- “Accounting Officer” means the officer responsible and accountable for the resources entrusted to the Authority, and who shall be responsible for the stewardship of public funds and assets;
- “the Act” means the Human and Fertilisation and Embryology Act 1990 (as amended);
- “Authority” means the Human fertilisation and Embryology Authority (HFEA);
- “the Board” means the members sitting in whole as the Authority
- “Chair of the Authority” means the person appointed by the Secretary of State for Health to chair the Authority and shall be deemed to include the Deputy Chair of the Authority, if the Chair is absent from the meeting or is otherwise unavailable;
- “Chief Executive” means the person appointed by the Authority to act as Chief Officer and Accounting Officer of the Authority;
- “Committee” means a committee established by the Authority;
- “Committee members” means persons formally appointed by the Chair of the Authority to sit on or to chair specific committees;
- “Corporate Management Group” (CMG) established by the Chief Executive for effective management of the HFEA (refer 3.6.2 & 3.6.3),
- “the Department” means the Department of Health;
- “Deputy Chair” means the member appointed by the Secretary of State to take on the Chair’s duties if the Chair is absent for any reason;
- “Lay member” means a member of the Authority, who is not, nor has been:
  - a medical practitioner registered under the medical Act 1983,
  - concerned with keeping or using gametes or embryos outside the body, or
  - directly concerned with commissioning or funding any research involving such keeping or use, or who has actively participated in any decision to do so;
- “Officer” means a member of the Senior Management Team;
- “Secretary of State” means the Secretary of State for Health; and

- “Senior Management Team” means those reporting directly to the Chief Executive and who are also members of the Corporate Management Group (CMG), including all Directors.

## Section 3: The Authority

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### 3.1 Responsibilities of Members

- 3.1.1 Members of the Authority shall, at all times, act in accordance with the provisions of the Act and with the provisions of the Code of Practice annexed to these Standing Orders.
- 3.1.2 The Authority shall not give the Chief Executive instructions which conflict with his/her duties as the Authority's Accounting Officer.
- 3.1.3 No Member shall solicit for any person any appointment as a member or employee of the Authority, or recommend any person for such appointment.
- 3.1.4 Members shall, as soon as possible, disclose to the Chief Executive any relationship between them and a candidate of whose candidature they become aware. It shall be the duty of the Chief Executive to report to the Authority any such disclosure made.
- 3.1.5 Members shall, in the conduct of Authority business, treat people equally and fairly and not discriminate unlawfully against anyone on the basis of their race or racial group, sex (including gender reassignment), sexual orientation, religion or belief marriage or civil partnership, pregnancy and maternity, age or disability.
- 3.1.6 In carrying out their public functions, Members shall have due regard to the need to eliminate any conduct prohibited under the Equality Act 2010 and to promote equality of opportunity and foster good relations between people with protected characteristics (as defined in the Equality Act 2010) and others.
- 3.1.7 Members shall, in their interactions with each other and with Authority staff, model the "ways of Working" agreed by the Authority:
- taking responsibility
  - challenging well
  - taking interest in others' ideas
  - demonstrating enthusiasm.
- 3.1.8 Member shall, in the conduct of Authority business, have regard to the functions and duties of the Authority set out in sections 8 and 8ZA of the Act.
- 3.1.9 Members shall, in the conduct of Authority business comply with Human Rights Act 1998; Equality Act 2010, freedom of information, environment information; and data protection; and with government policies on information assurance and data security. In addition, members shall have proper regard to the principles set out in the Statutory Code of Practice for Regulators (the Regulators Compliance Code).

3.1.10 Members shall ensure that the financial transactions of the Authority are carried out in accordance with the Standing Financial Instructions and financial procedures adopted by the Authority.

### **3.2 Responsibilities of members and employees**

3.2.1 In the conduct of operational activities, members and employees of the Authority shall comply with policies approved by the Authority, including policies relating to:

- a) Compliance and Enforcement;
- b) Complaints;
- c) Information access, security, integrity and risk management;
- d) Publication Scheme;
- e) Opening the Register;
- f) Records Management, including retention and disposal;
- g) Collection, Confirmation and Publication of Register Data;
- h) Forensic Readiness;
- i) Staff Security;
- j) Whistle blowing;
- k) Counter fraud and anti-theft;
- l) Health, Safety and Sustainability; and
- m) Human Resources.

3.2.2 Members and employees shall ensure compliance with the financial procedures for procurement and payment of goods and services, budget management and travel and subsistence adopted by the Authority.

### **3.3 Particular Responsibilities of Chair of the Authority**

3.3.1 The Chair of the Authority shall in addition to the responsibilities shared by all members have particular responsibility for:

- a) approving the agenda for meetings of the Authority;
- b) chairing meetings of the Authority;
- c) signing minutes of Authority meetings;
- d) briefing members;
- e) ensuring that these Standing Orders are complied with;
- f) appraisal of members;
- g) appraisal of Chief Executive;
- h) appointment of members to committees of the Authority;
- i) taking decisions on litigation;
- j) maintaining a log of whistle blowing incidents;

- k) liaison with the Secretary of State for Health and Minister for Public Health on behalf of the Authority;
- l) representing the Authority to the public; and
- m) issuing “Chair’s letters” setting out notification of a change of policy or the issuing of new directions under the Act.

3.3.2 The Chair of the Authority may consult with two or more members of the Authority before discharging the particular responsibilities set out in paragraph 3.3.1 above or before undertaking any action on behalf of the Authority.

### **3.4 Particular Responsibilities of Deputy Chair of the Authority**

3.4.1 Where the Chair of the Authority has died or has ceased to hold office, or where he/she has been unable to perform his/her duties as Chair owing to illness, absence from UK or any other cause, the Deputy Chair shall act as chair until a new chair is appointed or the existing Chair resumes his/her duties, as the case may be; and reference to the chair in these Standing Orders shall, so long as there is no Chair able to perform his/her duties, be taken to include references to the Deputy Chair.

### **3.5 Authority Equality Champion**

3.5.1 The Authority shall appoint a Member to act as Equality Champion.

3.5.2 The role of Equality Champion shall be to promote compliance with equalities legislation at board level and to report to the Authority.

### **3.6 Particular Responsibilities of the Chief Executive**

3.6.1 The Chief Executive is the Authority’s designated Accounting Officer and, as such is accountable to Parliament and the Secretary of State for:

- a) safeguarding the public funds for which he/she has been charged;
- b) handling those public funds ensuring propriety and regularity
- c) day-to-day operations and management of the Authority.

3.6.2 The Chief Executive shall establish the Corporate Management Group to ensure:

- a) effective management of the Authority’s business and operational activities;
- b) achievement of the Authority’s strategic and statutory objectives; and
- c) continuous improvement within the Authority;
- d) monitoring of compliance with applicable legislation, and oversight of executive working groups on particular subjects.

3.6.3 The Chief Executive shall determine the membership and terms of reference of the Corporate Management Group.

### **3.7 Registers of Interests and Hospitality**

3.7.1 The Authority shall maintain and publish a Register of Interests and a Register of Hospitality to record formally declarations of members and staff.

### **3.8 Declarations of Interest and Potential Conflicts**

3.8.1 At every meeting of the Authority or a committee of the Authority, members shall be required to declare any interests they may have.

3.8.2 Members shall identify any potential conflicts as soon as possible after receipt of papers in advance of any meeting of the Authority or a committee of the Authority.

3.8.3 Where a potential for a conflict of interests is identified, members shall consult and follow the Guidance on Conflicts of interests approved by the Authority in January 2009.

### **3.9 Direct reporting to Chair of the Authority**

3.9.1 The following persons shall be entitled to report directly and to bring matters to the attention of the Chair of the Authority:-

- a) Chief Executive;
- b) Senior Management Team;
- c) Head of Internal Audit; and
- d) External Auditors

### **3.10 Access to external legal advice by members**

3.10.1 All external legal advice must be commissioned through the Authority's legal advisers and no advice must be commissioned without the approval of the Chair of the Authority or the Chief Executive.

### **3.11 Register of policies**

3.11.1 The Authority shall maintain a register of all policies approved by it and relating to the effective running of the Authority, and shall review all such policies at regular intervals.

## Section 4: Meetings

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### 4.1 Ordinary Meetings

- 4.1.1 Members of the Authority shall meet as a board no fewer than five times in each calendar year, and such meetings shall be held at such intervals and venues as the Chair may determine.
- 4.1.2 Members of the public shall be invited to attend at least two meetings of the board of the Authority in any calendar year.

### 4.2 Extraordinary Meetings

- 4.2.1 In addition to the fixed ordinary meetings, extraordinary meetings of the board of the Authority may be called:
  - a) at any time by the Chair; and
  - b) subject to paragraph 4.2.2, at the request of any member.
- 4.2.2 An extraordinary meeting requested by a member shall only be held if:
  - a) the request is made in writing to the Chair of the Authority, specifying the item(s) to be considered at the meeting;
  - b) the written request is signed by at least one-third of the members of the Authority; and
  - c) the written request sets out the need for an extraordinary meeting and the reason why the matters to be considered should not be considered at the next ordinary meeting of the board of the Authority.

### 4.3 Written Resolutions

- 4.3.1 A written resolution shall be as valid and effectual as if it had been passed at a meeting of the board of the Authority provided that:
  - a) the resolution is circulated by email to all the members of the board of the Authority;
  - b) members shall have at least three days to respond to the resolution;
  - c) no fewer than one-third of the members of the Authority respond; and
  - d) the majority of those responding are in favour of, and approve, the resolution.

### 4.4 Notice of Meetings and written resolutions

- 4.4.1 The Chair of the Authority shall notify members of the dates of the Ordinary meetings of the board of the Authority in any calendar year at least one month before the beginning of that year.

- 4.4.2 Want of service of notice on any member shall not affect the validity of an ordinary meeting.
- 4.4.3 The Chair of the Authority shall notify members of the date of an extraordinary meeting or written resolution to be considered by the board of the Authority and shall provide members with such notice as is reasonable in the circumstances.

#### 4.5 Agendas

- 4.5.1 The Chair of the Authority, in consultation with the Chief Executive, shall determine the Agenda for all meetings of the board of the Authority.
- 4.5.2 The following matters shall be standing items on every agenda for an ordinary meeting of the board of the Authority:
- a) apologies;
  - b) declaration of interests;
  - c) Chair's briefing;
  - d) reports from the Chief Executive and the Directorates Report; and
  - e) reports from Committees and Working Groups.
- 4.5.3 A member desiring a matter to be included on an agenda shall make his/her request to the Chair at least 10 working days before the meeting, and should include appropriate supporting information. Requests made less than 10 days before a meeting may be included on the agenda at the discretion of the Chair.
- 4.5.4 No business other than that set out in the Agenda shall be considered at a meeting of the board of the Authority, except where the Chair considers that the nature or urgency of the matter is such that it would be desirable to consider the matter at that meeting.
- 4.5.5 Agenda items which are not considered at a meeting shall be carried forward for consideration at the next ordinary meeting, unless considered at an extraordinary meeting.

#### 4.6 Distribution of Papers

- 4.6.1 The Chief Executive shall endeavour to ensure that agendas and supporting papers (where possible) are sent to members in good time before a meeting of the board, and shall normally send out such papers five working days before the meeting.
- 4.6.2 Agendas and papers may be distributed by such method as the Chief Executive considers appropriate, including by email.
- 4.6.3 Agendas and papers for a meeting, including those sent by email, shall be deemed to have been received on the day following the day they were sent.

- 4.6.4 Provided that the agenda and/or papers for a meeting have been sent to members in accordance with this Standing Order, their non-receipt by any member shall not invalidate the business transacted at that meeting.
- 4.6.5 Papers may be tabled at a meeting of the board of the Authority only with the permission of the Chair.
- 4.6.6 Papers for consideration by the board of the Authority or a committee of the Authority shall be presented in the standard template approved by the Chief Executive.
- 4.6.7 The papers considered by members at a meeting of the board of the Authority shall be published in accordance with the Authority's Policy on the Publication of Authority and Committee papers and shall be made available to the public in accordance with the Authority's Publication Scheme and the Freedom of Information Act 2000.

#### 4.7 Chair of Meeting

- 4.7.1 At any meeting of the board of the Authority, the Chair, if present, shall preside. If the Chair is absent from the meeting, the Deputy Chair shall preside. If the Chair and Deputy Chair are absent, such member as the Members present shall choose, shall preside.
- 4.7.2 If the Chair of the Authority is absent temporarily or is disqualified from participating on the grounds of a declared conflict of interest the Deputy Chair, if present, shall preside. If the Chair and Deputy Chair are absent, or are disqualified from participating, such member as the members present shall choose, shall preside.
- 4.7.3 The decision of the Chair of the meeting on questions of order, procedure, relevancy, regularity and any other matters shall be final.

#### 4.8 Quorum

- 4.8.1 No business shall be transacted at a meeting unless at least one third of the members are physically present at that meeting.
- 4.8.2 Members shall not be permitted to attend meetings of the board of the Authority by telephone or videoconferencing.
- 4.8.3 In determining whether or not there is a quorum, the Chair shall take into account the provisions of section 4 (4) of Schedule 1 of the Act regarding the composition of the Authority. If the quorum comprises a majority of non-lay members, the Chair of the Authority may decide that a particular vote or decision cannot be taken. The decision of the Chair on such matters is final.
- 4.8.4 Any member (including the Chair of the Authority) who has been disqualified from participating in the discussion on any matter and/or from voting on any question by reason of the declaration of a conflict of interest, shall no longer

count towards the quorum. If a quorum is then not available for the discussion and/or the decision on any matter, that matter may not be discussed further or voted upon at that meeting. Such a position shall be recorded in the minutes of the meeting.

#### 4.9 Voting

- 4.9.1 The Authority shall normally seek to achieve consensus on issues requiring a decision by the members.
- 4.9.2 Where the Chair determines that a vote is necessary, the nature of that vote shall be at the discretion of the chair, and may be by oral expression or show of hands or by paper ballot if a majority of the members present so request.
- 4.9.3 Only those members (including the Chair of the Authority) actually present at the time that a vote is to be taken, shall be entitled to vote. Voting by proxy is not permitted.
- 4.9.4 Where a vote is held, the issue shall be decided by a majority of the votes of the members who are present at the meeting (including the Chair of the Authority) and who have not been disqualified from participating in the decision by reason of any declared conflict of interest.
- 4.9.5 In the event of the number of votes for and against a motion being equal, the Chair of the meeting shall have a second or casting vote.

#### 4.10 Minutes

- 4.10.1 The proceedings of every meeting of the board of the Authority shall be formally recorded.
- 4.10.2 The Chief Executive shall ensure that an Authority employee is present at every meeting of the board of the Authority to act as secretary to that meeting and to produce the minutes of the meeting.
- 4.10.3 The names of the Chair and members present at the meeting shall be recorded in the minutes.
- 4.10.4 The minutes shall not normally record:
  - a) the names of individual members who made specific comments, contributions or suggestions at a meeting; or
  - b) the vote (or abstention) of individual members.
- 4.10.5 If a member so requests, his/her vote or the fact that he/she abstained from participating in a discussion or voting on any matter, shall be recorded in the minutes.
- 4.10.6 The draft Minutes of the proceedings of a meeting of the board of the Authority shall be drawn up and submitted for agreement by the members at

the next meeting, and the person chairing that meeting shall sign the minutes with any agreed amendments which may be necessary.

4.10.7 The minutes of the meetings of the board of the Authority shall be published in accordance with the Authority's Policy on the Publication of Authority and Committee papers and shall be made available to the public in accordance with the Authority's Publication Scheme and the Freedom of Information Act 2000.

#### **4.11 Attendance and Reporting by officers and auditors**

4.11.1 The following persons shall be entitled to attend all meetings of the board of the Authority and to bring any matter to the attention of the members:

- a) Chief Executive;
- b) Senior Management Team;
- c) Head of Internal Audit; and
- d) External Auditors

#### **4.12 Attendance of non members**

4.12.1 Observers from the Department of Health and the Human Genetics Commission, as reconstituted and when relevant, and employees of the Authority may attend ordinary meetings of the board of the Authority, whether or not the public are also invited to that meeting.

4.12.2 At any meeting of the board of the Authority, the Chair may require all persons who are not members (including officers and employees) to withdraw for any part of a meeting, if the Chair considers it desirable for the members to meet in private.

4.12.3 Where members of the public are invited to a meeting, the Chair may require any person whose presence the Chair considers to be disruptive to the proceedings, to withdraw from the meeting.

4.12.4 The Chair of the Authority may invite such persons as he or she considers desirable to attend a meeting of the board of the Authority and to advise the members on any matter on the agenda for that meeting.

## Section 5: Reservation of powers to the Authority

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### 5.1 List of reserved matters

5.1.1 The following matters shall be reserved to the Authority and shall not be delegated:

- a) appointment of the Chief Executive, with the approval of the Secretary of State;
- b) disciplinary action against the Chief Executive;
- c) approval and amendments of Standing Orders;
- d) approval and amendments of Standing Financial Instructions and Financial procedures;
- e) establishing of committees and working groups;
- f) agreement of the terms of reference and reporting arrangements of committees and working groups;
- g) receiving reports from committees and working groups;
- h) requiring and receiving declaration of interests from members and officers;
- i) the appointment of Authority representatives on external bodies;
- j) approving the strategic aims and objectives of the Authority;
- k) approving the Authority's 5 year Corporate Plan;
- l) approving the Authority's annual Business Plan;
- m) approving the annual budget;
- n) approving the annual report and accounts;
- o) (in consultation with the Department of Health and the Treasury) approving the structure and level of fees levied on licence holders and applicants for licences;
- p) monitoring of the Authority's performance against the annual plan and budget;
- q) determination of all policies relating to the performance of the Authority's functions under Section 8 of the 1990 Act;
- r) ratification of any urgent decisions taken by the Chair in accordance with section 5.2 of these Standing Orders.

### 5.2 Emergency Powers

5.2.1 The powers which the board of the Authority has reserved to itself in paragraph 5.1 may, in an emergency, be exercised by the Chair of the Authority and the Chief Executive.

5.2.2 An emergency is any situation in which decisions or action are required and such decisions or actions cannot be postponed until the next meeting of the board of the Authority.

- 5.2.3 The Chair of the Authority shall, before exercising emergency powers under this section, make best endeavours to obtain the views of members of the Authority on the required decision or action.
- 5.2.4 The exercise of emergency powers by the Chair of the Authority and the Chief Executive shall be reported to the next meeting of the board of the Authority, and may be ratified by the members.

## Section 6: Arrangements for the exercise of functions by delegation

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### 6.1 Power to delegate

6.1.1 The matters below are delegated in accordance with section 9A of the Act.

### 6.2 Litigation

6.2.1 Decisions on litigation against or on behalf of the Authority shall be delegated to the Chair of the Authority.

6.2.2 Before making a decision on litigation, the Chair of the Authority may consult with the Deputy Chair of the Authority and the Chair of the Audit and Governance Committee, or where appropriate, with two other members of the Authority.

6.2.3 Subject to 6.2.4 below, the Chair of the Authority shall ensure that members are regularly updated on key decisions and stages reached, in respect of litigation affecting the Authority.

6.2.4 Where the Chair of the Authority considers that it would be inappropriate to update members on litigation issues because there are associated matters that are yet to be determined by a Committee of the Authority, including licence applications, the Chair may defer updating members until the associated matters are determined by the relevant Committee.

### 6.3 Licensing Functions

6.3.1 The Authority shall establish and maintain an Executive Licensing Panel composed of staff employed by the Authority.

6.3.2 The Authority delegates to the Executive Licensing Panel:

- a) the exercise of its routine licensing functions, as set out in annex B to these Standing Orders as amended from time to time by the Authority; and
- b) the power to issue directions under sections 24(5A) to (5E) and section 24(13) of the Act.

6.3.3 The Executive Licensing Panel shall be constituted and shall operate in accordance with the Executive Licensing Panel Protocol set out in annex C to these Standing Orders.

6.3.4 In accordance with Section 9A (2) of the Act, the Authority shall establish and maintain a Licence Committee, and a Research Licence Committee composed of Members of the Authority.

6.3.5 The Authority delegates to the Licence Committee and the Research Licence Committee:

- a) the exercise of its novel, complex or controversial licensing functions, as set out in annex B to these Standing Orders as amended from time to time by the Authority; and
- b) the power to issue directions under sections 24(5A) to (5E) and section 24(13) of the Act.

6.3.6 Save when considering representations under Section 19(4) of the Act, the Licence Committee and Research Licence Committee shall be constituted and shall operate in accordance with the Licence Committee Protocol set out in annex D to these Standing Orders.

6.3.7 When considering representations under Section 19(4) of the Act, the Licence Committee and Research Licence Committee shall be constituted and shall operate in accordance with the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 (as amended).

#### **6.4 Reconsideration of licensing decisions**

6.4.1 In accordance with section 20A of the Act, the Authority shall establish and maintain an Appeals Committee.

6.4.2 The Authority delegates to the Appeals Committee the power to carry out its functions under section 20 of the Act.

6.4.3 The Appeals Committee shall be constituted and shall operate in accordance with the Human Fertilisation and Embryology (Appeals) Regulations 2009.

#### **6.5 Disclosure of Information for Research Purposes**

6.5.1 The Authority shall establish and maintain:

- a) a Register Research Panel;
- b) a Register Research Review Panel ; and
- c) an Oversight Committee,

to exercise the Authority's functions under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 ("the 2010 Regulations").

6.5.2 The Authority delegates to the Register Research Panel, the power to:

- a) authorise access to Register data for the purposes of medical or non-medical research.
- b) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

- 6.5.3 The Authority delegates to the Register Research Review Panel, the power to:
- a) uphold or overturn the decisions of the Register Research Panel;
  - b) authorise access to Register data for the purposes of medical or non-medical research; and
  - c) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.
- 6.5.4 The membership, functions, and arrangement for meetings of the Register Research Panel; Register Research Review Panel; and the Oversight Committee, shall be as set out in Annex A to these Standing Orders.
- 6.5.5 In carrying out their functions:-
- a) the Register Research Panel and the Register Research Review Panel shall sit in private; and
  - b) the Register Research Panel, the Register Research Review Panel and the Oversight Committee shall comply with the requirements of the 2010 Regulations.”

## **6.6 Delegation to other Committees and Working Groups**

- 6.6.1 The Authority may agree from time to time to the delegation of functions and powers to other committees, sub-committees or working groups.
- 6.6.2 The constitution and terms of reference of these committees, sub-committees or working groups, and their specific delegated powers shall be approved by Members at meetings of the board of the Authority, and the minutes of that meeting shall record the matters delegated by the Authority.

## **6.7 Delegation to Officers**

- 6.7.1 Those functions of the Authority, which have not been reserved by the Authority or delegated to the Chair or a Committee or working group of the Authority, shall be exercised by the Chief Executive on behalf of the Authority.
- 6.7.2 The Chief Executive shall determine which functions he/she will perform personally and shall nominate officers to undertake the remaining functions for which he/she will retain accountability to the Authority.
- 6.7.3 The Chief Executive shall report periodically to the Authority on the exercise of powers so delegated.

## Section 7: Committees

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### 7.1 Power to establish committees and working groups

- 7.1.1 In accordance with section 9A (2) of the Act, the Authority shall establish and maintain the committees set out in Annex A to these Standing Orders.
- 7.1.2 In accordance with paragraph 9 of Schedule 1, the Authority may from time to time, establish working groups of members.
- 7.1.3 A proposal to establish a working group shall identify the purpose of the group, the likely budget and staff resources needed; the outputs required of the group, and the timeframe for which the group shall exist.
- 7.1.4 The Chief Executive shall ensure that a person is appointed to act as secretary to each committee or working group and to take the minutes of each meeting.

### 7.2 Membership of Committees and working groups

- 7.2.1 This paragraph does not apply to the Appeals Committee.
- 7.2.2 The Chair of the Authority shall appoint the Chair and members of Committees and working groups established by the Authority.
- 7.2.3 The Chair of the Authority shall only appoint persons who are not Members to a Committee where the Authority has agreed that such persons are suitable for appointment to a Committee of the Authority.
- 7.2.4 The remuneration for persons who are not members of the Authority but who have been appointed as a member of an Authority committee shall be as agreed from time to time with the Appointments Commission, or the Department of Health as appropriate.

### 7.3 Conduct of meetings of Committees and working groups

- 7.3.1 This paragraph does not apply to meetings of the Licence Committee, Research Licence Committee, Executive Licensing Panel or Appeal Committee.
- 7.3.2 Subject to paragraph 7.3.3 and 7.3.4 below, and in accordance with paragraph 9 of Schedule 1 to the Act, Committees and working groups established by the Authority may regulate their own proceedings.
- 7.3.3 The Chair of the Committee or working group shall at each meeting:
  - a) inquire whether any member has any interests to declare, and if so, ensure that such interests are recorded;

- b) where potential conflicts are identified, ensure that the Committee or working group refers to and follows the Guidance on Conflicts of Interests approved by the Authority;
- c) sign the minutes of any previous meetings with any agreed amendments that may be necessary;
- d) ensure that the proceedings of the Committee or working group comply with the terms of reference and delegated powers set out in Annex A to these Standing Orders or established by the Authority; and
- e) prepare a report for the next meeting of the board of the Authority.

7.3.4 With the permission of the Chair of the Committee or working group, members may participate in a meeting by the use of video-conferencing facilities, by email or other virtual means. However, attendance by telephone shall not usually be permitted.

#### **7.4 Distribution of agenda and papers**

7.4.1 The committee secretary shall send the agenda and papers to all committee members in good time before the meeting, and usually no less than five working days before the meeting.

7.4.2 Papers shall be distributed by such method as is determined by the Chair of the committee.

#### **7.5 Minutes of meetings**

7.5.1 Paragraph 4.10 of these Standing Orders shall apply with appropriate modifications.

#### **7.6 Publication of papers**

7.6.1 The minutes of the meetings of committees established by the Authority shall be published in accordance with the Authority's Policy on the Publication of Authority and Committee papers and shall be made available to the public in accordance with the Authority's Publication Scheme and the Freedom of Information Act 2000.

## **Section 8: Sealing and execution of documents**

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### **8.1 Application of Seal**

8.1.1 The application of the Authority's Seal shall be authenticated by the signature of the Chair or Deputy Chair of the Authority.

### **8.2 Signing of documents**

8.2.1 The following members and officers of the Authority shall be authorised to sign deeds or other documents on behalf of the Authority:

- a) Chair of the Authority;
- b) Deputy Chair of the Authority;
- c) Chief Executive; and
- d) Senior Management Team

### **8.3 Signing of contracts**

8.3.1 Officers and employees of the Authority shall be authorised to sign contracts on behalf of the Authority in accordance with the authorised delegations for ordering goods and services set out in the Financial Procedures approved by the Authority.

# **Human Fertilisation and Embryology Authority**

## **Standing Orders: Annex A**

### **Standing Committees and Non-Licensing Executive Panels Established by the Authority and Their Terms of Reference**

Approved 7 December 2011

## 1. Standing Committees of the Authority

- 1.1 The Authority shall maintain the following standing committees concerned with licensing:
  - a) Licence Committee;
  - b) Research Licence Committee; and
  - c) Appeals Committee
- 1.2 The membership and procedures of the Licence and Research Licence Committees (other than when considering representations made under section 19(4) of the Human Fertilisation and Embryology Act 1990) are set out in the Protocol for the conduct of meetings of the Licence and Research Licence Committees (Annex D to the Authority's Standing Orders).
- 1.3 The membership and procedures of the Licence and Research Licence Committees when considering representations made under section 19(4) of the Human Fertilisation and Embryology Act 1990 are set out in the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 (as amended).
- 1.4 The membership and procedures of the Appeals Committee are set out in the Human Fertilisation and Embryology (Appeals) Regulations 2009.
- 1.5 The Authority shall maintain the following non-licensing committees:
  - a) Audit and Governance Committee;
  - b) Compliance Committee;
  - c) Remuneration Committee;
  - d) Ethics and Law Advisory Committee;
  - e) Scientific and Clinical Advances Advisory Committee; and
  - f) Oversight Committee.
- 1.6 A report of the activities of the non-licensing standing committees shall be presented to every meeting of the Authority, and presentation of such reports shall be a standing item on the Agenda for all Authority meetings.
- 1.7 All the Authority's non-licensing standing committees may:
  - a) receive expert advice where the Chair of a Committee considers that such advice would assist the committee in its deliberations; and
  - b) sit with a legal adviser in attendance.

## 2. The Audit and Governance Committee

### Functions of the Audit and Governance Committee

2.1 The functions of the Audit and Governance Committee shall be to:

- a) oversee the general corporate governance of the Authority (including supervision and review of the operational effectiveness of the Authority's internal control and risk management procedures);
- b) ensure that the Authority complies with its statutory functions, and with the requirements of the Regulators Compliance Code, requirements applicable to Arms Length Bodies, and the principles and best practice guidance issued by the Better Regulation Executive;
- c) meet regularly with the Authority's internal and external auditors to ensure that the Authority is complying with statutory requirements and best practice relating to internal control systems risk management, audit, and financial reporting requirements;
- d) review the annual financial statements before their submission to the Authority focusing particularly on changes in, and compliance with accounting policies and practices; and
- e) review and manage the effectiveness of the Authority's whistle-blowing policy.

2.2 In particular, the Audit and Governance Committee shall:

- a) review the adequacy of all risk and control related disclosure statements, together with any accompanying statement from the Internal Auditors, prior to endorsement by the Authority;
- b) review the adequacy of structures, processes and responsibilities for identifying and managing key risks facing the Authority;
- c) review the adequacy of internal audit policies to ensure compliance with the Controls Assurance Standards and other relevant guidance;
- d) review the adequacy of policies and procedures for all work related to fraud and corruption as set out in the Secretary of State Directions and as required by the National Health Service Counter Fraud Service;
- e) make recommendations to the Authority about the appointment (and if relevant the dismissal) of the internal audit service and the audit fee payable;
- f) manage the relationship with the external auditor (the Comptroller and Auditor General), and ensure that any chargeable non-audit services provided do not compromise the auditors' independence or objectivity;

- g) review the planning, conduct and conclusions of the external audit process (including review of all reports and annual audit letters, together with the associated management responses);
- h) receive reports from the Tender Panel established in accordance with the Financial Procedures approved by the Authority; and
- i) receive reports about all consultancy contracts made by the Authority.

2.3 In pursuance of these functions, the Authority authorises the Audit and Governance Committee to:

- a) require a review or investigation of any procedures and activities undertaken by the Authority that fall within its remit;
- b) obtain from any employee of the Authority, such information as it considers relevant to the carrying out of its functions. (All employees are directed to co-operate with any request made by the Audit and Governance Committee);
- c) obtain such external legal or other professional advice as it considers necessary to enable it to fulfil its functions; and
- d) provide such advice or recommendations to the Chair and members of the Authority, and the Authority's Chief Executive, as it considers necessary or appropriate.

#### **Membership of the Audit and Governance Committee**

2.4 The Audit and Governance Committee shall consist of five members including:

- a) a chair (who shall be a member of the Authority);
- b) a deputy chair (who shall be a member of the Authority);
- c) one or two members of the Authority; and
- d) one or two persons who shall not be members of the Authority and who have relevant legal, financial, public sector or other corporate governance expertise.

2.5 The Chair of the Authority shall appoint the members of the Audit and Governance Committee.

2.6 Members of the Audit and Governance Committee shall normally be appointed for a term of three years.

#### **Meetings of the Audit and Governance Committee**

2.7 The quorum for a meeting of the Audit and Governance Committee shall be three members, which shall include the Chair or Deputy Chair.

2.8 The Audit and Governance Committee shall meet no fewer than four times a year.

- 2.9 The Audit and Governance Committee may hold additional meetings at the request of the Chair, members or officers of the Authority, or if the Chair of the Audit and Governance Committee considers that a meeting would be necessary or desirable.

#### **Attendance at meetings of the Audit and Governance Committee**

- 2.10 In addition to members of Audit and Governance Committee, the following persons shall normally attend its meetings:
- a) the Chief Executive(or his delegated representative);
  - b) the Director of Finance and Facilities;
  - c) a Legal Adviser;
  - d) such other members of the executive staff of the Authority as the Chair of the Audit and Governance Committee may agree should attend the proceedings;
  - e) a representative from the HFEA's Internal Auditors; and
  - f) a representative from the HFEA's External Auditors.
- 2.11 The Chair of the Audit and Governance Committee may invite such other persons (including non-members of the Authority and representatives from the Department of Health ) as the Chair considers appropriate, to attend the meetings of that Committee and/or to provide expert advice to inform the deliberations of the Committee.
- 2.12 The Chair of the Audit and Governance Committee may require non-members of the Committee to withdraw from any part of the meeting where the Chair considers it necessary or desirable for that Committee to deliberate in private.
- 2.13 The Chair of the Audit and Governance Committee may require representatives of the HFEA's Internal and External Auditors to attend the private deliberations of that Committee, if the Chair considers it necessary or desirable for such representatives to attend.

#### **Powers delegated by the Authority to the Audit and Governance Committee**

- 2.14 The Authority delegates to the Audit and Governance Committee, the following powers:
- a) approval of the internal audit programme; and
  - b) approval of the Statement on Internal Control or equivalent Annual Governance Statement included in the Annual Accounts.

### **3. The Compliance Committee**

#### **Functions of the Compliance Committee**

- 3.1 The functions of the Compliance Committee shall be to:
- a) issue general directions on behalf of the Authority;
  - b) consider individual applications from licensed centres and to issue special directions relevant to those applications (other than those directions reserved to the Licence Committee under the Human Fertilisation and Embryology Act 1990) on behalf of the Authority;
  - c) monitor and review the effectiveness of the Authority's Code of Practice, and propose amendments as necessary;
  - d) monitor and review the Authority's policies in relation to compliance and enforcement, investigation of serious incidents and serious adverse reactions and complaints made by patients against licensed centres;
  - e) monitor and review the effectiveness of the Authority's inspection processes; and
  - f) arrange for the inspection of licensed centres in accordance with Schedule 3B to the Act and in particular, to approve the schedule of centres which are to be inspected by the Compliance Directorate in any calendar year.

#### **Membership of the Compliance Committee**

- 3.2 The Compliance Committee shall consist of no more than seven members which shall include:
- a) the Chair, who shall be a lay member of the Authority;
  - b) the deputy Chair, who shall be a lay member of the Authority;
  - c) three other lay members; and
  - d) two clinical or scientific members, who need not be members of the Authority.

3.3 The Chair of the Authority shall appoint the members of the Compliance Committee.

3.4 Members of the Compliance Committee shall normally be appointed for a term of three years.

#### **Meetings of the Compliance Committee**

- 3.5 The quorum for a meeting of the Compliance Committee shall be three including the Chair or Deputy Chair of the Committee and one clinical or scientific member.

- 3.6 The Compliance Committee shall meet no fewer than four times each year, and may hold further meetings as required, including meetings to consider applications for Special Directions.

#### **Attendance at meetings of the Compliance Committee**

- 3.7 In addition to the Chair and members, the following persons shall normally attend the meetings of the Compliance Committee:
- a) the Director of Compliance; and
  - b) such other members of the executive staff of the Authority as the Chair of the Compliance Committee may agree should attend the proceedings.

#### **Powers delegated by the Authority to the Compliance Committee**

- 3.8 The Authority delegates to the Compliance Committee, the following powers:
- a) issue of General Directions on behalf of the Authority;
  - b) issue of Special Directions (other than those reserved to the Licence Committee under the Human Fertilisation and Embryology Act 1990);
  - c) approval of updates and minor revisions to the Code of Practice;
  - d) approval of amendments to the Authority's Compliance and Enforcement Policy;
  - e) approval of internal operational protocols to be used by the Authority's compliance department; and
  - f) arranging for the inspection of licensed centres in accordance with schedule 3B to the Act, and approval of the schedule of licensed centres to be inspected by the Compliance Directorate in any calendar year.

## **4. The Remuneration Committee**

### **Function of the Remuneration Committee**

- 4.1 The function of the Remuneration Committee shall be to:
- a) develop the Authority's pay policy and strategy;
  - b) monitor overall levels of remuneration;
  - c) specifically to review, moderate and approve the remuneration of the Chief Executive and Directors;
  - d) approve general staff pay increases; and
  - e) consider human resource issues referred to it by the Chief Executive or Chair of the Authority.

### **Membership of the Remuneration Committee**

- 4.2 The Remuneration Committee shall consist of three members, which shall include:
- a) a Chair (who shall be the Chair of the Authority);
  - b) a deputy Chair, who shall be a member of the Authority; and
  - c) the Chair of the Audit and Governance Committee.
- 4.3 The Chair of the Remuneration Committee shall be appointed for the same term as the Chair of the Authority.
- 4.4 Other members of the Remuneration Committee shall normally be appointed for a term of three years.

### **Meetings of the Remuneration Committee**

- 4.5 The quorum for a meeting of the Remuneration Committee shall be two members.
- 4.6 The Remuneration Committee shall meet at least once a year, and may hold further meetings at the discretion of the Chair.

### **Attendance at meetings of the Remuneration Committee**

- 4.7 In addition to the Chair and members, such other members of the executive staff of the Authority as the Chair considers necessary, may attend the meetings of the Remuneration Committee.

### **Powers delegated by the Authority to the Remuneration Committee**

- 4.8 The Authority delegates to the Remuneration Committee, the following powers:
- a) to approve the annual staff pay increase.

## **5. The Scientific and Clinical Advances Advisory Committee**

### **Function of the Scientific and Clinical Advances Advisory Committee**

- 5.1 The function of the Scientific and Clinical Advances Committee shall be to:
- a) advise the Authority on scientific and clinical developments (including research) in assisted conception, embryo research and related areas;
  - b) to make recommendations to the Authority on policy implications arising out of such developments;
  - c) to advise the Compliance Committee on implications for licensing and regulation arising out of such developments; and
  - d) where required, to work with the Ethics and Law Advisory Committee to consider the social, ethical and legal implications arising out of such developments.

### **Membership of the Scientific and Clinical Advances Advisory Committee**

- 5.2 The Scientific and Clinical Advances Advisory Committee shall consist of no more than nine members, which shall include:
- a) a Chair (who shall be a member of the Authority with clinical or scientific expertise);
  - b) a deputy Chair, who shall be a member of the Authority with clinical or scientific expertise);
  - c) the Chair of the Ethics and Law Advisory Committee; and
  - d) up to six other persons, who need not be members of the Authority.
- 5.3 The Chair of the Authority shall appoint the members of the Scientific and Clinical Advances Advisory Committee.
- 5.4 Members of the Scientific and Clinical Advances Advisory Committee shall normally be appointed for a term of three years.

### **Meetings of the Scientific and Clinical Advances Advisory Committee**

- 5.5 The quorum for a meeting of the Scientific and Clinical Advances Advisory Committee shall be four including the Chair or Deputy Chair of the Advisory Committee.
- 5.6 The Scientific and Clinical Advances Advisory Committee shall meet no fewer than three times each year, and may hold further meetings at the request of the Chair of the Authority.

**Attendance at meetings of the Scientific and Clinical Advances Advisory Committee**

- 5.7 In addition to the Chair and members, such other members of the executive staff of the Authority as the Chair considers necessary, may attend the meetings of the Scientific and Clinical Advances Advisory Committee.
- 5.8 The Chair of the Scientific and Clinical Advances Advisory Committee may invite such other persons (including non members of the Authority and representatives from the Department of Health) as the Chair considers appropriate, to attend the meetings of that Committee and/or to provide expert advice to inform the deliberations of the Committee.

**Powers delegated by the Authority to the Scientific and Clinical Advisory Committee**

- 5.9 The Authority does not delegate any powers to the Scientific and Clinical Advisory Committee.

## **6. The Ethics and Law Advisory Committee**

### **Function of the Ethics and Law Advisory Committee**

- 6.1 The function of the Ethics and Law Advisory Committee shall be to:-
- a) review the social, ethical and legal aspects of the work of the Authority;
  - b) provide advice to the Authority, and make recommendations on policy to be adopted by the Authority;
  - c) advise the Compliance Committee on social, ethical and legal considerations which may be affected by the Authority's Compliance and Enforcement Policy or Code of Practice; and
  - d) where required, work with the Scientific and Clinical Advances Advisory Committee to consider the social, ethical and legal implications arising out of scientific and clinical developments.

### **Membership of the Ethics and Law Advisory Committee**

- 6.2 The Ethics and Law Advisory Committee shall consist of no more than nine members, which shall include:-
- a) a Chair (who shall be a lay member of the Authority);
  - b) a deputy Chair, who shall be a lay member of the Authority;
  - c) the Chair of the Scientific and Clinical Advances Advisory Committee; and
  - d) up to six other persons possessing relevant expertise, who need not be members of the Authority.
- 6.3 The Chair of the Authority shall appoint the members of the Ethics and Law Advisory Committee.
- 6.4 Members of the Ethics and Law Advisory Committee shall normally be appointed for a term of three years.

### **Meetings of the Ethics and Law Advisory Committee**

- 6.5 The quorum for a meeting of the Ethics and Law Advisory Committee shall be four including the Chair or Deputy Chair of the Advisory Committee and three other members.
- 6.6 The Law and Ethics Advisory Committee shall meet no fewer than three times each year, and may hold further meetings at the request of the Chair of the Authority.

**Attendance at meetings of the Ethics and Law Advisory Committee**

- 6.7 In addition to the Chair and members, such other members of the executive staff of the Authority as the Chair considers necessary, may attend the meetings of the Ethics and Law Advisory Committee.
- 6.8 The Chair of the Ethics and Law Advisory Committee may invite such other persons (including non members of the Authority and representatives from the Department of Health ) as the Chair considers appropriate, to attend the meetings of that Committee and/or to provide expert advice to inform the deliberations of the Committee.

**Powers delegated by the Authority to the Ethics and Law Advisory Committee**

- 6.9 The Authority does not delegate any powers to the Ethics and Law Advisory Committee.

## 7. Oversight Committee

### Functions of the Oversight Committee

7.1 The functions of the Oversight Committee shall be to:

- a) monitor the grant of authorisations to access HFEA Register data made under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010
- b) monitor the processing of patient-, partner- and child-identifying Register data by research establishments
- c) consider annual reports submitted by research establishments.
- d) consider such other matters relating to the 2010 Regulations as the Committee determines.
- e) oversee the functions of the Register Research Panel and the Register Research Review Panel.
- f) make recommendations to the Register Research Panel and the Register Research Review Panel about improvements to processes and the operation of the Panels.
- g) approve Memorandum of Understanding (MoU) or any contractual arrangements between the HFEA and the National Information Governance Board, and any other agreements between the HFEA and other public bodies with an interest in the safeguarding of personal information in the United Kingdom where these relate to the disclosure of HFEA Register data for research purposes.
- h) approve variations of and amendments to such MoUs, contracts and agreements.

### Membership of the Oversight Committee

7.2 The Authority is the Oversight Committee and, when performing the statutory functions of the Oversight Committee as set out in regulation 21 of the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010, the relevant sections of the Standing Orders will apply.

### Meetings of the Oversight Committee

7.3 The quorum for a meeting of the Oversight Committee shall be seven.

7.4 The Oversight Committee shall consider annual reports submitted by research establishments and an overview report submitted by the Register Research Panel at least once a year.

### Attendance at meetings of the Oversight Committee

7.5 In addition to the members of the Oversight Committee, the following persons may attend meetings:-

HFEA Standing Orders approved by Authority 7 December 2011  
**Annex A: Standing Committees and Non-Licensing Executive Panels  
Established by the Authority and Their Terms of Reference**

- a) such members of the executive staff of the Authority as the Chair may agree should attend the proceedings of the Oversight Committee
- b) research specialists, who need not be members of the Authority, but have been invited by the Chair to act in an advisory capacity to the Committee
- c) legal advisers who have been invited by the Chair.

## **8. Executive Panels concerned with Disclosure of Information for Research Purposes**

### **8.1 Register Research Panel**

#### **Functions of the Register Research Panel**

8.1.1 The functions of the Register Research Panel shall be to:

- a) authorise or refuse to grant applications to access HFEA Register data made under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 or under section 33A(2)(h) of the Human Fertilisation and Embryology Act 1990 (as amended by the 2008 Act).
- b) suspend, revoke, vary or place conditions upon authorisation to access Register data.
- c) review annual reports submitted by research establishments.
- d) publish lay summaries of research projects involving the use of HFEA Register data.
- e) submit a report to the Authority's Oversight Committee about the work of the Register Research Panel not less than once a year.
- f) refer appeals against the decisions of the Register Research Panel to the Register Research Review Panel (comprised of the Chief Executive and the Director of Finance and Facilities); and
- g) liaise and collaborate with the National Information Governance Board and any other bodies in the UK with an interest in the safeguarding of personal data and the oversight of research studies involving the linkage of complex datasets.

#### **Membership of the Register Research Panel**

8.1.2 The membership of the Register Research Panel shall include the Director of Strategy and Information, who will serve as Chair of the Panel, the Authority's Caldicott Guardian and the Head of Information Technology.

#### **Meetings of the Register Research Panel**

8.1.3 The quorum for a meeting of the Register Research Panel shall be three.

8.1.4 Meetings of the Register Research Panel will be scheduled to follow the timetable of the National Information Governance Board's Ethics and Confidentiality Committee as set out in the Memorandum of Understanding between the Authority and the National Information Governance Board.

#### **Attendance at meetings of the Register Research Panel**

8.1.5 In addition to the members of the Register Research Panel, the following persons may attend meetings at the invitation of the Panel Chair:-

- a) administrative support personnel
- b) legal advisers
- c) specialists in the field of non-medical research.

## **8.2 Register Research Review Panel**

### **Functions of the Register Research Review Panel**

The functions of the Register Research Review Panel shall be to:-

- a) hear appeals against the decisions of the Register Research Panel;  
and
- b) uphold or vary the decisions of the Register Research Panel.

### **Membership of the Register Research Review Panel**

8.2.2 The membership of the Register Research Review Panel shall be:

- a) Chief Executive, who will act as the Chair of the Review Panel, and
- b) the Senior Information Risk Owner (SIRO) of the Authority.

### **Meetings of the Register Research Review Panel**

8.2.3 Meetings of the Register Research Review Panel shall be scheduled as required following receipt of an appeal against the decisions of the Register Research Panel.

### **Attendance at meetings of the Register Research Review Panel**

8.2.4 In addition to the members of the Register Research Review Panel, the following persons may attend meetings at the invitation of the Review Panel Chair:

- a) administrative support personnel; and
- b) legal advisers.

# **Human Fertilisation and Embryology Authority**

## **Standing Orders: Annex B**

### **Instrument of delegation in respect of Authority licensing functions**

Approved 7 December 2011

## Standing Orders: Annex B

### Instrument of delegation in respect of Authority licensing functions

#### 1. Routine licensing decisions delegated to Executive Licensing Panel

Consideration of renewal applications for licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under Section 16 of the Act
Consideration of renewal applications for research licences, which the Research Licence Committee has not reserved to itself for consideration, and exercise of the Authority's power to grant such licences under Section 16 of the Act
Consideration of interim inspections reports (treatment and storage and research)
The following variation of licences on application:- <ul style="list-style-type: none"><li>▪ change of Person Responsible/Licence Holder</li><li>▪ change of treatments authorised on licence</li><li>▪ change of centre name</li><li>▪ authorisation to undertake HLA tissue typing which does not include PGD testing for conditions not previously approved by the Authority</li><li>▪ change of premises</li><li>▪ and exercise of the Authority's power to vary licences under Section 18A of the Act.</li></ul>
Consideration of reports of random unannounced inspections
Consideration of reports of targeted inspections
Executive proposals to place additional conditions on licence and exercise of the Authority's power to issue notices under Section 19 of the Act

**2. Novel/complex or controversial licensing decisions delegated to Research Licence Committee**

Consideration of applications for initial research licences and exercise of the Authority's power to grant such licences under Section 16 of the Act
Consideration of renewal applications for research licences which the Research Licence Committee reserved to itself for consideration when granting the initial licence, and exercise of the Authority's power to grant such licences under Section 16 of the Act
Consideration of grade A incidents
Consideration of executive proposals to revoke/suspend licence and exercise of the Authority's powers to revoke/suspend licences in accordance with sections 18(1) and (2) and 19(c) of the Act
Consideration of representations under Section 19(4) of the Act
Exercise of the Authority's powers to vary a licence in accordance with Section 18A of the Act
Exercise of the Authority's power to issue notices under Section 19 of the Act

**3. Novel/complex or controversial licensing decisions delegated to Licence Committee**

Consideration of applications for initial licences for treatment, storage and provision of non-medical fertility services, and exercise of the Authority's power to grant such licences under Section 16 of the Act
Applications to undertake PGD testing for conditions not previously licensed by the Authority
Applications to undertake HLA tissue typing which involves PGD testing for conditions not previously licensed by the Authority
Consideration of grade A incidents
Consideration of executive proposals to revoke/suspend licence and exercise of the Authority's powers to revoke/suspend licences in accordance with Sections 18(1) and (2) and 19(c) of the Act
Consideration of representations under Section 19(4) of the Act
Exercise of the Authority's powers to vary a licence in accordance with Section 18A of the Act

# **Human Fertilisation and Embryology Authority**

## **Standing Orders: Annex C**

### **Protocol for the conduct of meetings of the Authority's Executive Licensing Panel**

Approved 7 December 2011

## Standing Orders: Annex C

### Protocol for the conduct of meetings of the Authority's Executive Licensing Panel

*This Protocol is made by the Authority in accordance with its powers under paragraph 9 of Schedule 1 to the Human Fertilisation and Embryology Act 1990 (as amended) ("**the Act**") to regulate its own proceedings; its duty as a public body to comply with the Human Rights Act 1998 ; its common law duties and powers to ensure fairness in its procedures; and its duties under paragraph 8.4 of the Statutory Code of Practice for Regulators to enforce in a transparent manner, and to be transparent in the way in which it applies and determines penalties.*

*This Protocol aims to ensure fairness and consistency in the proceedings before the Authority's Executive Licence Panel ("**the Panel**") and should be followed save where fairness requires otherwise.*

*The Panel shall retain the power and duty to take such action, (provided always that any action is consistent with the requirements of the Act) as they consider appropriate and necessary to ensure fairness in a particular matter.*

*This Protocol was approved by the Authority on 9th September 2009.*

#### 1. Composition and function of the panel

- 1.1. The Authority shall maintain an Executive Licensing Panel.
- 1.2. The function of the Panel is to:
  - a) perform the Authority's licensing functions under the Act in accordance with the delegated powers specified in the Authority's Standing Orders; and
  - b) promote compliance with the requirements of the Act and the Code of Practice issued by the Authority.
- 1.3. In making its decisions, the Panel shall have regard to policies approved by the Authority, and where relevant, to the Indicative Applications and Indicative Sanctions Guidance.
- 1.4. The Panel shall consider matters on the papers at a meeting in accordance with the provisions of this Protocol.
- 1.5. The Panel shall consist of a Chair and deputy Chair and a pool of staff, appointed by the Chief Executive from amongst the staff of the Authority, and approved by the Chair of the Authority. In the absence of the Chair of the Panel, the deputy Chair or other person nominated by the Chair of the Panel may act as Chair of the Panel.
- 1.6. The Panel shall sit with three members at each meeting.
- 1.7. No member of the Panel present at a meeting shall abstain from voting.

- 1.8. Decisions of a Panel shall be taken by simple majority (and the Chair of the Panel shall not have a casting vote).
- 1.9. Members of the Panel shall attend regular training and update sessions on human rights and regulatory law, and matters relating to the provision of fertility treatment.

## **2. Advisers to committees**

- 2.1. Where the Chair of the Panel considers it appropriate, the Panel may seek written advice from a legal, clinical or specialist adviser before making its decision.
- 2.2. The Chair of the Panel shall ensure that the applicant, the proposed or actual Person Responsible, licence holder or person whose licence is under consideration ("the person concerned") is afforded a reasonable opportunity to comment on any written advice received by the Panel before the Panel makes its decision.
- 2.3. Where the Panel does not accept the advice tendered by an adviser, the Chair of the Panel should ensure that:
  - a) a written record is kept of the advice tendered, and the reasons why the Panel refused to accept that advice; and
  - b) the written record is sent to the person concerned, together with the decision of the Panel, and the reasons for its decision.

## **3. Secretary to panel**

- 3.1. A secretary shall be present at every meeting of the Panel.
- 3.2. The function of the Secretary shall be to make all administrative arrangements necessary for the proceedings of the Panel to be effective, and to keep a record of:
  - a) the Panel's decision and of the reasons for such decision;
  - b) any advice tendered by a legal, clinical or specialist adviser; and
  - c) any declarations of interest (or potential conflicts of interest) made by a member of the Panel during the proceedings.
- 3.3. The Secretary shall not participate in the decision making of the Panel (and is not entitled to vote).

## **4. Determination of agenda items**

- 4.1. The Secretary shall work with the Compliance Directorate to determine which matters are to be placed on the agenda of the Panel.

**Annex C: Protocol for the conduct of meetings of the Authority's Executive Licensing Panel**

4.2. In determining the agenda for the Panel, the relevant officers shall have regard to the Instrument of Delegation set out in Annex B to the Authority's Standing Orders.

4.3. Where the Secretary or the Compliance Directorate are unsure whether a matter should be placed on the agenda of the Panel or on the agenda of the Licence Committee, the presumption should be that the matter should be placed on the agenda of the Panel. Where necessary, the Secretary should consult the Chair of the Panel.

## **5. Conduct of meeting**

5.1. The Panel shall consider matters on the papers.

5.2. Subject to paragraph 5.3, only the Chair and members of the Panel, and the Secretary may be present at a meeting of the Panel.

5.3. Members of the Authority's staff who have been appointed to the Panel, or an external lawyer or auditor charged by the Authority with audit and evaluation of the effectiveness of the Panel may attend a meeting of the Panel as observers, or as part of their induction training. However, such observers shall not take any part in the discussion or deliberation of the Panel, and are not entitled to vote.

## **6. Documents before the Panel**

6.1. At each meeting, the Panel shall be provided with copies of:

- a) this Protocol;
- b) relevant edition(s) of the HFEA Code of Practice;
- c) the Human Fertilisation and Embryology Act 1990 (as amended);
- d) the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (where relevant);
- e) Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- f) any relevant decision trees and explanatory notes approved by the Authority;
- g) guidance for members of the Authority and its committees on the handling of conflicts of interest approved by the Authority on 21st January 2009;
- h) indicative applications guidance on the time period for which licences should be granted approved by the Authority on 9th September 2009 (where relevant);
- i) indicative sanctions guidance approved by the Authority on 18th March 2009 (where relevant);

- j) licence application (where relevant) and any relevant documentation in support of the application from the applicant and/or proposed Person Responsible for the centre to be licensed;
- k) recommendation of the Authority's Inspector dealing with the matter and any relevant supporting documentation (normally including three years' worth of a centre's licensing history and inspection reports, as appropriate, and in the case of applications for a research licence, any relevant academic literature and advice from the Authority's Scientific and Clinical Advances Advisory Committee)
- l) the Compliance and Enforcement Policy approved by the Authority.

6.2. The Panel shall not normally receive the recommendation of the Authority's Inspector dealing with the matter or any relevant supporting documentation from that Inspector, unless the applicant or person concerned (as appropriate) has been provided with a reasonable opportunity to comment on this material beforehand.

## **7. Panel papers**

7.1. The Secretary shall normally send the papers for a meeting of the Panel to the Chair and members of the Panel scheduled to attend the meeting, seven days in advance of the meeting.

7.2. Upon receipt of the papers, members of the Panel must identify any potential conflicts of interest as soon as possible.

7.3. Where an actual or potential conflict is identified, members must inform the Chair of the Panel and the Secretary as soon as possible, and the procedure set out in the Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009 shall be followed in deciding whether or not a conflict exists.

7.4. No member of the Panel shall consider a matter if that member has an actual or potential conflict of interest in relation to that matter.

7.5. Members of the Panel shall read the papers thoroughly in advance of the meeting and shall refrain from discussing matters to be considered by the Panel with anyone except the other members of the Panel, at the Panel meeting.

7.6. Members of the Panel shall only discuss Panel business and the papers to be considered by the Panel when the Panel is in session.

## **8. Procedure to be followed at the meeting**

- 8.1. Before any papers are considered by the Panel, the Chair of the Panel should:
- a) check that the Panel is quorate; and
  - b) ask for declarations of interest from each member.

- 8.2. Any interests declared should be noted and recorded by the Secretary.
- 8.3. Where a potential or actual conflict is identified, the Panel should follow the procedure set out in the Guidance for Authority and Committee members on Handling Conflicts of Interest approved by the Authority on 21st January 2009.
- 8.4. Each item on the agenda should be considered separately.
- 8.5. Where the Panel is considering an application to grant or renew a licence, the Chair should direct the members of the Panel to consider the requirements of Section 16 of the Act.
- 8.6. In making its decision, the Panel may be aided by the relevant decision tree. Each stage of the decision tree should be considered separately, and in order.
- 8.7. Before the Panel makes its decision, the Chair may adjourn to:
  - a) seek the advice of a legal, clinical or specialist adviser; and
  - b) require further information from the applicant or Person Responsible for the centre to be licensed (as appropriate), or from the Authority's Inspector dealing with the matter.
- 8.8. In accordance with section 16(4) of the Act, where the Panel considers that the information provided with an application is insufficient to enable it to determine that application, it need not consider the application until the applicant has provided it with such further information as the Panel may require.

## **9. Decision to be taken by the panel**

### ***Applications to grant (or renew a licence)***

- 9.1. On each application before it, the Panel must decide:
  - a) whether the requirements of S16 of the Act have been satisfied, and if so, whether to grant(renew) the application in principle (under section 16(5) of the Act, the actual granting of a licence can only take effect upon written acknowledgment of licence conditions by the applicant or (where different) the proposed Person Responsible);
  - b) if a licence is to be granted (renewed), whether any additional conditions should be attached to the licence in addition to those standard licence conditions which must be attached in accordance with sections 12-15 of the Act (under paragraphs 1(2); 1A (2); 2(2); and 3(6) of Schedule 2 to the Act, the Authority has a general power to impose conditions on different categories of licence); and
  - c) if a licence is to be granted (renewed), the Panel must decide the period for which that new licence is to be granted(under paragraphs 1(5); 1A (3); and 2(3) of Schedule 2 to the Act, licences for treatment, non-medical fertility services; and storage may be granted for a period of up to five years. However, under paragraph 3(8) of Schedule 2 to the

Act, licences for research can only be granted for a period of up to three years).

- 9.2. In determining the period of any licence to be granted (renewed), the Panel should consider the Indicative Applications Guidance approved by the Authority.

***Particular requirements for applications authorising use of embryos for training purposes***

- 9.3. Before the Panel can grant (or renew) an application for a treatment licence authorising the use of embryos for training purposes, it must consider the requirements of paragraphs 1(3) and 1(4A) of Schedule 2 to the Act. In particular, the Panel must consider whether the activity is necessary and desirable for the purpose of providing treatment services; and whether the proposed use of embryos is necessary for training purposes.
- 9.4. In deciding whether the proposed use of embryos is necessary for training purposes, the Panel shall have regard to the list of training purposes approved by the Authority.
- 9.5. Particular requirements for applications authorising embryo testing
- 9.6. Before the Panel can grant (or renew) an application authorising the testing of embryos, it must consider the requirements of paragraph 1ZA of Schedule 2 to the Act.
- 9.7. Where the application seeks authorisation for the testing of an embryo in circumstances in which there is a particular risk that an embryo may have a gene, chromosome or mitochondrion abnormality, the Panel must consider the requirement of paragraph 1ZA(2) of Schedule 2 to the Act. In particular, the Panel must be satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.
- 10. Procedure for adding non standard conditions and for refusal, variation or revocation of licence**
- 10.1. If the Panel is minded to refuse to grant, revoke or vary a licence, or minded to grant a licence subject to non standard conditions, it must follow the procedure in section 19(1) of the Act.
- 10.2. If the Panel is minded to vary or revoke a licence, it must follow the procedure in section 19(2) of the Act.
- 10.3. If the Panel is minded to vary a licence otherwise than in accordance with the application, it must follow the procedure in section 19(3) of the Act.
- 10.4. In all cases, the Panel must issue a notice. The notice needs to set out certain information, and therefore the Panel should use the appropriate template approved by the Authority and enclosed at annex 1.

10.5. After issuing the notice, the Panel must refer the matter to the Licence Committee or Research Licence Committee for consideration and have no further dealings with the matter.

## **11. Reasons for panel's decision**

11.1. The Panel shall give reasons for each decision that it makes. These reasons must be recorded in the minutes.

11.2. The reasons shall set out:

- a) any relevant findings of fact made by the Panel;
- b) any matters taken into account by the Panel (including any advice received from a legal, clinical, scientific or specialist adviser); and
- c) why the Panel reached its decision.

11.3. Additionally, in the case of applications to authorise the use of embryos for training purposes, the reasons must set out why the Panel considers that the activity is necessary and desirable for the purpose of providing treatment services; and why the Panel considers that the proposed use of embryos is necessary for training persons.

11.4. Additionally, in the case of applications to authorise embryo testing for gene, chromosome or mitochondrion abnormalities, the reasons must set why the Panel is satisfied that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition, and why the disability/illness/condition is considered to be serious.

11.5. The reasons should tell the person concerned in broad terms why the decision was reached, and may in some circumstances require an explanation of why a particular argument was rejected.

11.6. Where additional conditions have been proposed, or where the Panel has issued a Notice of Proposal, the reasons should indicate why the Panel considers this course of action to be a proportionate response to any concerns identified from the papers before it.

11.7. The reasons should refer to the Indicative Applications Guidance and Indicative Sanctions Guidance where relevant.

## **12. Postponements and adjournments of meetings**

12.1. The Chair may, of his or her own motion, or upon the application of a party to the proceedings, postpone any meeting of which notice has been given before such meeting begins.

12.2. The Chair may, of his or her own motion, adjourn the proceedings at any stage.

- 12.3. In considering whether or not to grant a request for postponement, or to adjourn, the Chair of the Panel should, amongst other matters, have regard to-
- a) the public interest in the expeditious disposal of the proceedings;
  - b) fairness to the parties; and
  - c) the conduct of the person seeking the postponement or adjournment.

- 12.4. Where the proceedings have been postponed or adjourned, the secretary should, as soon as practicable, notify the parties of the date and time of the postponed or resumed meeting.

### **13. Burden and standard of proof**

- 13.1. The Authority's inspector dealing with the matter should bear the burden of establishing that a licence should be revoked, varied (otherwise than on an application) or that a licence should be suspended.
- 13.2. The person to whom the notice under section 19(1) is given should bear the burden of establishing that a licence should not be refused or additional conditions should not be imposed.
- 13.3. Where facts are in dispute, the Panel should consider whether they have been established in accordance with the civil standard of proof.
- 13.4. Where the Panel considers that a finding on disputed facts can only be made after oral evidence is heard at a hearing, it shall issue a notice of proposal under Section 19; invite the person to whom the notice is addressed to make oral representations to the Licence/Research Licence Committees and refer the matter for a hearing to be held in accordance with the Human Fertilisation and Embryology Act (Procedure for Revocation, Variation or Refusal of a Licence) Regulations 2009 (as amended).

### **14. Evidence at meetings**

- 14.1. The Panel may receive any written or real evidence whether or not such evidence would be admissible in a civil court of law in England and Wales, provided that it is satisfied that such evidence is relevant to the issues on which it has to make a decision, and that it is fair to admit such evidence.
- 14.2. **The Panel shall have regard to the Code of Practice issued by the Authority in the circumstances set out in section 25(6) of the Act.**

### **15. Directions**

- 15.1. The Authority has delegated to the Panel the power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.
- 15.2. When:
- a) postponing or adjourning the consideration of a matter;

- b) refusing, varying, suspending or revoking a licence, or
- c) considering evidence of an adverse incident or non compliance with the Act, Code of Practice, licence conditions or directions issued by the Authority,

the Panel should consider whether or not to issue directions under section 24 of the Act.

## **16. Evaluation and report to the Authority**

- 16.1. The Chair of the Panel shall hold regular periodic meetings for the purpose of reviewing decisions made by the Panel to ensure consistency in the Panel's decision making processes.
- 16.2. The Chair of the Panel shall present a report to the Chairs of the Licence Committee and the Research Licence Committee at six monthly intervals detailing the activities of the Panel and identifying trends and feedback for the sector.
- 16.3. The Chair of the Executive Licensing Panel shall prepare an annual written report to the Authority detailing the activities of the Panel (see also the equivalent paragraph for Licensing Committee).

## Annex 1: Templates For Notices Of Proposal

### Notice Of Proposal To Refuse A Licence

#### HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY NOTICE OF PROPOSAL TO REFUSE A LICENCE

TO: **[INSERT NAME]**, APPLICANT AT **[INSERT CENTRE DETAILS]**

In accordance with section 19 of the Human Fertilisation and Embryology Act 1990 (as amended) ("the Act"), **WE HEREBY GIVE YOU NOTICE** that:

on **[date]**, the Licence Committee/Research Licence Committee/Executive Licensing Panel of the Human Fertilisation and Embryology Authority considered an application for **[insert type of licence applied for]** for the **[insert name of centre]** and proposes to refuse a licence for this centre, for the reasons set out in the Schedule attached to this Notice.

A copy of the relevant part of the Act is enclosed for your convenience.

In accordance with section 19(4) of the Act, if you wish to make representations to a Committee about this proposal, you must give **written** notice to the Authority within 28 days commencing from the date of this Notice which is specified below.

Your Notice must contain the information set out in the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of a Licence) Regulations 2009. A copy of these Regulations is enclosed for your convenience.

Provided such written notice is given by you within the period specified above, the Committee will, before making its determination, consider any representations that you wish to make which may be:

- a) oral representations made by you or another acting on your behalf at a hearing; **or**
- b) written representations made by you.

If you do not give written notice within the period specified above, or if you do not wish to make representations, the Committee will proceed to make its determination.

Please inform the Authority by **[DATE-28 days from date below]** whether you wish to make representations, and if so, what kind of representations.

**Signed** \_\_\_\_\_  
**Name** \_\_\_\_\_ **Chair**  
**Date** \_\_\_\_\_

SCHEDULE OF REASONS FOR PROPOSING TO REFUSE LICENCE **[INSERT REASONS BELOW]**

## Notice Of Proposal To Vary Or Revoke A Licence

### HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY NOTICE OF PROPOSAL TO VARY OR REVOKE A LICENCE

TO: **[INSERT NAME]**, PERSON RESPONSIBLE AT **[INSERT CENTRE DETAILS]**  
**[INSERT NAME]**, LICENCE HOLDER AT **[INSERT CENTRE DETAILS]**

In accordance with section 19 of the Human Fertilisation and Embryology Act 1990 (as amended) ("the Act"), **WE HEREBY GIVE YOU NOTICE** that:

on **[date]**, the Licence Committee/Research Licence Committee/Executive Licensing Panel of the Human Fertilisation and Embryology Authority made a proposal to vary the licence for the **[insert name of centre]** by **[insert variation proposals]** for the reasons set out in the Schedule attached to this Notice.

**[OR]**

on **[date]**, the Licence Committee/Research Licence Committee/Executive Licensing Panel of the Human Fertilisation and Embryology Authority made a proposal to revoke the licence for the **[insert name of centre]** for the reasons set out in the Schedule attached to this Notice.

A copy of the relevant part of the Act is enclosed for your convenience.

In accordance with section 19(4) of the Act, if you wish to make representations to a Committee about this proposal, you must give **written** notice to the Authority within 28 days commencing from the date of this Notice which is specified below.

Your Notice must contain the information set out in the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of a Licence) Regulations 2009. A copy of these Regulations is enclosed for your convenience.

Provided such written notice is given by you within the period specified above, the Committee will, before making its determination, consider any representations that you wish to make which may be:

- a) oral representations made by you or another acting on your behalf at a hearing; **or**
- c) written representations made by you.

If you do not give written notice within the period specified above, or if you do not wish to make representations, the Committee will proceed to make its determination.

Please inform the Authority by **[DATE-28 days from date below]** whether you wish to make representations, and if so, what kind of representations.

**Signed**

**Name**

**Chair**

**Date**

SCHEDULE OF REASONS **[INSERT REASONS BELOW]**

## Notice Of Proposal To Grant An Application For A Licence

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

NOTICE OF PROPOSAL 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 TO THE HUMAN FERTILISATION AND EMBRYOLOGY ACT  
1990(AS AMENED)

TO: **[INSERT NAME]**, APPLICANT AT **[INSERT CENTRE DETAILS]**

In accordance with section 19 of the Human Fertilisation and Embryology Act 1990 (as amended) ("the Act"), **WE HEREBY GIVE YOU NOTICE** that:

on **[date]**, the Licence Committee/Research Licence Committee/Executive Licensing Panel of the Human Fertilisation and Embryology Authority made a proposal to grant the application for a licence for the **[insert name of centre]** subject to the following condition(s):

- **[insert conditions here]** for the reasons set out in the Schedule attached to this Notice.

A copy of the relevant part of the Act is enclosed for your convenience.

In accordance with section 19(4) of the Act, if you wish to make representations to a Committee about this proposal, you must give **written** notice to the Authority within 28 days commencing from the date of this Notice which is specified below.

Your Notice must contain the information set out in the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of a Licence) Regulations 2009. A copy of these Regulations is enclosed for your convenience.

Provided such written notice is given by you within the period specified above, the Committee will, before making its determination, consider any representations that you wish to make which may be:

- oral representations made by you or another acting on your behalf at a hearing; **or**
- written representations made by you.

If you do not give written notice within the period specified above, or if you do not wish to make representations, the Committee will proceed to make its determination.

Please inform the Authority by **[DATE-28 days from date below]** whether you wish to make representations, and if so, what kind of representations.

**Signed**

**Name**

**Date**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Chair**

SCHEDULE OF REASONS **[INSERT REASONS BELOW]**

## **Human Fertilisation and Embryology Authority**

### **Standing Orders: Annex D Protocol for the conduct of meetings of the Licence Committee and Research Licence Committee**

Approved 7 December 2011

## **Standing Orders: Annex D**

# **Protocol for the conduct of meetings of the Licence Committee and Research Licence Committee**

*This Protocol is made by the Authority in accordance with its powers under paragraph 9 of Schedule 1 to the Human Fertilisation and Embryology Act 1990 (as amended) (“the Act”) to regulate its own proceedings; its duty as a public body to comply with the Human Rights Act 1998 ; its common law duties and powers to ensure fairness in its procedures; and its duties under paragraph 8.4 of the Statutory Code of Practice for Regulators to enforce in a transparent manner, and to be transparent in the way in which it applies and determines penalties.*

*This Protocol aims to ensure fairness and consistency in the proceedings before the Authority’s Licence and Research Licence Committees and should be followed save where fairness requires otherwise.*

*The Licence and Research Licence Committees shall retain the power and duty to take such action, (provided always that any action is consistent with the requirements of the Act) as they consider appropriate and necessary to ensure fairness in a particular matter.*

*This Protocol was approved by the Authority on 9th September 2009 and adopted by the Chairs of the Authority’s Licence and Research Licence Committees on the same date.*

### **1. Composition and function of committees**

- 1.1. The Authority shall maintain a Licence Committee and a Research Licence Committee.
- 1.2. The function of the Licence and Research Licence Committees is to:
  - a) perform the Authority’s licensing functions under the Act in accordance with the delegated powers specified in the Authority’s Standing Orders; and
  - b) promote compliance with the requirements of the Act and the Code of Practice issued by the Authority.
- 1.3. Applications for research licences shall normally be considered by the Research Licence Committee.
- 1.4. In making their decisions, the Licence and Research Licence Committees shall have regard to policies approved by the Authority, and where relevant, to the Indicative Applications and Indicative Sanctions Guidance.
- 1.5. Save where a Licence or Research Licence Committee is considering representations in accordance with Section 19 of the Act, it shall consider matters on the papers at a meeting in accordance with the provisions of this Protocol.

- 1.6. Where a Licence or Research Licence Committee is considering representations made under section 19(4) of the Act, it shall follow the procedure set out in the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of Licences) Regulations 2009 (as amended).
  - 1.7. The Licence Committee and Research Licence Committee shall each consist of no more than seven members (including a Chair and deputy Chair), appointed by the Chair of the Authority from amongst the Members of the Authority. In the absence of the Chair of the Committee, the Deputy Chair or other person nominated by the Chair of the Authority may act as Chair of the Committee.
  - 1.8. The quorum for a meeting of the Licence Committee or Research Licence Committee shall be three.
  - 1.9. No member of a Licence Committee or Research Licence Committee present at a meeting shall abstain from voting.
  - 1.10. Decisions of a Licence Committee or Research Licence Committee shall be taken by simple majority (and the Chair of a Committee shall not have a casting vote).
  - 1.11. Where there is a tied vote:
    - a) in the case of an application for a licence, that application shall not be granted;
    - b) in the case of a proposal to impose non standard conditions on a licence, or to vary, suspend or revoke a licence, that proposal shall not succeed; and
    - c) in any other case, the motion under consideration by the Licence Committee or Research Licence Committee shall not be passed.
  - 1.12. Members of the Licence Committee and Research Licence Committee shall attend regular training and update sessions on human rights and regulatory law, and matters relating to the provision of fertility treatment.
- 2. Advisers to committees**
- 2.1. A legal adviser shall be present at every meeting of the Licence Committee or Research Licence Committee.
  - 2.2. Where the Chair of the Licence Committee or Research Licence Committee considers it appropriate, a clinical, scientific or specialist adviser may be present at a meeting or hearing of that Committee.
  - 2.3. The function of an adviser to a Committee shall be to:
    - a) advise that Committee on any areas within the adviser's expertise; and

- b) intervene to advise that Committee on an issue where it appears that without an intervention there is the possibility of an error being made.
- 2.4. With the consent of the Chair of the Licence Committee or Research Licence Committee, an adviser who is present at a meeting of that Committee may be present during the private deliberations of the Committee, but the adviser shall not participate in the decision making of that Committee (and is not entitled to vote).
- 2.5. The Chair of the Licence Committee or Research Licence Committee shall ensure that a written record is kept of any advice tendered to the Committee by an adviser.
- 2.6. The Chair of the Licence Committee or Research Licence Committee shall also ensure that a written record is kept of any interventions made by an adviser during the private deliberations of that Committee.
- 2.7. The Chair of the Licence Committee or Research Licence Committee shall ensure that a copy of any advice tendered by an adviser to that Committee is sent to the parties to the proceedings.
- 2.8. Where any advice tendered by an adviser to the Licence Committee or Research Licence Committee is not accepted by that Committee:
- a) the Chair of the Committee shall ensure that a written record is kept of the advice tendered, and the reasons why the Committee refused to accept that advice; and
  - b) a copy of the record of the advice tendered and the reasons why the Committee refused to accept that advice should be sent to the parties to the proceedings.

### **3. Secretary to committees**

- 3.1. A secretary shall be present at every meeting of the Licence Committee and Research Licence Committee.
- 3.2. The function of the Secretary shall be to make all administrative arrangements necessary for the proceedings of the Licence Committee to be effective, and to keep a record of:
- a) the Committee's decision and the reasons for such decision;
  - b) any advice tendered by a legal, clinical, scientific or specialist adviser (and any interventions made by them when they are present during the private deliberations of the committee); and
  - c) any declarations of interest (or potential conflicts of interest) made by a member of the Committee during the proceedings.

- 3.3. The Secretary shall not participate in the decision making of the committee (and is not entitled to vote).
- 3.4. At the conclusion of every meeting of the Licence Committee or Research Licence Committee, the Secretary shall collate feedback from the Chair and members of the Committee on matters that the Chair considers should be brought to the attention of the Authority's Compliance Committee or to the Director of Compliance.

#### **4. Determination of agenda items**

- 4.1. The Secretary shall work with the Compliance Directorate to determine which matters are to be placed on the agenda of the Licence Committee or Research Licence Committee.
- 4.2. In determining the agenda for a Committee, the relevant officers shall have regard to the Instrument of Delegation set out in Annex B to the Authority's Standing Orders.
- 4.3. Where the Secretary and Compliance Directorate are unsure whether a matter should be placed on the agenda of a Committee or on the agenda of the Executive Licensing Panel, the presumption should be that the matter should be placed on the agenda of the Panel. Where necessary, the Secretary should consult the Chair of the Licence or Research Licence Committee.

#### **5. Conduct of meeting**

- 5.1. The Licence Committee and Research Licence Committee shall consider matters on the papers.
- 5.2. Subject to paragraph 5.3. only the Chair and members of the Committee, and the Secretary and advisers to that Committee may be present at the meeting of the Committee.
- 5.3. Members of the Authority who have been appointed to the Licence Committee or Research Licence Committee, or members of staff who have been appointed to the Executive Licensing Panel may attend a meeting of the Committee as observers, as part of their induction training. However, such observers shall not take any part in the discussion or deliberation of the Committee, and are not entitled to vote.

#### **6. Documents before committees**

- 6.1. At each meeting, the Licence and Research Licence Committee shall be provided with copies of:
  - a) this Protocol;
  - b) relevant edition(s) of the HFEA Code of Practice;

- c) the Human Fertilisation and Embryology Act 1990 (as amended);
  - d) the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 (where relevant);
  - e) Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
  - f) any relevant decision trees and explanatory notes approved by the Authority;
  - g) guidance for members of the Authority and its committees on the handling of conflicts of interest approved by the Authority on 21st January 2009;
  - h) indicative applications guidance on the time period for which licences should be granted approved by the Authority on 9th September 2009 (where relevant);
  - i) indicative sanctions guidance approved by the Authority on 18th March 2009 (where relevant);
  - j) licence application (where relevant) and any relevant documentation in support of the application from the applicant and/or proposed Person Responsible for the centre to be licensed;
  - k) recommendation of the Authority's Inspector dealing with the matter and any relevant supporting documentation (normally including three years worth of a centre's licensing history and inspection reports as appropriate, and in the case of applications for a research licence, any relevant academic literature and advice from the Authority's Scientific and Clinical Advances Advisory Committee);
  - l) the Compliance and Enforcement Policy approved by the Authority
- 6.2. The Licence Committee or Research Licence Committee shall not normally receive the recommendation of the Authority's Inspector dealing with the matter or any relevant supporting documentation from that Inspector, unless the applicant or person concerned (as appropriate) has been provided with a reasonable opportunity to comment on this material beforehand.

## **7. Committee papers**

- 7.1. The Secretary shall normally send the papers for a meeting of the Licence Committee or Research Licence Committee to the Chair and members of that Committee, seven days in advance of the meeting.
- 7.2. Upon receipt of the papers, members of the Committee must identify any potential conflicts of interest as soon as possible.

- 7.3. Where an actual or potential conflict is identified, members must inform the Chair of the Committee and the Secretary as soon as possible, and the procedure set out in the Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009 shall be followed in deciding whether or not a conflict exists.
- 7.4. No member of the Licence Committee or Research Licence Committee shall consider a matter if that member has an actual or potential conflict of interest in relation to that matter.
- 7.5. Members of the Committee shall read the papers thoroughly in advance of the meeting and shall refrain from discussing matters to be considered by the Committee with anyone except the other members of the Committee, at the Committee meeting.
- 7.6. Members of the Committee shall only discuss Committee business and the papers to be considered by the Committee when the Committee is in session.

## **8. Procedure to be followed at the meeting**

- 8.1. Before any papers are considered by the Licence Committee or Research Licence Committee, the Chair of the Committee should:
  - a) check that the Committee is quorate; and
  - b) ask for declarations of interest from each member.
- 8.2. Any interests declared should be noted and recorded by the Secretary.
- 8.3. Where a potential or actual conflict is identified, the Chair of the Committee should follow the procedure set out in the Guidance for Authority and Committee members on Handling Conflicts of Interest approved by the Authority on 21 January 2009.
- 8.4. Each item on the agenda should be considered separately.
- 8.5. Where the Committee is considering an application to grant or renew a licence, the Chair should direct the members of the Committee to consider the requirements of Section 16 of the Act.
- 8.6. In making its decision, the Committee may be aided by the relevant decision tree. Each stage of the decision tree should be considered separately, and in order.
- 8.7. Before the Committee makes its decision, the Chair may adjourn to:
  - a) seek the advice of a legal, clinical or specialist adviser; and
  - b) require further information from the applicant or Person Responsible for the centre to be licensed (as appropriate), or from the Authority's Inspector dealing with the matter.

8.8. In accordance with section 16(4) of the Act, where the Committee considers that the information provided with an application is insufficient to enable it to determine that application, it need not consider the application until the applicant has provided it with such further information as the Committee may require.

## **9. Decision to be taken by the committee**

### **9.1 Applications to grant (or renew a licence)**

9.1.1 On each application before it, the Committee must decide:

- a) whether the requirements of S16 of the Act have been satisfied, and if so, whether to grant(renew) the application in principle (under section 16(5) of the Act, the actual granting of a licence can only take effect upon written acknowledgment of licence conditions by the applicant or (where different) the proposed Person Responsible);
- b) if a licence is to be granted (renewed), whether any additional conditions should be attached to the licence in addition to those standard licence conditions which must be attached in accordance with sections 12-15 of the Act (under paragraphs 1(2); 1A (2); 2(2); and 3(6) of Schedule 2 to the Act, the Authority has a general power to impose conditions on different categories of licence); and
- c) if a licence is to be granted (renewed), the Committee must decide the period for which that new licence is to be granted(under paragraphs 1(5); 1A (3); and 2(3) of Schedule 2 to the Act, licences for treatment, non-medical fertility services; and storage may be granted for a period of up to five years. However, under paragraph 3(8) of Schedule 2 to the Act, licences for research can only be granted for a period of up to three years).

9.1.2 In determining the period of any licence to be granted (renewed), the Committee should consider the Indicative Applications Guidance approved by the Authority.

### **9.2 Particular requirements for applications authorising use of embryos for training purposes**

9.2.1 Before the Committee can grant (or renew) an application for a treatment licence authorising the use of embryos for training purposes, it must consider the requirements of paragraphs 1(3) and 1(4A) of Schedule 2 to the Act. In particular, the Committee must consider whether the activity is necessary and desirable for the purpose of providing treatment services; and whether the proposed use of embryos is necessary for training persons.

9.2.2 In deciding whether the proposed use of embryos is necessary for training purposes, the Committee shall have regard to the list of training purposes approved by the Authority.

### **9.3 Particular requirements for applications authorising embryo testing**

- 9.3.1 Before the Licence Committee can grant (or renew) an application authorising the testing of embryos, it must consider the requirements of paragraph 1ZA of Schedule 2 to the Act.
- 9.3.2 Where the application seeks authorisation for the testing of an embryo in circumstances in which there is a particular risk that an embryo may have a gene, chromosome or mitochondrion abnormality, the Licence Committee must consider the requirement of paragraph 1ZA(2) of Schedule 2 to the Act. In particular, the Licence Committee must be satisfied that there is a **significant risk** that a person with the abnormality will have or develop a **serious** physical or mental disability, a **serious** illness or any other **serious** medical condition.

### **9.4 Particular requirements for applications for research licences**

- 9.4.1 Before the Committee can grant (renew) an application for a research licence, it must consider the requirements of Paragraphs 3(5) and 3A (1) of Schedule 2 to the Act.
- 9.4.2 In particular, the Committee must be satisfied that any proposed use of embryos or human admixed embryos is (and in the case of applications for renewal) or remains necessary for the purposes of the research.
- 9.4.3 In addition, the Committee must consider whether the activities to be authorised by the licence are or remain necessary or desirable:
- a) for the listed purposes set out in paragraph 3A (2) or in Regulations; or
  - b) for the purpose of providing knowledge that may be capable of being applied for the purpose of
  - c) increasing knowledge about serious disease or other serious medical conditions, or
  - d) developing treatments for serious disease or other serious medical conditions.

## **10. Procedure for adding non standard conditions and for refusal, variation or revocation of licence**

- 10.1. If the Committee is minded to refuse to an application to grant, revoke or vary a licence, or minded to grant a licence subject to non standard conditions, it must follow the procedure in section 19(1) of the Act.
- 10.2. If the Committee is minded to vary or revoke a licence, it must follow the procedure in section 19(2) of the Act.
- 10.3. If the Committee is minded to vary a licence otherwise than in accordance with the application, it must follow the procedure in section 19(3) of the Act.

- 10.4. In all cases, the Committee must issue a notice. The notice needs to set out certain information, and therefore the Committee should use the appropriate template approved by the Authority and enclosed at annex 1.
- 10.5. In addition to issuing the notice, the Committee must give the person to whom the notice is addressed, an opportunity to make representations before making its decision. Representations may be oral and written.
- 10.6. Representations shall not be considered by the Committee that issues the notice. Where a notice has been issued by the Licence Committee, any representations shall be considered by the Research Licence Committee and vice-versa. Where a notice has been issued by the Executive Licensing Panel, representations may be considered by the Licence Committee or Research Licence Committee.
- 10.7. Where the person to whom the notice has been given indicates that he wishes to make representations, the Committee hearing those representations shall consider the matter in accordance with the provisions of the Human Fertilisation and Embryology Authority (Procedure for Revocation, Variation or Refusal of a Licence) Regulations 2009 (as amended).
- 10.8. Where after the expiry of the period of 28 days from the date on which the notice was served, the person to whom the notice was given has not responded, or has confirmed that he does not wish to make representations, the Committee shall resume its consideration of the matter and shall proceed to make its decision.

## **11. Reasons for committee's decision**

- 11.1. The Committee shall give reasons for each decision that it makes. These reasons must be recorded in the minutes.
- 11.2. The reasons shall set out:
  - a) any relevant findings of fact made by the Committee;
  - b) any matters taken into account by the Committee (including any advice received from a legal, clinical, scientific or specialist adviser); and
  - c) why the Committee reached its decision.
- 11.3. Additionally, in the case of applications to authorise the use of embryos for training purposes, the reasons must set out why the Committee considers that the activity is necessary and desirable for the purpose of providing treatment services; and why the Committee considers that the proposed use of embryos is necessary for training persons.
- 11.4. Additionally, in the case of applications to authorise embryo testing for gene, chromosome or mitochondrion abnormalities, the reasons must set why the Committee is satisfied that there is a significant risk that a person with the

abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition, and why the disability/illness/condition is considered to be serious.

- 11.5. Additionally, in the case of applications to grant (renew) licences for research, the reasons must set out why the Committee is satisfied that any proposed use of embryos or human admixed embryos is or remains necessary for the purposes of the research, and why the Committee considers that the activities to be authorised by the licence are or remain **necessary or desirable**:
- a) for the listed purposes set out in paragraph 3A (2) or in Regulations; or
  - b) for the purpose of providing knowledge that may be capable of being applied for the purpose of:
    - i. increasing knowledge about serious disease or other serious medical conditions, or
    - ii. developing treatments for serious disease or other serious medical conditions.
- 11.6. The reasons should tell the person concerned in broad terms why the decision was reached, and may in some circumstances require an explanation of why a particular argument was rejected.
- 11.7. Where additional conditions have been proposed, or where the Committee has issued a Notice of Proposal, the reasons should indicate why the Committee considers this course of action to be a proportionate response to any concerns identified from the papers before it.
- 11.8. The reasons should refer to the Indicative Applications Guidance and Indicative Sanctions Guidance where relevant.

## **12. Postponements and adjournments of meetings**

- 12.1. The Chair may, of his or her own motion, or upon the application of a party to the proceedings, postpone any meeting of which notice has been given before such meeting begins.
- 12.2. The Chair may, of his or her own motion, adjourn the proceedings at any stage.
- 12.3. In considering whether or not to grant a request for postponement, or to adjourn, the Chair of the Committee should, amongst other matters, have regard to:
- a) the public interest in the expeditious disposal of the proceedings;
  - b) fairness to the parties; and
  - c) the conduct of the person seeking the postponement or adjournment.

12.4. Where the proceedings have been postponed or adjourned, the Secretary should, as soon as practicable, notify the parties of the date and time of the postponed or resumed meeting.

### **13. Burden and standard of proof**

13.1. The Authority's inspector dealing with the matter should bear the burden of establishing that a licence should be revoked, varied (otherwise than on an application) or that a licence should be suspended.

13.2. The person to whom the notice under section 19(1) is given should bear the burden of establishing that a licence should not be refused or additional conditions should not be imposed.

13.3. Where facts are in dispute, the Licence Committee should consider whether they have been established in accordance with the civil standard of proof.

13.4. Where the Committee considers that a finding on disputed facts can only be made after oral evidence is heard at a hearing, it shall issue a notice of proposal under Section 19; invite the person to whom the notice is addressed to make oral representations and hold a hearing in accordance with the Human Fertilisation and Embryology Act (Procedure for Revocation, Variation or Refusal of a Licence) Regulations 2009 (as amended).

### **14. Evidence at meetings**

14.1. The Committee may receive any written or real evidence whether or not such evidence would be admissible in a civil court of law in England and Wales, provided that it is satisfied that such evidence is relevant to the issues on which it has to make a decision, and that it is fair to admit such evidence.

14.2. The Committee shall have regard to the Code of Practice issued by the Authority in the circumstances set out in section 25(6) of the Act.

### **15. Directions**

15.1. The Authority has delegated to the Licence Committee and to the Research Licence Committee the power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.

15.2. When:

- a) postponing or adjourning the consideration of a matter;
- b) refusing, varying, suspending or revoking a licence, or
- c) considering evidence of an adverse incident or non compliance with the Act, Code of Practice, licence conditions or directions issued by the Authority,

the Chair should consider whether or not to issue directions under section 24 of the Act.

**16. Evaluation and report to the Authority**

- 16.1. The Chairs of the Licence Committee and Research Licence Committee shall hold regular periodic meetings for the purpose of reviewing decisions taken by their respective Committees to ensure consistency in the decision making processes of the Committees, and to review reports prepared by the Chair of the Executive Licensing Panel on the activities of the Panel. The Chairs may also reflect on any general licensing trends or issues arising from such review and propose such action to the Executive or Authority as they consider appropriate.
- 16.2. The Chairs of the Licence Committee and Research Licence Committee shall each prepare an annual written report to the Authority detailing the activities of their Committee (see also the equivalent paragraph for the Executive Licensing Panel).

## Annex 1: Templates For Notices Of Proposal

### Notice Of Proposal To Refuse A Licence

#### HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

#### NOTICE OF PROPOSAL TO REFUSE A LICENCE

TO: **[INSERT NAME]**, APPLICANT AT **[INSERT CENTRE DETAILS]**

In accordance with section 19 of the Human Fertilisation and Embryology Act 1990 (as amended) (“the Act”), WE HEREBY GIVE YOU NOTICE that:

on [date], the Licence Committee/Research Licence Committee/Executive Licensing Panel of the Human Fertilisation and Embryology Authority considered an application for **[insert type of licence applied for]** for the **[insert name of centre]** and proposes to refuse a licence for this centre, for the reasons set out in the Schedule attached to this Notice.

A copy of the relevant part of the Act is enclosed for your convenience.

In accordance with section 19(4) of the Act, if you wish to make representations to a Committee about this proposal, you must give written notice to the Authority within 28 days commencing from the date of this Notice which is specified below.

Your Notice must contain the information set out in the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of a Licence) Regulations 2009. A copy of these Regulations is enclosed for your convenience.

Provided such written notice is given by you within the period specified above, the Committee will, before making its determination, consider any representations that you wish to make which may be:

- a) oral representations made by you or another acting on your behalf at a hearing; or
- e) written representations made by you.

If you do not give written notice within the period specified above, or if you do not wish to make representations, the Committee will proceed to make its determination.

Please inform the Authority by **[DATE-28 days from date below]** whether you wish to make representations, and if so, what kind of representations.

Signed \_\_\_\_\_

Name \_\_\_\_\_

Chair \_\_\_\_\_

Date \_\_\_\_\_

SCHEDULE OF REASONS FOR PROPOSING TO REFUSE LICENCE **[INSERT REASONS BELOW]**

## Notice Of Proposal To Vary Or Revoke A Licence

HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY  
NOTICE OF PROPOSAL TO VARY OR REVOKE A LICENCE

TO: **[INSERT NAME]**, PERSON RESPONSIBLE AT **[INSERT CENTRE DETAILS]**  
**[INSERT NAME]**, LICENCE HOLDER AT **[INSERT CENTRE DETAILS]**

In accordance with section 19 of the Human Fertilisation and Embryology Act 1990 (as amended) (“the Act”), WE HEREBY GIVE YOU NOTICE that:

on **[date]**, the Licence Committee/Research Licence Committee/Executive Licensing Panel of the Human Fertilisation and Embryology Authority made a proposal to vary the licence for the **[insert name of centre]** by **[insert variation proposals]** for the reasons set out in the Schedule attached to this Notice.

**[OR]**

on **[date]**, the Licence Committee/Research Licence Committee/Executive Licensing Panel of the Human Fertilisation and Embryology Authority made a proposal to revoke the licence for the **[insert name of centre]** for the reasons set out in the Schedule attached to this Notice.

A copy of the relevant part of the Act is enclosed for your convenience.

In accordance with section 19(4) of the Act, if you wish to make representations to a Committee about this proposal, you must give written notice to the Authority within 28 days commencing from the date of this Notice which is specified below.

Your Notice must contain the information set out in the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of a Licence) Regulations 2009. A copy of these Regulations is enclosed for your convenience.

Provided such written notice is given by you within the period specified above, the Committee will, before making its determination, consider any representations that you wish to make which may be:

- a) oral representations made by you or another acting on your behalf at a hearing; or
- f) written representations made by you.

If you do not give written notice within the period specified above, or if you do not wish to make representations, the Committee will proceed to make its determination.

Please inform the Authority by **[DATE-28 days from date below]** whether you wish to make representations, and if so, what kind of representations.

Signed \_\_\_\_\_

Name \_\_\_\_\_

Chair

Date \_\_\_\_\_

SCHEDULE OF REASONS **[INSERT REASONS BELOW]**

## Notice Of Proposal To Grant An Application For A Licence

### HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

#### NOTICE OF PROPOSAL 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 TO THE HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990(AS AMENED)

TO: **[INSERT NAME]**, APPLICANT AT **[INSERT CENTRE DETAILS]**

In accordance with section 19 of the Human Fertilisation and Embryology Act 1990 (as amended) (“the Act”), WE HEREBY GIVE YOU NOTICE that:

on **[date]**, the Licence Committee/Research Licence Committee/Executive Licensing Panel of the Human Fertilisation and Embryology Authority made a proposal to grant the application for a licence for the **[insert name of centre]** subject to the following condition(s):

- **[insert conditions here]** for the reasons set out in the Schedule attached to this Notice.

A copy of the relevant part of the Act is enclosed for your convenience.

In accordance with section 19(4) of the Act, if you wish to make representations to a Committee about this proposal, you must give written notice to the Authority within 28 days commencing from the date of this Notice which is specified below.

Your Notice must contain the information set out in the Human Fertilisation and Embryology (Procedure for Revocation, Variation or Refusal of a Licence) Regulations 2009. A copy of these Regulations is enclosed for your convenience.

Provided such written notice is given by you within the period specified above, the Committee will, before making its determination, consider any representations that you wish to make which may be:

- oral representations made by you or another acting on your behalf at a hearing; or
- written representations made by you.

If you do not give written notice within the period specified above, or if you do not wish to make representations, the Committee will proceed to make its determination.

Please inform the Authority by [DATE-28 days from date below] whether you wish to make representations, and if so, what kind of representations.

Signed

Name

Chair

Date

SCHEDULE OF REASONS **[INSERT REASONS BELOW]**

## **Human Fertilisation and Embryology Authority**

### **Standing Orders: Annex E Code of Conduct for Authority members, General Functions & Duties of the Authority, and Principles**

Approved 7 December 2011

## 1. Code of Conduct for Authority members

All members of the Authority UNDERTAKE to:-

- have regard to the functions and duties of the Authority set out in sections 8 and 8ZA of the Human Fertilisation and Embryology Act 1990 (as amended) (“the Act”) and which are annexed to this Code, when undertaking the business of the Authority or a committee of the Authority;
- comply with the Standing Orders and relevant protocols and policies approved by the Authority when undertaking the business of the Authority or a committee of the Authority;
- follow and support by example the principles published by the Committee on Standards in Public Life (the Nolan Principles) which are annexed to this Code;
- follow and support by example best practice on equality and diversity issues and promote compliance by others;
- comply with the statement of general principles published by the Authority in accordance with Section 8(ca) (ii) of the Human Fertilisation and Embryology Act 1990 (as amended) which are annexed to this Code;
- ensure that actions taken in a personal capacity do not bring the Authority into disrepute;
- be alert to the possibility of any conflicts of interest, and to declare any potential conflicts as soon as practicable;
- in the event of a potential conflict of interest, consult and follow the Authority’s Guidance on Conflicts of Interests;
- ensure that entries relating to them in the register of interests maintained by the Authority are accurate, complete and up-to-date;
- declare any hospitality received which may be relevant to their work as an Authority member in the register of interests maintained by the Authority for that purpose;
- only discuss Authority and committee papers at formal meetings of the Authority or committee to which the papers relate;
- keep the deliberations of the Authority or committee meetings which are not open to the public confidential, and not to disclose such deliberations to any external party (save in accordance with the Authority’s publication policy or where required to by a Court, or by law);

- use any information acquired solely by virtue of their membership of the Authority or a committee of the Authority only for the purpose of Authority or committee proceedings, and not to use such information for personal gain;
- comply with the provisions of section 33A of the Human Fertilisation and Embryology Act 1990 (as amended) and to uphold strictly the confidentiality of any patient identifying information that may be revealed to them as members of the Authority or a committee of the Authority;
- make no public comment on behalf of the Authority without first obtaining approval from the Chair of the Authority;
- when providing media interviews or commenting in public, make it clear that they are speaking in a private capacity or as a member of the Authority;
- make every effort to attend all meetings, hearings and training sessions at which their presence is required;
- once diaries have been checked and meetings scheduled, only cancel their attendance under exceptional and wholly unavoidable circumstances;
- take all reasonable steps to give advance warning of absence to the Chair of the Authority or committee of which they are a member in the event that they are unable to attend a scheduled meeting or hearing;
- prepare for any meeting or hearing by reading any papers sent to them beforehand; and
- undertake periodic training provided or organised by the Authority.

I hereby declare that I have read and understood this document and undertake to abide by the principles set out in this Code and to support these principles by example.

**Signed** \_\_\_\_\_

**Name** \_\_\_\_\_

**Date** \_\_\_\_\_

## 2. General functions and duties of the Authority

### Section 8: General functions of the Authority

The Authority shall

- a) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State, if he asks it to do so, about these matters,
- b) publicise the services provided to the public by the Authority or provided in pursuance of licences,
- c) provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purpose of activities governed by this Act, or may wish to do so,
- (ca) maintain a statement of the general principles which it considers should be followed:
  - (i) in the carrying –on of activities governed by this Act, and
  - (ii) in the carrying-out of its functions in relation to such activities,
- (cb) promote, in relation to activities governed by this Act, compliance with:
  - (i) requirements imposed by or under this Act, and
  - (ii) the code of practice under section 25 of this Act,
- d) perform such other functions as may be specified in regulations

### Section 8ZA: Duties in relation to carrying out its functions

- (1) The Authority must carry out its functions effectively, efficiently and economically.
- (2) In carrying out its functions, the Authority must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed).

### 3. The seven principles underpinning public life

- Selflessness** Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or other friends.
- Integrity** Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties.
- Objectivity** In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.
- Accountability** Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office
- Openness** Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.
- Honesty** Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.
- Leadership** Holders of public office should promote and support these principles by leadership and example.

## 4. Statement of general principles

Published by the Authority in accordance with section 8(ca) (ii) of the Human Fertilisation and Embryology Act 1990 (as amended)

### Purpose

We are the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. We set standards for, and issue licences to, centres. We provide authoritative information for the public, in particular for people seeking treatment, donor conceived people and donors. We determine the policy framework for fertility issues, which are sometimes ethically and clinically complex.

### Principles

- We treat people and their information with sensitivity, respect and confidentiality
- We observe the highest standards of integrity and professionalism in putting into effect the law as it governs our sector
- We consult widely, listening to and learning from those with an interest in what we do
- We keep abreast of scientific and clinical advances
- We exercise our functions consistently, proportionately, openly and fairly.