

# Standing Orders

Effective 1 April 2016

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## Foreword<sup>1</sup>

1. The Human Fertilisation and Embryology Authority (HFEA) is an executive non-departmental public body sponsored by the Department of Health. The HFEA 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 HFEA is the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. The HFEA sets standards for, and issues licences to, centres. It provides authoritative information for the public, in particular for people seeking treatment, donor-conceived people and donors. The HFEA determines the policy framework for fertility issues, which are sometimes ethically and clinically complex.
3. The HFEA is committed to adopting best practice in corporate governance. These Standing Orders form part of the corporate governance framework with which the HFEA must comply, and which includes:
  - the Act
  - Regulations issued by the Secretary of State for Health or the HFEA
  - the framework agreement between the HFEA and the Department of Health, or any other memorandum of understanding (MoU) or other agreement
  - Standing Financial Instructions adopted by the HFEA, and
  - Financial procedures for procurement and payment of goods and services, budget management and travel and subsistence.
4. As a public body, the HFEA is also required to comply with applicable legislation including that relating to human rights, equalities, freedom of information, environment information and data protection; and with relevant government policies on information assurance and data security. In addition, the HFEA is expected to comply with the statutory code of practice for regulators (The Regulators' Code).
5. In accordance with the Act (under Section 8) the HFEA shall:
  - (i) 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/she asks it to do so, about these matters
  - (ii) publicise the services provided to the public by the HFEA or provided in pursuance of licences
  - (iii) 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 the Act, or may wish to do so

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

- (iv) maintain a statement of the general principles which it considers should be followed in the carrying-on of activities governed by the Act, and in the carrying-out of its functions in relation to such activities
- (v) promote, in relation to activities governed by this act, compliance with requirements imposed by or under this act, and the Code of Practice under Section 25 of the Act, and
- (vi) perform such other functions as may be specified in regulations.

6. In accordance with the Act (under Section 8ZA) the HFEA must carry out its functions effectively, efficiently and economically and, so far as relevant, have regard to the principles of best regulatory practice.
7. These Standing Orders take account of the relevant Cabinet Office guidance for public bodies which is intended to secure the public service values of impartiality, integrity, objectivity, openness and accountability, and to ensure that value for money is optimised.
8. These Standing Orders primarily govern the procedures for meetings of the Authority and the committees established by the Authority.
9. In the conduct of operational activities, Authority members and employees are also expected to comply with the HFEA's published principles and policies approved by the Authority and employees of the HFEA are, in addition, expected to comply with the requirements set out in the employee handbook.

# Standing Orders

Effective 1 April 2016

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## 1. Use of Standing Orders

### 1.1. Power to make Standing Orders

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

- 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, Authority members and employees.

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 can be amended by the Authority, provided that:

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

### 1.4. Standing Orders to be given to Authority members, committee members and officers

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

- a) existing Authority members, committee 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 Authority members, committee members, officers and employees shall have a duty to disclose any non-compliance with these Standing Orders to the Chair of the HFEA or Chief Executive.

1.5.2. If for any reason these Standing Orders are not complied with, 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 committee chairs, where relevant.

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## 2. Interpretation

### 2.1. Role of Chair of the Authority

2.1.1. The Chair of the HFEA 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:

'the Act' means the Human and Fertilisation and Embryology Act 1990 (as amended)

'Adviser' means persons appointed to provide advice to the Authority, its committees or working groups

'Advisory group' means a group of persons appointed to provide advice to the Authority, its committees or working groups

'Chair of the HFEA' means the person appointed by the Secretary of State for Health to chair the HFEA 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 HFEA to act as Chief Officer and Accounting Officer of the Authority

'Committee' means a committee established by the HFEA (under s.9A(2) of the Act)

'Committee members' means persons formally appointed by the Chair of the HFEA to sit on or to chair specific committees

'Corporate Management Group' (CMG) means the executive management group established by the Chief Executive for effective management of the HFEA

'Deputy Chair of the HFEA' means the HFEA member appointed by the Secretary of State to take on the Chair's duties if the Chair of the HFEA 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 actively participated in any decision to do so

'Officer' means a member of the CMG

'Secretary of State' means the Secretary of State for Health

'Working group' means a non-standing committee of the HFEA, established and maintained for a specific purpose

'Working group members' means persons formally appointed by the Chair of the HFEA to sit on or to chair specific working groups.

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## 3. The Authority

### 3.1. Responsibilities of Authority members

- 3.1.1. Authority members shall, at all times, act in accordance with the provisions of the Act and with the provisions of the Code of conduct for Authority members annexed to these Standing Orders.
- 3.1.2. Authority members shall not give the Chief Executive instructions which conflict with his/her duties as the Authority's accounting officer.
- 3.1.3. No Authority 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. Authority 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. Authority members 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.
- 3.1.6. Authority members shall, in the conduct of Authority business, comply with all relevant legislation applying to public bodies and with government policies on information assurance and data security. In addition, Authority members shall have proper regard to the principles set out in the statutory code of practice for regulators (The Regulators' Code).
- 3.1.7. Authority members shall ensure that the financial transactions of the Authority are carried out in accordance with the Standing Financial Instructions and other financial procedures adopted by the Authority.
- 3.1.8. The Authority shall appoint an Authority member to act as equality champion, who will promote compliance with equalities legislation and from time-to-time report to the Authority on it.

### 3.2. Responsibilities of Authority members, committee members and employees

- 3.2.1. In the conduct of operational activities, Authority members and employees shall comply with applicable policies approved by the HFEA.
- 3.2.2. Authority members, committee 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 HFEA shall in addition to the responsibilities shared by all Authority 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 Authority members
- e) ensuring that these Standing Orders are complied with
- f) the appraisal of Authority members
- g) the appraisal of the Chief Executive
- h) the appointment of members to committees or working groups
- i) taking decisions on litigation
- j) ensuring a log of whistle blowing incidents is maintained
- k) liaison with the Secretary of State for Health and other relevant Ministers on behalf of the Authority
- l) representing the HFEA to the public, and
- m) issuing 'Chair's letters' to licensed centres setting out changes of policy, the issuing of new directions under the Act, or any other important messages.

3.3.2. The Chair of the HFEA may consult with two or more Authority members as appropriate before discharging the particular responsibilities set out 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 HFEA 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 the 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.** Particular responsibilities of the Chief Executive

3.5.1. The Chief Executive is the HFEA'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 when doing so
- c) day-to-day operations and management of the HFEA.

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

- d) effective management of the HFEA's business and operational activities
- e) achievement of the HFEA's strategic and statutory objectives
- f) continuous improvement within the HFEA, and

g) monitoring of compliance with applicable legislation, and oversight of executive working groups on particular subjects.

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

### **3.6.** Registers of interests and hospitality

3.6.1. The HFEA shall maintain and publish a register of interests and a register of hospitality, formally to record declarations of Authority members and employees.

### **3.7.** Declarations of interest and potential conflicts

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

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

3.7.3. Where a potential for a conflict of interests is identified, Authority members and committee members shall consult and follow the 'Guidance for Authority and committee members on handling conflicts of interest'.

### **3.8.** Access to external legal advice by Authority members

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

### **3.9.** Register of policies

3.9.1. 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.

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## 4. Meetings

### 4.1. Ordinary meetings

- 4.1.1. Members of the Authority shall usually meet as a full Authority no fewer than six times in each calendar year, and such meetings shall be held at such intervals and venues as the Chair may determine.
- 4.1.2. All ordinary meetings of the Authority will be open to members of the public to attend.
- 4.1.3. All ordinary meetings may begin with a private session of the Authority (which may, at the Chair's discretion, be attended by officers, advisers, auditors or Department of Health representatives), at which may normally be discussed:
  - a) the Authority's risk register
  - b) any legal update
  - c) any commercially sensitive matters, and
  - d) any other business that the Chair judges is reasonable to be conducted in private.

### 4.2. Extraordinary meetings

- 4.2.1. In addition to the fixed ordinary meetings, extraordinary meetings 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 Authority member.
- 4.2.2. An extraordinary meeting requested by an Authority 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 Authority members, 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 Authority.
- 4.2.3. It will be for the Chair to decide whether the extraordinary meeting is held in public or in private.

### 4.3. Written resolutions

- 4.3.1. A written resolution shall be as valid and effectual as if it had been passed at a full meeting of the Authority provided that:
  - a) the resolution is circulated by email to all Authority members
  - b) Authority members shall have at least three days to respond to the resolution
  - c) no fewer than one-third of the Authority members 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. Other than in exceptional circumstances, the Chair of the HFEA shall notify Authority members of the dates of the ordinary meetings of the Authority in any calendar year at least one month before the beginning of that year.
- 4.4.2. Failure to serve notice on any Authority member shall not affect the validity of an ordinary meeting.
- 4.4.3. The Chair of the HFEA shall notify Authority members of the date of an extraordinary meeting or written resolution to be considered by the Authority and shall provide Authority 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 full Authority.
- 4.5.2. An Authority 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.
- 4.5.3. Papers may be tabled at a meeting of the full Authority only with the permission of the Chair and no business other than that set out in the Agenda shall be considered at a meeting 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.
- 4.5.4. Agenda items which are not considered at a meeting may be carried forward for consideration at an appropriate later ordinary meeting, or 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 Authority members in good time before an Authority meeting, and shall usually 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 Authority members in accordance with this standing order, their non-receipt by any Authority member shall not invalidate the business transacted at that meeting.
- 4.6.5. Papers for consideration by the full Authority or by a committee shall be presented in the standard template approved by the Chief Executive.

- 4.6.6. The papers considered by Authority members at a meeting of the Authority and the minutes of the meetings of the Authority shall be published in accordance with the HFEA's policy on the publication of Authority and committee papers and shall be made available to the public in accordance with the HFEA's publication scheme and the Freedom of Information Act 2000.

#### **4.7.** Chair of meeting

- 4.7.1. At any meeting 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 Authority member as the Authority members present shall choose, shall preside.
- 4.7.2. If the Chair of the HFEA 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 Authority member as the Authority 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 Authority members are in attendance at that meeting.
- 4.8.2. At the discretion of the Chair, Authority members may attend meetings of the Authority by telephone or video-conferencing.
- 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 Authority members, the Chair of the HFEA 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 Authority 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 usually seek to achieve consensus on issues requiring a decision by the Authority 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 Authority members present so request.



- 4.9.3. Only those Authority members (including the Chair of the Authority) actually in attendance 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 Authority members who are in attendance 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 Authority shall be formally recorded. The recording shall be made available on the Authority's website as soon as is reasonably practicable.
- 4.10.2. The Chief Executive shall ensure that an employee is present at every meeting 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 Authority members present at the meeting shall be recorded in the minutes.
- 4.10.4. The minutes shall not usually record:
  - a) the names of individual Authority members who made specific comments, contributions or suggestions at a meeting, or
  - b) the vote (or abstention) of individual Authority members.
- 4.10.5. If an Authority 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 Authority shall be drawn up and submitted for agreement by the Authority members at the next meeting, and the person chairing that meeting shall sign the minutes with any agreed amendments which may be necessary.

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

- 4.11.1. The following persons shall be entitled to attend all meetings of the Authority and to bring any matter to the attention of the Authority members:
  - a) Chief Executive
  - b) Corporate Management Group
  - c) internal auditors, and
  - d) external auditors.

#### **4.12.** Attendance of non-Authority members

- 4.12.1. Observers from the Department of Health and employees of the Authority may attend ordinary meetings of the Authority.
- 4.12.2. At any meeting of the Authority, the Chair may require persons who are not Authority members (including members of the public, officers, other observers, and employees) to withdraw for any part of a meeting, if the Chair considers it desirable for the Authority members to meet in private or in the absence of some of those present.
- 4.12.3. The Chair of the HFEA 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 HFEA may invite such persons as he or she considers desirable to attend a meeting of the Authority and to advise the Authority members on any matter on the agenda for that meeting.

## 5. Reservation of powers to the Authority

### 5.1. List of reserved matters

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

- a)e) appointment of the Chief Executive, with the approval of the Secretary of State
- b)a) disciplinary action against the Chief Executive
- e)b) approval and amendments of Standing Orders
- d)c) establishing of committees and working groups
- e)d) agreement of the terms of reference and reporting arrangements of committees and working groups
- f)e) receiving reports from committees, working groups and individual members
- g)f) the appointment of HFEA representatives on external bodies
- h)g) approving the strategic aims of the HFEA
- i)h) approving the HFEA's corporate strategy or any equivalent documentation required by the Department of Health
- j)i) approving the HFEA's annual business plan
- k)j) approving the annual budget
- l)k) approving the annual report and accounts
- m)l) (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
- n)m) monitoring of the HFEA's performance against the annual plan and budget
- e)n) determination of all policies relating to the performance of the HFEA's functions under Section 8 of the Act
- p)o) approval of the annual update to the Code of Practice and General Directions
- e)p) ratification of any urgent decisions taken by the Chair in accordance with section 5.2 of these Standing Orders.

### 5.2. Emergency powers of Chair and Chief Executive

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

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

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

## 6. Arrangements for the exercise of functions by delegation

### 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 HFEA shall be delegated to the Chair of the HFEA.

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

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

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

### 6.3. Licensing functions

6.3.1. The HFEA shall establish the role of Licensing Officer. The HFEA delegates to the Licensing Officer (who shall be an HFEA employee, member of the Executive Licensing Panel and be appointed by the Chief Executive):

~~a)~~ g) the exercise of certain administrative licensing functions, as set out in annex B to these Standing Orders and amended from time to time by the Authority.

6.3.2. The HFEA shall establish and maintain an Executive Licensing Panel. The HFEA delegates to the Executive Licensing Panel:

~~a)~~ r) the exercise of certain routine licensing functions (including those delegated to the Licensing Officer), as set out in annex B to these Standing Orders and amended from time to time by the HFEA; and

~~b)~~ s) 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 HFEA shall establish and maintain a Licence Committee which will include Authority members and such additional committee members as the HFEA considers necessary.

6.3.5. The HFEA delegates to the Licence Committee:

- a) the exercise of its complex or controversial licensing functions (but also including those delegated to the ELP and Licensing Officer), as set out in annex B to these Standing Orders as amended from time to time by the HFEA, 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 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 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 HFEA shall establish and maintain an Appeals Committee.
- 6.4.2. The HFEA 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 HFEA 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.

- 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, and
- 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.

## **6.6.** Delegation of amendments to the Code of Practice, General Directions and other guidance

6.6.1. The HFEA may agree from time to time to the delegation of revisions to the Code of Practice and General Directions.

6.6.2. The terms of reference of such delegations shall be approved by Authority members at meetings of the Authority, and the minutes of that meeting shall record the matters delegated by the HFEA.

## **6.7.** Delegation to other committees, working groups and individual members

6.7.1. The HFEA may agree from time to time to the delegation of functions and powers to other committees, sub-committees, working groups, or individual members.

6.7.2. The constitution and terms of reference of these committees, sub-committees or working groups, and their specific delegated powers and those of any individual member shall be approved by Authority members at meetings of the Authority, and the minutes of that meeting shall record the matters delegated by the Authority.

## **6.8.** Delegation to officers

6.8.1. Those functions of the Authority, which have not been reserved by the Authority or delegated to the Chair (in Section 5 of these Standing Orders); or delegated to a committee, working group, panel, or officer (in Section 6 of these Standing Orders), shall be exercised by the Chief Executive on behalf of the Authority.

6.8.2. The Chief Executive shall determine which functions he/she will perform personally and shall nominate officers or other employees, as appropriate, to undertake the remaining functions for which he/she will retain accountability to the Authority.

6.8.3. The Chief Executive shall report periodically to the Authority on the exercise of powers so delegated.

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## 7. Committees, working groups and advisory groups

### 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 Authority members and other members as deemed necessary by the Authority.
- 7.1.3. A proposal to establish a working group shall identify the purpose of the group, the likely budget and employee 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 HFEA shall appoint the Chair of a Committee, committee members and the Chair and members of working groups established by the Authority.
- 7.2.3. The Chair of the HFEA shall only appoint persons who are not Authority members to a committee or working group where the Appointments Committee has agreed that such persons are suitable for appointment to a committee.
- 7.2.4. The remuneration for persons who are not Authority members but who have been appointed as a committee or working group member shall be as agreed from time to time with the Department of Health.
- 7.2.5. The terms of office for members of committees or working groups shall be decided by that committee or working group's Chair, but shall not normally be for more than three years.

### 7.3. Conduct of meetings of committees and working groups

- 7.3.1. This paragraph does not apply to meetings of the Licence Committee, Executive Licensing Panel or Appeals 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)d) \_\_\_\_\_ inquire whether any committee or working group member has any interests to declare, and if so, ensure that such interests are recorded
  - b)e) \_\_\_\_\_ where potential conflicts are identified, ensure that the committee or working group refers to and follows the 'Guidance for Authority and committee members on handling conflicts of interest'



e)f) \_\_\_\_\_ where appropriate, sign the minutes of any previous meetings with any agreed amendments that may be necessary, and

e)g) \_\_\_\_\_ 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.

7.3.4. With the permission of the Chair of the committee or working group, committee members may participate in a meeting by the use of telephone- or video-conferencing facilities, or other appropriate means.

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

7.4.1. The committee secretary shall send the agenda and papers to all committee or working group 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 committee Chair.

#### **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 shall be published in accordance with the HFEA's Policy on the Publication of Authority and Committee Papers and shall be made available to the public in accordance with the HFEA's publication scheme and the Freedom of Information Act 2000.

#### **7.7.** Advisers and advisory groups

7.7.1. The Authority delegates to the Chief Executive and his/her Senior Management Team the power to appoint advisers or advisory groups to support committees or working groups, and to determine remuneration necessary (if any) for those appointees.

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## 8. Sealing and execution of documents

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

a)h) \_\_\_\_\_ Chair of the Authority

b)j) \_\_\_\_\_ Deputy Chair of the Authority

e)l) \_\_\_\_\_ Chief Executive, and

e)k) \_\_\_\_\_ Members of the Corporate Management Group.

### 8.3. Signing of contracts

8.3.1. Officers and employees 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.

# Standing orders: Annex A

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**Standing committees and additional committees established by the Authority and their terms of reference**

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## 1. Standing committees of the Authority

- 1.1.** The Authority shall maintain the following standing committees concerned with licensing:
- a) Licence Committee, and
  - b) Appeals Committee.
- 1.2.** The membership and procedures of the Licence Committee (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 Committee (Annex D to the Authority's Standing Orders).
- 1.3.** The membership and procedures of the Licence Committee 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 additional committees:
- a) Audit and Governance Committee
  - b) Statutory Approvals Committee
  - c) Remuneration Committee
  - d) Appointments 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 ordinary meeting of the Authority (if they have met since the last Authority meeting), and presentation of such reports shall be a standing item on the agenda for all ordinary Authority meetings.
- 1.7.** All the Authority's additional standing committees may:
- a) receive expert advice where the committee Chair considers that such advice would assist the committee in its deliberations, and
  - b) sit with a legal adviser in attendance and may allow the legal adviser to remain with the committee during any private deliberations.
- 1.8.** Where an issue is considered by a committee across several meetings, the validity of the proceedings of that committee shall not be affected by reason only that members of that committee,

- a) who were in attendance at a former meeting were not in attendance at a later meeting of the committee, or
- b) who were not in attendance at a former meeting of the committee are in attendance at a later meeting.

**1.9.** The validity of the proceedings of any of the committees shall not be affected by reason only of:

~~a)c)~~ a defect in the appointment of any committee member, or

~~b)d)~~ a vacancy in the membership of that committee.

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## 2. The Audit and Governance Committee

### Purpose of the committee

- 2.1.** The purpose of the Audit and Governance Committee is to oversee corporate governance, risk, audit arrangements and financial matters.

### Delegated powers and functions of the Audit and Governance Committee

- 2.2.** The Authority delegates to the Audit and Governance Committee, the following powers:

~~a)~~**e)** approval of the internal audit programme, and

~~b)~~**f)** approval of the statement on internal control or equivalent annual governance statement included in the annual accounts.

- 2.3.** The functions of the Audit and Governance Committee shall be to:

~~a)~~**g)** 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)~~**h)** ensure that the Authority complies with its statutory functions, and with the requirements of the regulators' code, requirements applicable to arm's length bodies, and the principles and best practice guidance issued by the Better Regulation Executive

~~e)~~**i)** 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)~~**j)** 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)~~**k)** review and manage the effectiveness of the Authority's whistle-blowing policy.

- 2.4.** 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 (including renewal) and, where necessary, 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.

**2.5.** In pursuance of these functions, the Authority authorises the Audit and Governance Committee to:

- a)l) \_\_\_\_\_ require a review or investigation of any procedures and activities undertaken by the Authority that fall within its remit
- b)k) \_\_\_\_\_ obtain from any employee, 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)
- e)l) \_\_\_\_\_ obtain such external legal or other professional advice as it considers necessary to enable it to fulfil its functions, and
- e)m) \_\_\_\_\_ provide such advice or recommendations to the Chair, the Authority members and the Authority's Chief Executive, as it considers necessary or appropriate.

### Membership of the Audit and Governance Committee

**2.6.** The Audit and Governance Committee shall consist of up to five members including:

- a)n) \_\_\_\_\_ a Committee Chair (who shall be an Authority member)
- b)o) \_\_\_\_\_ a Deputy Committee Chair (who shall be an Authority member)
- e)p) \_\_\_\_\_ two persons who shall not be Authority members and who have relevant legal, financial, public sector or other corporate governance expertise.

**2.7.** The Chair of the HFEA shall appoint the members of the Audit and Governance Committee.

**2.8.** Members of the Audit and Governance Committee shall usually be appointed for a term of three years.

### Meetings of the Audit and Governance Committee

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

**2.10.** The Audit and Governance Committee shall usually meet no fewer than four times a year.

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

- 2.11.** In addition to members of Audit and Governance Committee, the following persons shall usually attend its meetings:
- a)g) \_\_\_\_\_ the Chief Executive (or his delegated representative)
  - b)r) \_\_\_\_\_ the Director of Finance and Resources
  - e)s) \_\_\_\_\_ the Head of ~~Governance and Licensing~~Corporate Governance
  - d)t) \_\_\_\_\_ the Committee Secretary
  - e)u) \_\_\_\_\_ a representative from the Department of Health
  - f)v) \_\_\_\_\_ a representative from the Authority's internal auditors, and
  - g)w) \_\_\_\_\_ a representative from the Authority's external auditors.
- 2.12.** The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the committee and/or to provide advice to inform the deliberations of the committee.
- 2.13.** The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Audit and Governance Committee to withdraw from the meeting to enable the committee to deliberate in private.



### 3. The Statutory Approvals Committee

#### Purpose of the committee

- 3.1.** The purpose of the Statutory Approvals Committee is to keep under review and to authorise the use of embryo testing; [to authorise the use of mitochondrial donation treatment](#); to issue Special Directions for the import/export of gametes; and to authorise the use of novel processes in licensed activities.

#### Delegated powers and functions of the Statutory Approvals Committee

- 3.2.** The Authority delegates to the Statutory Approvals Committee the following powers:

~~a)~~x) the authorisation of the use of embryo testing for conditions not previously authorised by the Authority (under Schedule 2, paragraph 1ZA(1)(a), (b) and (c) of the Act)

~~b)~~y) the authorisation of the use of embryo testing to establish whether the tissue of any resulting child would be compatible with that of a sibling that suffers from a serious medical condition (under Schedule 2, paragraph 1ZA(1)(d))

z) the authorisation of the use of embryo testing to establish whether an embryo is one of those whose creation was brought about by using the gametes of a particular person (under Schedule 2, paragraph 1ZA(1)(e))

~~e)~~aa) [the authorisation of the use of maternal spindle transfer \(MST\) and/or pronuclear transfer \(PNT\) for a named patient \(under The Human Fertilisation and Embryology \(Mitochondrial Donation\) Regulations 2015\)](#)

~~e)~~bb) the issuing of Special Directions for the import/export of gametes or embryos (under section 24 of the Act), and

~~e)~~cc) the authorisation of the use of novel processes in licensed activities.

- 3.3.** The functions of the Statutory Approvals Committee shall include:

~~a)~~dd) keeping under review the genetic conditions authorised by the Authority for embryo testing.

#### Membership of the Statutory Approvals Committee

- 3.4.** The Statutory Approvals Committee shall consist of no more than six members, which shall include:

~~a)~~ee) a Committee Chair (who shall be a lay Authority member)

~~b)~~ff) a Deputy Committee Chair (who shall be a lay Authority member);

~~e)~~gg) up to four other Authority members.

- 3.5.** The Chair of the HFEA shall appoint the members of the Statutory Approvals Committee.

- 3.6.** Members of the Statutory Approvals Committee shall usually be appointed for a term of three years.

### Meetings of the Statutory Approvals Committee

- 3.7.** The quorum for a meeting of the Statutory Approvals Committee shall be three including the Committee Chair or Deputy Committee Chair and two other members.
- 3.8.** The Statutory Approvals Committee shall usually meet 12 times per year. At the discretion of the Chair, the committee may meet additionally at short notice (and, if necessary, by telephone- or video-conference) if the Chair considers there is an item (or items) which cannot be delayed until the next meeting.
- 3.9.** No member of the Statutory Approvals Committee present at a meeting shall abstain from voting.
- 3.10.** Decisions of the Statutory Approvals Committee to authorise embryo testing or novel processes, or to issue Special Directions, require a simple majority (and in the event of a tie, the Committee Chair shall have a casting vote).

### Attendance at meetings of the Statutory Approvals Committee

- 3.11.** In addition to members of the Statutory Approvals Committee, the following persons shall usually attend its meetings:
- a)hh) a legal adviser
  - b)ii) a specialist adviser
  - e)jj) the Head of Corporate Governance ~~and Licensing~~
  - d)kk) the Committee Secretary.
- 3.12.** The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Statutory Approvals Committee and/or to provide advice to inform the deliberations of the Statutory Approvals Committee.
- 3.13.** The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the committee to withdraw from the meeting to enable the committee to deliberate in private.

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## 4. The Remuneration Committee

### Purpose of the committee

- 4.1. To consider matters relating to remuneration and human resources.

### Delegated powers and functions of the Remuneration Committee

- 4.2. The Authority delegates to the Remuneration Committee the power to approve annual employee pay levels.

- 4.3. The functions of the Remuneration Committee shall be to:

a)ll) develop the Authority's pay policy and strategy

b)mm) monitor overall levels of remuneration

e)nn) review, moderate and approve the remuneration of the Chief Executive and Directors, and

e)oo) consider human resource issues referred to it by the Chief Executive or Chair of the Authority.

### Membership of the Remuneration Committee

- 4.4. The Remuneration Committee shall consist of three members, which shall include:

a)pp) a Committee Chair (who shall be the Chair of the Authority)

b)qq) a Deputy Committee Chair (who shall be the Deputy Chair of the Authority), and

e)rr) the Chair of the Audit and Governance Committee.

### Meetings of the Remuneration Committee

- 4.5. The quorum for a meeting of the Remuneration Committee shall be two.

- 4.6. The Remuneration Committee shall usually meet at least once a year.

### Attendance at meetings of the Remuneration Committee

- 4.7. The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Remuneration Committee and/or to provide expert advice to inform the deliberations of the committee.

- 4.8. The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Remuneration Committee to withdraw from the meeting to enable the committee to deliberate in private.

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## 5. The Appointments Committee

### Purpose of the committee

- 5.1.** To oversee the appointments of external members contributing to the work of the committees and working groups.

### Functions of the Appointments Committee

- 5.2.** The Authority delegates to the Appointments Committee, the following functions:

- ~~a)ss)~~ Advising the Chair of the HFEA on the appointment of all non-Authority members to the committees and working groups
- ~~b)tt)~~ Monitoring the balance of expertise, experience and backgrounds of committee members in accordance with the purpose and requirements of each committee or working group, and
- ~~e)uu)~~ Oversight of the Authority's mechanisms for identifying and appointing non-Authority members to the committees and working groups.

### Membership of the Appointments Committee

- 5.3.** The Appointments Committee shall consist of three members, which shall include:

- ~~a)vv)~~ a Committee Chair (who shall be the Chair of the Authority)
- ~~b)ww)~~ a Deputy Committee Chair (who shall be the Deputy Chair of the Authority), and
- ~~e)xx)~~ the Chair of the Audit and Governance Committee.

### Meetings of the Appointments Committee

- 5.4.** The quorum for a meeting of the Appointments Committee shall be two.
- 5.5.** The Appointments Committee shall usually meet at least once a year.

### Attendance at meetings of the Appointments Committee

- 5.6.** The Committee Chair may invite such other persons (including employees) as the he/she considers appropriate, to attend the meetings of the Appointments Committee and/or to provide expert advice to inform the deliberations of the Committee.
- 5.7.** The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Appointments Committee to withdraw from the meeting to enable the committee to deliberate in private.

## 6. The Scientific and Clinical Advances Advisory Committee

### Purpose of the committee

- 6.1.** The purpose of the Scientific and Clinical Advances Advisory Committee is to advise the Authority on scientific and clinical developments (including research) in assisted conception, embryo research and related areas.

### Functions of the Scientific and Clinical Advances Advisory Committee

- 6.2.** The functions of the Scientific and Clinical Advances Advisory Committee shall be to:

a)yy) ~~make recommendations to the Authority on the safety and efficacy of policy implications arising out of scientific and clinical developments (including research) in assisted conception, embryo research and related areas~~

zz) make recommendations to the Authority on patient information relating to those scientific and clinical developments

b)aaa) advise the Authority on significant implications for licensing and regulation arising out of such developments, and

e)bbb) where required, work with the Authority members to consider the social, ethical and legal implications arising out of such developments.

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

- 6.3.** The Scientific and Clinical Advances Advisory Committee shall consist of five Authority members, which shall include:

a)ccc) a Committee Chair (who shall be an Authority member)

b)ddd) a Deputy Committee Chair (who shall be an Authority member), and

e)eee) three other Authority members.

- 6.4.** In addition, up to eight other persons, who shall not be Authority members, shall be appointed as expert advisers to the committee. Such persons shall not be entitled to vote.

- 6.5.** At least one of the Authority members of the Scientific and Clinical Advances Advisory Committee shall have clinical or scientific expertise.

- 6.6.** The Chair of the HFEA shall appoint the members of the Scientific and Clinical Advances Advisory Committee.

- 6.7.** Members of the Scientific and Clinical Advances Advisory Committee shall usually be appointed for a term of three years. Expert advisers may be appointed for a period of one, two or three years.

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

- 6.8.** The quorum for a meeting of the Scientific and Clinical Advances Advisory Committee shall be three including the Committee Chair or Deputy Committee Chair of the committee.

- 6.9.** The Scientific and Clinical Advances Advisory Committee shall usually meet three times each year.

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

- 6.10.** The Committee Chair may invite such other persons (including employees) as he/she considers appropriate, to attend the meetings of the Scientific and Clinical Advances Advisory Committee and/or to provide expert advice to inform the deliberations of the committee.
- 6.11.** The Committee Chair may determine when and whether it is necessary or desirable for any non-members of the Scientific and Clinical Advances Advisory Committee to withdraw from the meeting to enable the committee to deliberate in private.

## 7. Oversight Committee

### Purpose of the Oversight Committee

- 7.1.** The purpose of the Oversight Committee is to fulfil the functions set out in the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 ('the 2010 Regulations').

### Functions of the Oversight Committee

- 7.2.** The functions of the Oversight Committee shall be to:

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

### Membership of the Oversight Committee

- 7.3.** 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

- 7.4.** The quorum for a meeting of the Oversight Committee shall be four.
- 7.5.** The Oversight Committee shall consider an overview report submitted by the Register Research Panel at least once a year.

### Attendance at meetings of the Oversight Committee

- 7.6.** The Chair of the HFEA may invite such other persons (including non-Authority members and representatives from the Department of Health) as he/she considers appropriate, to attend the

meetings of the Oversight Committee and/or to provide expert advice to inform the deliberations of the committee.

- 7.7.** The Chair of the HFEA may determine when and whether it is necessary or desirable for any non-members of the Oversight Committee to withdraw from the meeting to enable the committee to deliberate in private.



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

### Register Research Panel

#### Purpose of the Register Research Panel

- 8.1.** The purpose of the Register Research Panel is to consider applications made under the Human Fertilisation and Embryology (Disclosure of Information for Research Purposes) Regulations 2010 (“the 2010 Regulations”).

#### Delegated powers and functions of the Register Research Panel

- 8.2.** The Authority delegates to the Register Research Panel, the power to:
- a) nnn) authorise access to Register data for the purposes of medical or non-medical research, and
  - b) ooo) deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.
- 8.3.** The functions of the Register Research Panel shall be to:
- a) ppp) comply with the requirements of the 2010 Regulations
  - b) qqq) review annual reports submitted by research establishments
  - e) rrr) publish lay summaries of research projects involving the use of Authority Register data
  - e) sss) submit a report to the Authority’s Oversight Committee about the work of the Register Research Panel not less than once a year
  - e) ttt) refer appeals against the decisions of the Register Research Panel to the Register Research Review Panel, and
  - f) uuu) liaise and collaborate with any appropriate 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

- 8.4.** The Register Research Panel shall consist of:
- (1) vvv) the Director of Compliance and Information, who will act as the Chair of the Register Research Panel
  - g) www) the Authority’s Caldicott Guardian, and
  - h) xxx) the Head of Information Technology.

### Meetings of the Register Research Panel

- 8.5.** The quorum for a meeting of the Register Research Panel shall be three.
- 8.6.** Meetings of the Register Research Panel will be scheduled as required and in accordance with any memorandum of understanding between the Authority and bodies responsible for national information governance.
- 8.7.** Meetings of the Register Research Panel will be private.

### Attendance at meetings of the Register Research Panel

- 8.8.** In addition to the Chair and members of the Register Research Panel, such other employees as the Chair considers necessary may attend the meetings of the Register Research Panel.
- 8.9.** The Chair of the Register Research Panel may invite such other persons (including non-Authority members and representatives from the Department of Health) as the Chair considers appropriate, to attend the meetings of that panel and/or to provide expert advice to inform the deliberations of the panel.

### Register Research Review Panel

#### Purpose of the Register Research Review Panel

- 8.10.** To consider appeals against the decisions of the Register Research Panel in accordance with Regulation 12 of the 2010 Regulations.

#### Delegated powers and function of the Register Research Review Panel

- 8.11.** The Authority delegates to the Register Research Review Panel, the power to:
- ~~(1)yyy~~ uphold or overturn the decisions of the Register Research Panel
  - ~~i)zzz~~ authorise access to Register data for the purposes of medical or non-medical research, and
  - ~~j)aaa~~ deny, suspend, revoke, vary or impose conditions upon authorisation to access Register data.

#### Membership of the Register Research Review Panel

- 8.12.** The Register Research Review Panel shall consist of:
- ~~(1)bbb~~ the Chief Executive, who will act as the Chair of the Register Research Review Panel, and
  - ~~k)ccc~~ the Senior Information Risk Owner (SIRO) of the Authority.

#### Meetings of the Register Research Review Panel

- 8.13.** 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

- 8.14.** In addition to the Chair and members of the Register Research Review Panel, such other employees as the Chair considers necessary may attend the meetings of the Register Research Review Panel.
- 8.15.** The Chair of the Register Research Review Panel may invite such other persons (including non-Authority members and representatives from the Department of Health) as the Chair considers appropriate, to attend the meetings of that panel and/or to provide expert advice to inform the deliberations of the panel.

## Standing Orders: Annex B

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

#### 1. Licensing functions delegated to a Licensing Officer

Consideration of the following variations of licences on application (under Section 18A(2) of the Act):

- change of licence holder, and
- change of a centre's name or address.

Consideration of applications for voluntary revocation of licences under Section 18(1) of the Act

#### 2. Licensing functions delegated to the Executive Licensing Panel

**All powers delegated to a Licensing Officer in table 1, above, plus:**

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

Consideration of applications for the renewal of 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 Licence Committee has not reserved to itself for consideration or which do not raise complex or controversial issues, and exercise of the Authority's power to grant such licences under Section 16 of the Act

Consideration of interim inspections reports (treatment and/or storage, and research)

The following variation of licences either on application or otherwise:-

- change of Person Responsible (under Section 18A(1) of the Act)
- changes to licensed activities (under Section 18A(2) of the Act), and
- change of a centre's premises (under Section 18A(2) of the Act).

Authorisation to undertake HLA tissue typing for genetic conditions previously authorised by the Authority

Consideration of reports of random unannounced inspections

Consideration of reports of targeted inspections

Consideration of executive proposals to place non-standard conditions on licences and exercise of the Authority's power to issue notices under Section 19 of the Act

Exercise of the Authority's power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act

### 3. Licensing functions delegated to Licence Committee in relation to research licences

**All powers related to research licences delegated to a Licensing Officer in table 1 and Executive Licensing Panel in table 2, above, plus:**

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 and exercise of the Authority's power to grant such licences under Section 16 of the Act

Consideration of Grade A incidents and, where appropriate, Grade B incidents

Consideration of executive proposals to revoke/suspend licences 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

### 4. Licensing decisions delegated to Licence Committee relating to treatment and/or storage licences

**All powers delegated to a Licensing Officer in table 1 and Executive Licensing Panel in table 2, above, plus:**

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

Consideration of Grade A incidents and, where appropriate, Grade B incidents

Consideration of executive proposals to revoke/suspend licences 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

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## 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 9 September 2009.

#### 2.1. 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 relevant policies and guidance approved by the Authority.
- 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 (or Deputy Chairs) and a pool of employees, appointed by the Chief Executive from amongst the employees of the Authority. In the absence of the Chair of the Panel, a 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 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 Chair of the Panel considers it appropriate, the panel may sit with a legal adviser in attendance. Any advice provided in the course of a meeting shall be recorded in the minutes.
- 2.4. 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 the 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:
  - (c) the panel's decision and of the reasons for such decision
  - ~~(e)~~(d) any advice tendered by a legal, clinical or specialist adviser, and
  - ~~(e)~~(e) 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. 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.
- 4.2. Where the relevant officers 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 Chair of the Panel should be consulted.

## 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, the Secretary, and the Head of Corporate Governance and Licensing may be present at a meeting of the panel.
- 5.3. Employees of the Authority 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 have access to:
- (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) General Directions 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 Authority and committee members on handling conflicts of interest'
  - (h) ~~the indicative applications guidance on the time period for which licences should be granted~~ 'Guidance on licensing' (where relevant)
  - ~~(i) the indicative sanctions guidance (where relevant)~~
  - ~~(j)~~(i) the 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)~~(j) the recommendation of the Authority's inspector dealing with the matter and any relevant supporting documentation (usually including three years' worth of a centre's licensing history, 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)~~(k) the compliance and enforcement policy.
- 6.2. The panel shall not usually 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 usually 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 Authority and committee members on handling conflicts of interest' 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'.
- 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 a licence (for the purposes of the panel, this covers renewal applications only)

- 9.1. On each application before it, the panel must decide:
- (a) whether the requirements of section 16 of the Act have been satisfied, and if so, whether to make a proposed decision to grant (renew) the licence
  - (b) if the proposed decision is for the licence is to be granted (renewed), whether it is on the same or different terms, including whether any additional conditions should be attached to the licence in addition to the standard licence conditions, and
  - (c) if the proposed decision is for the licence is to be granted (renewed), for what period that new licence is to be granted.
- 9.2. In determining the period of any licence to be granted (renewed), the panel should consider the indicative applications guidance.

### Particular requirements for applications authorising embryo testing

- 9.3. Before the panel can grant an application authorising the testing of embryos, it must consider the requirements of paragraph 1ZA of Schedule 2 to the Act.
- 9.4. 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 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 panel is minded to revoke a licence on application, it must follow the procedure in section 19A(2) of the Act.
- 10.3. If the panel is minded to vary or revoke a licence otherwise than on application, it must follow the procedure in section 19(2) of the Act.
- 10.4. 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.
- 10.5. In all cases where the panel has refused, varied or revoked a licence otherwise than on application, it must issue a notice under section 19A (4) and (5) of the Act.
- 10.6. After issuing any notice under section 19A (4) and (5) of the Act, the panel must refer the matter to the Licence Committee for consideration and have no further dealings with the matter.

## 11. Reasons for the 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 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.
- 11.4. 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.
- 11.5. Where additional conditions have been proposed 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.
- 11.6. 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, it shall refuse the application and issue a notice of proposal under Section 19; invite the person to whom the notice is addressed to make oral representations to the Licence Committee 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 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) making a proposed decision to refuse, vary, suspend or revoke 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 Chair of the 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 Licence Committee).

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## Standing Orders: Annex D

### Protocol for the conduct of meetings of the 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 Committee and should be followed save where fairness requires otherwise.

The Licence Committee 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 9 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 the Committee

- 1.1. The Authority shall maintain a Licence Committee.
- 1.2. The function of the Licence Committee 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 Licence Committee shall have regard to policies approved by the Authority, and where relevant, to the indicative applications guidance and indicative sanctions guidance.
- 1.4. Save where a 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.
- 1.5. Where a 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).
- 1.6. The Licence Committee shall consist of no more than six members including a Chair and Deputy Chair, appointed by the Chair of the Authority. In the absence of the Committee Chair, the Deputy Chair or other person nominated by the Chair of the HFEA may act as Committee Chair.
- 1.7. The quorum for a meeting of the Licence Committee shall be three.
- 1.8. No member of a Licence Committee present at a meeting shall abstain from voting.

- 1.9. Decisions of a Licence Committee shall be taken by simple majority (and the Chair of a Licence Committee shall not have a casting vote).
- 1.10. 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 shall not be passed.
- 1.11. Members of the 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 the Committee**

- 2.1. A legal adviser shall be present at every meeting of the Licence Committee.
- 2.2. Where the Chair of the 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, 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 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 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 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 is not accepted by that committee:
  - (a) the Committee Chair shall ensure that a written record is kept of the advice tendered, and the reasons why the committee refused to accept that advice; and
  - (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. Executive support to the committee

- 3.1. A secretary shall be present at every meeting of the 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. The Head of Corporate Governance and Licensing shall usually be present at every meeting of the committee. At the conclusion of every meeting of the Licence Committee, the Head of Corporate Governance and Licensing 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 Director of Compliance and Information.

### 4. Determination of agenda items

- 4.1. 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.
- 4.2. Where the relevant officers 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 Committee Chair should be consulted.

### 5. Conduct of meeting

- 5.1. The Licence Committee shall consider matters on the papers.
- 5.2. Subject to paragraph 5.3 only the Chair and members of the committee, the Head of Corporate Governance and Licensing and the secretary, and advisers to that committee may be present at the meeting of the committee.
- 5.3. Members of the Licence Committee, or employees who have been appointed to the Executive Licensing Panel, may attend a meeting of the committee as observers, or 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 the committee

- 6.1. At each meeting, the Licence Committee shall have access to:



- (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 Authority and committee members on handling conflicts of interest
- (h) ~~the indicative applications guidance on the time period for which licences should be granted~~ 'Guidance on licensing' (where relevant)
- ~~(i) the indicative sanctions guidance~~
- ~~(j)~~(i) the 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)~~(i) the recommendation of the Authority's inspector dealing with the matter and any relevant supporting documentation (usually including three years' worth of a centre's licensing history 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)~~(k) the compliance and enforcement policy.

6.2. The Licence Committee shall not usually 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 usually send the papers for a meeting of the 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 Committee Chair and the secretary as soon as possible, and the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest' shall be followed in deciding whether or not a conflict exists.
- 7.4. No member of the 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, the Committee Chair 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 Committee Chair should follow the procedure set out in the 'Guidance for Authority and committee members on handling conflicts of interest'.
- 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:
- (c) seek the advice of a legal, clinical or specialist adviser, and
  - ~~(e)~~(d) 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**

### **Applications to grant a licence (including renewals)**

- 9.1. On each application before it, the committee must decide:
- (a) whether the requirements of section 16 of the Act have been satisfied, and if so, whether to make a proposed decision to grant (renew) the licence
  - (b) if the proposed decision is for the licence to be granted (renewed), whether it is on the same or different terms, including whether any additional conditions should be attached to the licence in addition to the standard licence conditions, and

- (c) if the proposed decision is for the licence to be granted (renewed), for what period that that new licence is to be granted.

- 9.2. In determining the period of any licence to be granted (renewed), the committee should consider the indicative applications guidance.

### Particular requirements for applications authorising embryo testing

- 9.3. 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.
- 9.4. 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.

### Particular requirements for applications for research licences

- 9.5. 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.
- 9.6. 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.
- 9.7. In addition, the committee must consider whether the activities to be authorised by the licence are or remain necessary or desirable:
- ~~(a)~~(d) for the listed purposes set out in paragraph 3A (2) or in regulations;
  - ~~(b)~~(a) for the purpose of providing knowledge that may be capable of being applied for the purpose of;
  - ~~(c)~~(b) increasing knowledge about serious disease or other serious medical conditions; or
  - ~~(d)~~(c) 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 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. 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.
- 10.5. 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 a Licence Committee normally comprised of members who are not Authority members. Where a notice has been issued by the Executive Licensing Panel, representations may be considered by the Licence Committee.
- 10.6. 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).
- 10.7. 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 the 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:
- (d) any relevant findings of fact made by the committee;
  - (e) any matters taken into account by the committee (including any advice received from a legal, clinical, scientific or specialist adviser); and
  - (f) why the committee reached its decision.
- 11.3. 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.
- 11.4. 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)~~(g) for the listed purposes set out in paragraph 3A (2) or in regulations; or
  - ~~(b)~~(h) 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.

- 11.5. 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 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.
- 11.7. 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 Committee Chair should, amongst other matters, have regard to:
  - 4.1.1.k.1.(a) the public interest in the expeditious disposal of the proceedings
  - 4.1.1.k.2.(b) fairness to the parties, and
  - 4.1.1.k.3.(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 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, it shall refuse the application and 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 the power to issue directions under sections 24(5A) to (5E) and 24(13) of the Act.

- 15.2. When:

1.1.1.k.1.(d) postponing or adjourning the consideration of a matter

1.1.1.k.2.(e) making a proposed decision to refuse, vary, suspend or revoke a licence, or

1.1.1.k.3.(f) 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 Chair and Deputy Chair of the Licence Committee shall hold regular periodic meetings for the purpose of reviewing decisions taken by the Committee to ensure consistency in the decision-making processes of the Committee, and to hear updates from the Chair of the Executive Licensing panel on the activities of the panel. The Chair 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 Chair of the Licence Committee shall prepare an annual written report to the Authority detailing the activities of his/her Committee (see also the equivalent paragraph for the Executive Licensing Panel).

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## **Standing Orders: Annex E**

### **Code of Conduct for Authority members and the seven principles underpinning public life**

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## 1. Code of Conduct for Authority members

All Authority members **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
- comply with the Standing Orders and relevant protocols and policies approved by the Authority when undertaking the business of the Authority or a committee
- 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
- in the conduct of Authority business, treat people equally and fairly and not discriminate unlawfully against anyone on the basis of any protected characteristics including their race or racial group, sex (including gender reassignment), sexual orientation, religion or belief marriage or civil partnership, pregnancy and maternity, age or disability
- in carrying out their public functions, have due regard to the need to eliminate any conduct prohibited under equality legislation including the Equality Act 2010, and to promote equality of opportunity and foster good relations between people with protected characteristics and 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
- in their interactions with each other and with employees, model the ‘ways of working’ agreed by the Authority
  - taking responsibility
  - challenging well
  - taking interest in others’ ideas
  - demonstrating enthusiasm.
- 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 for Authority and committee members on handling conflicts of interest’
- 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)
- ensure that any telephone or videoconferencing facilities used to attend Authority or committee meetings are appropriate and ensure confidentiality
- use any information acquired solely by virtue of their membership of the Authority or a committee 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 of a committee
- 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 an Authority member
- 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 HFEA 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.

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## 2. The seven principles underpinning public life

The principles of public life apply to anyone who works as a public office-holder. This includes all those who are elected or appointed to public office, nationally and locally, and all people appointed to work in the civil service, local government, the police, courts and probation services, NDPBs, and in the health, education, social and care services. All public office-holders are both servants of the public and stewards of public resources. The principles also have application to all those in other sectors delivering public services.

### Selflessness

Holders of public office should act solely in terms of the public interest.

### Integrity

Holders of public office must avoid placing themselves under any obligation to people or organisations that might try inappropriately to influence them in their work. They should not act or take decisions in order to gain financial or other material benefits for themselves, their family, or their friends. They must declare and resolve any interests and relationships.

### Objectivity

Holders of public office must act and take decisions impartially, fairly and on merit, using the best evidence and without discrimination or bias.

### Accountability

Holders of public office are accountable to the public for their decisions and actions and must submit themselves to the scrutiny necessary to ensure this.

### Openness

Holders of public office should act and take decisions in an open and transparent manner. Information should not be withheld from the public unless there are clear and lawful reasons for so doing.

### Honesty

Holders of public office should be truthful.

### Leadership

Holders of public office should exhibit these principles in their own behaviour. They should actively promote and robustly support the principles and be willing to challenge poor behaviour wherever it occurs.