



HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY ("THE AUTHORITY")

GUIDANCE ON PERIODS FOR WHICH NEW OR RENEWED LICENCES SHOULD BE GRANTED

1. PREAMBLE

This guidance is produced by the Authority to assist those making applications under Section 16 of the Human Fertilisation and Embryology Act 1990 (as amended) ("the Act").

This guidance is produced in accordance with the Authority's powers under paragraph 9 of Schedule 1 to 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 guidance aims to ensure fairness and consistency in the proceedings before the Authority's Licence and Research Licence Committees and the Executive Licensing Panel composed of employees of the Authority, and should be followed save where fairness requires otherwise.

The Authority's Licence and Research Licence Committees and the Executive Licensing Panel shall retain the power and duty to take such action (provided always that any action is consistent with the requirements of the Act and delegated powers) as they consider appropriate and necessary to ensure fairness in a particular matter.

This Guidance has been approved by the Authority and was adopted by the Licence and Research Licence Committees on 9th September 2009. This Guidance comes into force on 1st October 2009.

2. PERIOD FOR WHICH LICENCES CAN BE GRANTED

Under Paragraphs 1(5), 1A(3), and 2(3) of Schedule 2 to the Act, licences for treatment; non-medical fertility services; and storage may be granted (or renewed) for a period not exceeding five years.

Under paragraph 3(8) of schedule 2 to the Act, licences for research may be granted (or renewed) for a period not exceeding three years.

3. GENERAL PRINCIPLES-FAIRNESS AND PROPORTIONALITY

In deciding the duration of any licence to be granted (or renewed), the Licence and Research Licence Committees and the Executive Licensing Panel have to exercise a discretion.

The Licence and Research Licence Committees and the Executive Licensing Panel are required to exercise their discretion in a way which is fair, reasonable, and proportionate. This will require them to weigh the interests of the person applying for a licence against the Authority's statutory duties (and in particular, its duty to promote compliance with the requirements of the Act and the Code of Practice issued under Section 25 of the Act), and the public interest.

4. CRITERIA FOR DECISION MAKING

4.1. In making its decision, the Licence and Research Licence Committees and the Executive Licensing Panel shall have regard to the:-

- a) regulatory principles governing the conduct of licensed activities issued by the Authority in accordance with section 8 of the Act and which are set out in the 8th edition of the Code of Practice;
- b) recommendations contained in the report of the inspection of the premises to be licensed;
- c) information provided with the licence application, and any response from the person making the application to the recommendation in the inspection report; and
- d) any relevant previous licensing history.

Licences for Treatment/Storage/Non-Medical Fertility Services

4.2 The Licence and Research Licence Committees or Executive Licensing Panel will normally grant an initial treatment/storage/non-medical fertility services licence for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence.

4.3. The Licence and Research Licence Committees or Executive Licensing Panel will normally take into account evidence of the matters set out in the table below when deciding the duration of a licence to be granted on an application to renew an existing treatment/storage/non-medical fertility services licence. The table below is not intended to be an exhaustive list.

Adherence to the regulatory principles published by the Authority
history of compliance with statutory requirements; Directions issued by the Authority; Licence Conditions; and the Code of Practice issued by the Authority

Compliance with recommendations made by Licence Committee/Executive Licensing Panel/Compliance Department
Co-operation by the Centre/Person Responsible with incident investigations and routine inspections
Status of the quality management systems in place at the premises to be licensed
Status of the premises and facilities at the premises to be licensed
Number of incidents reported by the centre in comparison to the average number of incidents reported per centre
Number of complaints made to the Authority against the Centre in comparison to the average number of complaints per centre
Timely provision of accurate Register data to the Authority
Number of multiple embryo transfers in comparison to the annual range set by the Authority
Number of live births in comparison to the national average

- 4.4 The Licence Committee or Executive Licensing Panel will normally only grant a renewal licence for treatment/storage/non-medical fertility services for a period of up to four years where the evidence before it reveals no concerns in the matters specified in the table at paragraph 4.3 above. This is to bring the granting of a renewal licence into line with the Compliance cycle approved by the Authority in July 2009 and to reduce the regulatory burden on centres by reducing the number of inspections over time.
- 4.5 The Licence Committees or Executive Licensing Panel may grant a treatment/storage/non medical fertility services renewal licence for a period of up to three years, where the evidence before it reveals concerns in any of the matters specified in the table at paragraph 4.3 above.
- 4.6 Where the evidence before it reveals major concerns, the Licence Committee or Executive Licensing Panel may decide not to grant a renewal licence at all.

Licences for Research

- 4.7 The Research Licence Committee will normally take into account evidence of the matters set out in the table below when deciding the duration of a licence to be granted on an application for an initial licence or an application to renew an existing licence. The table below is not intended to be an exhaustive list

The research history of the centre applying for the project to be licensed, and in particular whether or not the centre has been licensed to undertake research previously
Novelty of the research project
Adherence to the regulatory principles published by the Authority
History of compliance with statutory requirements; Directions issued by the Authority; Licence Conditions; and the Code of Practice issued by the Authority
Compliance with recommendations made by Licence Committee/Executive Licensing Panel/Compliance Department
Co-operation by the Centre/Person Responsible with routine inspections
Status of the premises and facilities at the premises to be licensed

Progress of research project
Any relevant recommendations in the peer review
Compliance with good research governance and generally accepted guidance published by professional bodies

5. CODE OF PRACTICE

Under Section 25(6) of the Act, the Licence and Research Licence Committees and the Executive Licensing Panel **shall**, in considering whether there has been any failure to comply with any conditions of a licence, and in particular, conditions requiring anything to be “proper” or “suitable”, take account of any relevant provision in the Code of Practice issued by the Authority.

6. REASONS

The Licence and Research Licence Committees and Executive Licensing Panel will provide written reasons for their decisions. The reasons will set out clearly the matters that they took into account when deciding the duration of the licence granted.

The reasons will indicate why the decision taken is considered to be proportionate, in all the circumstances of the case.

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* Excluding control sheet