



## **HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY INDICATIVE SANCTIONS GUIDANCE FOR LICENCE COMMITTEES**

### **1. PREAMBLE**

*The Licence Committees of the Human Fertilisation and Embryology Authority (“the Authority”) have produced this guidance on sanctions to assist those licence holders and Persons Responsible named on the licence (and their representatives), who have been notified in accordance with Section 19 of the Human Fertilisation and Embryology Act 1990 (as amended) (“the Act”), that the Licence Committee is minded to revoke or vary their licence*

*The Licence Committees are mindful of the Authority’s duty as a public body to comply with the Human Rights Act 1998 ; the Authority’s common law duties and powers to ensure fairness in its procedures; and the Authority’s 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 various Licence Committees and should be followed save where fairness requires otherwise.*

*A 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 and any Regulations made under the Act) as it considers appropriate and necessary to ensure fairness in a particular matter.*

*This Guidance was approved by the Authority on 9<sup>th</sup> September 2009 and subsequently adopted by the Chairs of the Authority’s Licence and Research Licence Committees. This Guidance comes into force on 1<sup>st</sup> October 2009.*

### **2. SANCTIONS AVAILABLE TO LICENCE COMMITTEE**

#### **2.1 Variation of Licence**

Under Section 18A(3) of the Act, the Authority may vary any of the terms of a licence where it has the power to revoke a licence.

## **2.2 Suspension of Licence**

Under Section 19C (1) of the Act, where the Authority –

- a) has reasonable grounds to suspect that there are grounds for revoking the licence; and
- b) is of the opinion that the licence should immediately be suspended,

it may by notice suspend the licence for such period not exceeding three months as may be specified in the notice.

Under Section 19C (2), the Licence Committee may, by further notice, renew or further renew the original suspension.

## **2.3 Revocation of Licence**

Under Section 18(2) of the Act, the Authority may revoke a licence if –

- a) it is satisfied that any information given for the purposes of the application for the licence was in any material respect false or misleading;
- b) it is satisfied that the person responsible has failed to discharge, or is unable because of incapacity to discharge, the duty under section 17,
- c) it is satisfied that the person responsible has failed to comply with directions given in connection with any licence,
- d) it ceases to be satisfied that the premises specified in the licence are suitable for the licensed activity,
- e) it ceases to be satisfied that any premises which are relevant third party premises in relation to a licence are suitable for the activities entrusted to the third party by the person who holds the licence,
- f) it ceases to be satisfied that the holder of the licence is a suitable person to hold the licence,
- g) it ceases to be satisfied that the person responsible is a suitable person to supervise the licensed activity,

- h) the person responsible dies or is convicted of an offence under this Act, or
- i) it is satisfied that there has been any other material change of circumstances since the licence was granted.

### **3. PURPOSE OF SANCTIONS**

The purpose of sanctions is to:-

- a) promote compliance with the requirements of the Act and the Code of Practice issued by the Authority;
- b) protect those using, or affected by, the services offered at centres licensed by the Authority; and
- c) maintain public confidence in the conduct of licensed activities within the United Kingdom.

### **4. GENERAL PRINCIPLES-FAIRNESS AND PROPORTIONALITY**

The Authority has delegated the power to impose sanctions to its Licence and Research Licence Committees (“Licence Committees”).

In considering whether or not to apply a sanction, the Authority’s Licence Committees have to exercise a discretion.

The Licence Committees are required to exercise that discretion in a way which is fair and reasonable. This will require the Licence Committees to weigh the interests of the Licence Holder or Person Responsible against the three factors set out in section 3 above, and the public interest.

In making a decision on sanction, the Licence Committees shall have regard to the range of sanctions available, and will seek to ensure that any sanction applied is proportionate, in all the circumstances of the case. This will involve a consideration of—

- a) any mitigating or aggravating features;
- b) the personal circumstances of the licence holder or Person Responsible and any mitigation advanced on their behalf; and
- c) any testimonials or character references provided in support of the licence holder or Person Responsible.

## 5. CODE OF PRACTICE

Under Section 25(6) of the Act, the Licence Committee (on behalf of the Authority) **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.

Further, in considering whether or not to vary or revoke a licence, the Licence Committee (on behalf of the Authority) **may** take into account any observance of, or failure to observe, the provisions of the Code.

## 6. AGGRAVATING FEATURES

The following is a non-exhaustive list of factors which the Licence Committees may consider to be aggravating features of any matters of non compliance reported to it:-

Breach of patient confidentiality
Breach of statutory storage periods for storage of gametes/embryos
Failure to obtain required consents relating to use/storage of gametes and embryos and/or to keep proper records of such consents
Failure to comply with consents relating to use/storage of gametes and embryos
Failure to provide Authority with information required to be included in the Statutory Register under Section 31 of the Act
Failure to comply with witnessing protocols and procedures
Failure to comply with multiple birth minimisation strategy without good reason
Failure to comply with recommendations or warnings made by Inspector/Compliance Department
Failure to comply with recommendations or warnings issued by Licence Committee
Dishonesty
Failure to notify Authority of incidents
Failure to co-operate with investigation or inspection
Failure to properly investigate complaints from users of, or persons affected by, the service offered by the centre
Abuse of trust/position
Disregard for system of regulation
Disregard of generally accepted/established guidelines or Code of Practice
Repeated breaches of licence conditions or failure to comply with Directions issued by the Authority
Failure to notify Authority of material change in circumstances
Failure to respond to correspondence from Authority

## 7. MITIGATING FEATURES

The following is a non-exhaustive list of factors which the Licence Committees may consider to be mitigating features of any matters of non compliance reported to it:-

Full co-operation with inspection/investigation
No attempt to conceal non compliance
Demonstrated insight
Early and effective remedial action taken

## 8. CASES IN WHICH VARYING A LICENCE TO INCLUDE ADDITIONAL CONDITIONS LICENCE MAY BE APPROPRIATE

Where the criteria set out in Sections 18A (3) and 18(2) of the Act are satisfied, the Licence Committees (on behalf of the Authority) may decide to vary a licence in the following non-exhaustive list of circumstances:-

Non compliance is capable of being remedied
Appropriate realistic and verifiable conditions can be formulated
Evidence that licence holder or Person Responsible has insight and is likely to comply with any conditions imposed

## 9. CASES IN WHICH A SUSPENSION OF A LICENCE MAY BE APPROPRIATE

Where the criteria set out in Sections 19C (1) of the Act are satisfied, the Licence Committees (on behalf of the Authority) may decide to suspend a licence in the following non-exhaustive list of circumstances:-

Potential risk to users of, or persons affected by, the services offered at the centre requires immediate action
Potential risk to gametes or embryos requires immediate action
Evidence of widespread or serious management/ procedural/ quality control/safety/consent failures
Public confidence in the conduct of licensed activities requires immediate action
No suitable person available to act as Person Responsible
No conditions can be adequately framed/conditions would be unworkable in practice
Evidence of previous breach of conditions or Directions issued by the Authority
Evidence of disposition towards non compliance

## 10. CASES IN WHICH REVOCATION OF A LICENCE MAY BE APPROPRIATE

Where the criteria set out in Section 18(2) of the Act are satisfied, the Licence Committees (on behalf of the Authority) may decide to revoke a licence in the following non-exhaustive list of circumstances:-

Public confidence in the conduct of licensed activities demands of no lesser sanction.
Behaviour is fundamentally incompatible with system of regulation
Evidence of widespread or serious management/ procedural/ quality control/safety failures
No conditions can be adequately framed/conditions would be unworkable in practice
Evidence of previous breach of conditions or Directions issued by the Authority
Evidence of disposition towards non compliance
Disregard of previous advice/warnings given by Inspector or Compliance Department
Disregard of previous advice/warnings given by Licence Committee

## 11. REASONS

The Licence Committees will give reasons for the decision they make. The reasons will set out clearly the matters that the Licence Committees took into account in deciding whether or not to impose a sanction, and if so, what sanction to impose.

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

## Control sheet

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2	At meeting on 9/9/09, Authority requested that references to “blatant” and “lack of insight” be deleted. Document updated to comply with the provisions of the amended Act which took effect on 1 <sup>st</sup> October 2009	David Gomez	1 <sup>st</sup> October 2009

\* Excluding control sheet