

## **FACT SHEET 5: HFEA LICENSING AND INSPECTIONS**

### **Why we inspect?**

- Every centre in the UK that provides IVF or donor insemination (DI) treatment, the storage of gametes (sperm or eggs) or embryos, or that carries out human embryo research is required by law to be inspected and licensed by the HFEA. We inspect to ensure centres provide safe and high quality services according to standards in the *Code of Practice* and the HFE Act.
- Activities under the HFE Act requiring a licence from the HFEA are:
  - ✓ Bringing about the creation of an embryo in vitro (embryo includes an egg in the process of fertilisation)
  - ✓ Keeping or using an embryo
  - ✓ Storing any gametes
  - ✓ Using donated sperm, donated eggs in the course of providing treatment services for any woman

We issue licences for treatment, storage or for research

### **HFEA licensed centres**

All centres that are licensed by the HFEA are expected to have appropriate clinical governance procedures in place. In NHS treatment centres/clinics, these procedures are expected to be in accordance with standards required by the Health Care Commission, and as set out in the HFEA *Code of Practice*.

In addition all centres must appoint key personnel to fulfil certain roles.

- All centres must name a 'Person Responsible' under whose supervision the licensed activities will be carried out.
- They must ensure that staff have suitable qualifications and experience; proper equipment is used; proper arrangements are made for the keeping and disposal of gametes and embryos at the treatment centre; the centre complies with all the conditions of its HFEA licence; and ensure any adverse incident which has occurred at the treatment centre is reported to the HFEA without delay.
- Each licensed centre is expected to have a person to act as the 'Nominal Licensee', who is the person who holds the HFEA licence. As only the Nominal Licensee can ask the HFEA to vary the centre's licence in order to designate another individual to be the Person Responsible it is important that the Nominal Licensee is a different person from the Person Responsible. Ideally the post of Nominal Licensee should be held by someone who sits on the hospital's or host management company's executive board.

### **HFEA Code of Practice**

The HFE Act requires the HFEA to produce a *Code of Practice* to guide centres on the standards they should establish in carrying out their licensed activities.

## **Our Inspectors**

The HFEA currently employs 80 part-time inspectors who are experts in the field and assist the HFEA in inspecting centres. Not only does the licensing process ensure that proper standards are maintained, but also assists in informing the HFEA about current and developing clinical practice. We recruited 20 new inspectors in 2003, chosen through a 2-day assessment centre and training event. A new team of full-time senior regulatory managers are in place who have completed a rigorous training programme. Senior Regulatory Managers chair all inspections and bring greater consistency, professionalism and shared learning to HFEA inspections.

## **Inspection protocols**

The HFEA is committed to continually reviewing and advancing its inspection processes and protocols. These protocols prompt inspectors to cover all relevant areas of compliance whilst encouraging wider discussion of general issues of good practice. The protocols are based on the requirements of the HFE Act, the HFEA and all other relevant professional guidelines.

There are three types of inspection:

### **Initial Inspections**

- Before granting a licence, the HFE Act requires the Authority to inspect the premises where the proposed licensed activities will be carried out. An inspection will be organised once a full application has been received and peer reviews have been completed.
- Inspections will normally be carried out by a team of inspectors chaired by an HFEA senior regulatory manager, and can take up to two days depending on the size and type of the centre, although most only take one full day. On the visit the inspection team will be expected to cover the areas outlined in the Inspection Protocols found on the HFEA website.
- A report is prepared which goes to an HFEA Licence Committee for decision. This decision can be to grant a licence, grant a licence subject to specific conditions or refuse a licence. There is an appeals process when a Licence Committee refuses to grant or vary a licence.

### **Interim Inspections**

Under the HFEA's three-year inspection cycle, each centre that has been granted a three-year licence receives an 'interim' inspection each year before they apply to renew their licence and receive a full inspection. These interim inspections enable the inspection team and subsequent Licence Committee to gather information regarding the centre's current activities. Interim inspections usually have a particular focus that will have been determined by types of treatment offered at the centre, the outcome of previous inspections and / or any issues that have arisen during the year. The interim inspection is also a means for the HFEA to monitor compliance with any conditions or recommendations that a centre may have on its licence, and also with any recent HFEA policy developments.

Licensed centres are inspected annually. The inspection process measures a centre's compliance with:

- The HFE Act
- Directions as issued by the HFEA
- The HFEA *Code of Practice*
- HFEA Chair's Letters these are used to communicate new or revised HFEA policy in between editions of the *Code of Practice*

An inspection team usually includes a clinician, a scientist and a person with a background in another field, such as counselling or nursing. All inspections are chaired by members of the HFEA Executive who provide a consistent point of contact between the HFEA and licensed centres.

### **Unannounced inspections**

We carry out a programme of unannounced inspections. In 2004 there will be four randomly chosen and four based on risk assessment. These inspections follow a specially designed protocol, the details of which can be found on the HFEA website.

### **HFEA Licence committees**

- HFEA Licence Committees make all licensing decisions. Each Committee is made up of five HFEA Members who determine whether a licence should be granted, suspended or revoked. If a licence is granted, centre specific conditions may be attached to that licence.
- Established centres that have been licensed for several years and are considered to be consistently compliant with both the law and the HFEA *Code of Practice* are issued with three-year licences. A new centre normally qualifies for a three-year licence only if it achieves good compliance during its first two years.

### **Publishing Inspection Reports**

All reports from inspections after September 2003 are made publicly available on application to the HFEA.