



# **About the Human Fertilisation and Embryology Authority**

**October 2009**

# 1. THE UK REGULATORY SCHEME

## The origins of the regulatory scheme

- 1.1. In July 1984, the Report of the Committee of Inquiry into Human Fertilisation and Embryology was presented to the UK Parliament. In the opening parts of the Report, the Chair of that Committee, Mary Warnock, stated:

“The task you set to the Inquiry was not an easy one. The issues raised reflect fundamental moral, and often religious, questions which have taxed philosophers and others down the ages....there remain nonetheless certain differences between us...focused on the very subjects, surrogacy and research on human embryos, which, to judge from the evidence, arouse the greatest public anxiety.”(page 1)

“What is common...is that people generally want *some principle or other* to govern the development and use of the new techniques. There must be *some* barriers that are not to be crossed, *some* limits fixed, beyond which people must not be allowed to go.”(page 2)

“But we foresee real dangers in the law intervening too fast and too extensively in areas where there is no clear public consensus. Furthermore both medical science and opinion within society may advance with startling rapidity.” (page 7)

- 1.2. The “Warnock Committee” was set up in July 1982, in response to the public excitement and concern generated by the birth of Louise Brown in July 1978. The remit of the Committee was to “consider recent and potential developments in medicine and science related to human fertilization and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of these developments; and to make recommendations.”
- 1.3. The Committee made some 64 recommendations and enunciated key principles, many of which are reflected in the legislation governing human fertilisation and embryology in the United Kingdom today. These key principles include the special status of the embryo outside the human body, which is deserving of protection by law; the requirements for patients and donors to be offered counseling, and for them to provide informed consent before treatment is given or donations made; the need to consider the welfare of any child to be born as a result of fertility treatment; the right of the donor conceived to access certain information about their genetic parents; and the 14 day limit on keeping an embryo in vitro for the purpose of research.

## **The Human Fertilisation and Embryology Act 1990**

- 1.4. Following extensive consultation by the United Kingdom government in 1986, and the publication of a government white paper in 1987, the Human Fertilisation and Embryology Bill received Royal Assent in 1990.
- 1.5. The Human Fertilisation and Embryology Act 1990, then, establishes the legislative framework which governs assisted reproduction and embryo research in the United Kingdom. The scheme of the act is to prohibit certain activities completely, and to allow other specified activities to be carried out only under the authority of a licence (or in some cases, under a contractual agreement between the person holding the licence and a third party-“a third party agreement”).
- 1.6. The outright prohibitions created by the Act (as amended) include:-
  - a) placing non permitted gametes or embryos in a woman (including human admixed embryos, non human embryos or gametes)(sections 3(2) and 4A(1));
  - b) keeping or using a human embryo or human admixed embryo after the appearance of the primitive streak (sections 3(3)(a) and 4A(3));
  - c) placing a human embryo or human admixed embryo in an animal (sections 3(3)(b) and 4A(4); and
  - d) using female germ cells taken or derived from an embryo or foetus, or using embryos created by using such cells, for the purposes of providing fertility services for a woman (section 3A);
- 1.7. Gametes which have not been produced by or extracted from ovaries or testes, or which have had alterations made to their nuclear or mitochondrial DNA are not classed as permitted gametes.
- 1.8. Embryos which have not been created by the fertilisation of permitted gametes or which have had alterations made to their nuclear or mitochondrial DNA or to which cells have been added (other than by division of the embryo’s own cells) are not classified as permitted embryos.
- 1.9. The prohibition on placing non permitted embryos in a woman prevents “Human cloning” otherwise known as “reproductive cloning.”
- 1.10. The activities which can only be carried out under the authority of a licence (or a third party agreement) include:-
  - a) creating human embryos (section 3(1));
  - b) using or keeping human embryos (section 3(1A));

- c) storing gametes (section 4(1)(a));
- d) using sperm (other than partner donated sperm which has not been processed or stored) to provide treatment services (section 4(1)(b));
- e) using the eggs of a woman which have been processed or stored, or the eggs of any other woman, to provide treatment services (section 4(1)(b));
- f) procuring, testing, processing or distributing gametes intended for human application (section 4(1A));
- g) creating, keeping or using human admixed embryos (section 4A(2)); and
- h) mixing human gametes with animal gametes (section 4A (2)).

1.11. A person who breaches the outright prohibitions listed above, or who carries out an activity which can only be carried out under the authority of a licence or a third party agreement, without holding such a licence or being party to a third party agreement, commits a criminal offence. If convicted, the penalty for such an offence may be imprisonment for up to ten years, a fine, or both (section 41(1) and (2)).

1.12. The licensing scheme, then, is an essential part of the legislative framework and the Act created the Human Fertilisation and Embryology Authority (“the HFEA”) as the body to administer this licensing scheme, in addition to other functions to be described below. By section 11 and Schedule 2 of the Act, the HFEA can only issue four types of licence:-

- a. licences for treatment;
- b. licences for non-medical fertility services (e.g procuring and distributing sperm);
- c. licences for storage of gametes, embryos and human admixed embryos; and
- d. licences authorising activities for the purposes of a project of research

1.13. Licences for treatment, non medical fertility services, and storage may be granted for a period of up to 5 years (schedule 2, paragraphs 1(5), 1A (3), and 2(3)). Licences for research may be granted for a period of up to 3 years (schedule 2, paragraph 3(8)).

1.14. A licence can not authorise both treatment and research activities. A separate licence is required for each activity.

1.15. A licence can not apply to premises in different places; a separate licence is required for each premises at which licensed activities are to be carried out.

- 1.16. The HFEA does not grant licences to undertake research on a general basis. Rather, Licences are granted to centres to undertake specific projects of research, and in order to be granted a licence, centres must demonstrate to the HFEA that a number of specific statutory requirements in relation to that particular research project are satisfied.
- 1.17. By virtue of sections 12 to 15 of the Act, every licence issued by the HFEA is automatically subject to a number of standard licence conditions. These relate to issues such as record keeping; traceability; obtaining of relevant consents in writing; provision of information and counseling to patients and donors; time limits for storage of gametes and embryos; the provision of information and documentation to the HFEA; and the HFEA's right of access to, and inspection of, centres.
- 1.18. In relation to treatment licences, a key provision requires centres to take account of the welfare of any child to be born as a result of the treatment to be provided (including the need of that child for supportive parenting) and of any other child who may be affected by that birth (section 13(5)). The HFEA has issued guidance defining the concept of "supportive parenting" and about how such risk assessments should be conducted.
- 1.19. The legislative framework has a number of additional features which are designed to bring a degree of both flexibility and control, in order to cater for future scientific developments and unforeseen circumstances. Firstly, there is a power in the 1990 Act for the Secretary of State to issue secondary legislation in the form of Regulations in certain circumstances. An example is the power contained in section 3ZA (5) of the Act to make regulations about what should be classified as a "permitted" egg or a "permitted" embryo.
- 1.20. Secondly, although every licence issued by the HFEA is automatically subject to a number of statutory conditions set out in the Act, the Act provides the HFEA with a power to issue "Directions" to set aside these conditions in certain circumstances.
- 1.21. Thirdly, under the Act, the HFEA has the power to issue additional conditions to each type of licence (schedule 2), and to issue directions requiring licensed centres to provide it with certain information about activities undertaken by that centre. The HFEA has recently used this power to require licensed centres providing treatment services to implement a "multiple births minimisation strategy."

- 1.22. Fourthly, the Act requires the HFEA to issue a Code of Practice giving guidance to licensed centres about the conduct of licensed activities. This Code of Practice is updated periodically, and allows new guidance to be produced in relation to new technologies and methods of carrying out licensed activities. The Code of Practice must be approved by the Secretary of State for Health. From 1<sup>st</sup> October 2009, the new 8<sup>th</sup> Code of Practice will be in force.
- 1.23. Lastly, a standard condition of all licences issued by the HFEA is that centres must not carry out new methods of conducting a licensed activity unless they have first notified the HFEA and have been given approval by the HFEA to carry out those activities by these new methods.
- 1.24. Central to the licensing scheme is the concept of the “Person Responsible.” Every application for a licence must nominate a named individual to act as the Person Responsible for that licensed centre (section 16(2)). The Person Responsible does not have to be the holder of the Licence (for example the Licence Holder may be a corporate body such as a Health Trust). The Person Responsible has a number of specific statutory duties under section 17 of the Act. These include:
- a) ensuring that the conditions of the licence are complied with;
  - b) notifying the HFEA and providing it with a report about any serious adverse incidents or serious adverse reactions;
  - c) ensuring that staff at the licensed centre are of good character, and are suitably trained and qualified;
  - d) ensuring that proper equipment and suitable practices are used in the conduct of licensed activities; and
  - e) ensuring proper arrangements are made for the keeping and disposal of gametes and embryos.
- 1.25. The HFEA requires all individuals wishing to act as Person Responsible to have satisfactorily completed its PR Assessment Programme; to have relevant qualifications; and to have at least two years practical experience in the relevant field.
- 1.26. Section 33A of the Act contains very strict provisions relating to the confidentiality of information about treatments that apply both to the HFEA and to licensed centres. The level of confidentiality attached to such information exceeds the normal confidentiality attaching to routine medical records. Breach of these confidentiality requirements is a criminal offence.
- 1.27. Further details about the HFEA’s licensing scheme are set out in the Guide to Licensing.

## **The Human Fertilisation and Embryology Act 2008**

- 1.28 Since the 1990 Act was enacted, there have been significant scientific developments, a number of Legal challenges based around the definition of an embryo in the Act, and significant societal changes, including the enactment of legislation relating to equality and unfair discrimination, and the establishment of civil partnerships for same sex couples.
- 1.29 In 2004, the UK Government announced a review of the 1990 Act, and the House of Commons Science and Technology Committee (“the Gibson Committee”) set up an inquiry into Human Reproductive Technologies and the Law.
- 1.30 The Committee produced a report in 2005, with over 100 recommendations. Like the Warnock Committee previously, not all members of the Science and Technology Committee were able to sign up to the recommendations, and a separate dissenting report was produced.
- 1.31 In 2005, the Department of Health issued a public consultation on how the 1990 legislation should be updated. The document sought views on 74 distinct issues, including whether the current model of regulation should be retained, whether the HFEA should be replaced by a new regulatory body combining its functions with those of the Human Tissue Authority, and whether the welfare of the child consideration should be retained in legislation or instead be a matter of clinical practice. The Department received over 500 responses to the consultation and taking these responses into account, produced a white paper in December 2006.
- 1.32 The White Paper proposed that the creation of hybrid embryos would not be permitted. This proposal prompted a further inquiry by the House of Commons Science and Technology Select Committee specifically looking at the governments proposals for the regulation of hybrid and chimera embryos. The Committee recommended that the creation of hybrid embryos, specifically cytoplasmic hybrids should be permitted under licence from the HFEA. After considering the recommendation of the Science and Technology Committee, and listening the arguments put forward by scientists, the government proposed to allow the creation of hybrid and chimera embryos, but not a true hybrid.
- 1.33 The draft Bill was subject to Parliamentary scrutiny by a joint Committee of both houses, prior to the production of the final Bill that would be formally introduced into parliament. This Committee also produced a set of recommendations. The Committee recommended that the proposals to

establish a new regulatory authority combining the functions of the HFEA and the HTA were not included in the Bill

- 1.34 The Bill was introduced into the Parliament in November 2007. The Government allowed a free vote for government MPs on three key areas: the need for a father; saviour siblings; and human admixed embryos. These were the areas that were the subject of most debate and proposed amendments. On 13 November 2008, the Bill received Royal Assent. With the exception of the new legal parenthood provisions which come into force in April 2009, the majority of the provisions of the new Act will be commenced in October 2009.
- 1.35 The 2008 Act, then, is the result of a long process of engagement which began in 2004. Draft proposals have been the subject of detailed consultation, and extensive scrutiny both prior to the introduction of the draft Bill into Parliament and through the passage of the Bill through Parliament. The Government made changes to its initial proposals in response to concerns raised, and views expressed in parliamentary debates.
- 1.36 The 2008 is primarily an amending Act. In addition to the substantial amendments to the HFEA's licensing process, the main changes brought about by the 2008 Act are:
  - a) ensuring that the creation and use of all human embryos outside the body-***whatever the process used in their creation***-is subject to regulation;
  - b) a ban on selecting the sex of offspring for non-medical reasons;
  - c) retention of the duty to take account of "the welfare of the child" when providing fertility treatment, but removal of the reference to "the need for a father" and replacement with the concept of "supportive parenting";
  - d) provisions to recognize same-sex couples as legal parents of children conceived through the use of donated sperm, eggs or embryos;
  - e) altering restrictions on the use of HFEA collected data to make it easier to do follow up research; and
  - f) provisions clarifying the scope of legitimate embryo research activities, including explicit rules on embryo testing

1.37. An illustrative text produced by the Department of Health which shows the provisions of the 1990 Act, as amended by the 2008 Act is available on [www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH080211](http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH080211).

1.38. However, reference must still be made to the 2008 Act in relation to stand alone provisions dealing with legal parenthood.

## 2. THE HFEA

- 2.1 The HFEA is an executive Non-Departmental Public Body sponsored by the Department of Health. The HFEA was created by Section 5 of the Human Fertilisation and Embryology Act 1990, and began operating on 1<sup>st</sup> August 1991.
- 2.2 The HFEA has just 22 members on its board, and some 85 members of staff (the executive). Members of the board are appointed by the Secretary of State for Health through the public appointments commission-the body that appoints members of the public to positions in public life. The board members are required to operate in accordance with the principles published by the Parliamentary Committee on Standards in Public Life. The Chair of the HFEA is Professor Lisa Jardine, CBE. Members come from a variety of different walks of life including academia; and the Church; the scientific and clinical communities. The patient and donor conceived persons perspective is also represented on the board. By Schedule 1 of the 1990 Act, there must be a lay majority on the board.
- 2.3 The board holds 7-9 meetings a year, two of which must be held in public. In addition to board meetings, members of the HFEA sit on its five standing committees:
- a) Audit and Governance Committee
  - b) Compliance Committee
  - c) Remuneration Committee;
  - d) Scientific and Clinical Advances Advisory Committee;
  - e) Ethics and Law Advisory Committee
- 2.4 In addition to these committees, some members of the board sit on the Licence Committee, and others sit on the Research Licence Committee. The intention is that each member of the board will have an opportunity to sit on a Licence or Research Licence Committee at some point during their tenure of office.
- 2.5 The procedures of the HFEA's Board and Committees are set out in Standing Orders.

- 2.6 The HFEA is funded partly by grant-in-aid from the government, and partly by fees charged to centres licensed by it. The aim is full recovery of regulatory costs. The HFEA has a management agreement with the Department of Health and the Department requires the HFEA to meet a number of performance indicators. Representatives from the Department meet regularly with the executive of the HFEA, and attend the meetings of the HFEA board and committees.
- 2.7 The HFEA is required to prepare an annual report to the Secretary of State for Health, and these reports are laid before the UK Parliament (section 7). A copy of the latest annual report and accounts is available on the Authority's website.
- 2.8 By section 8 of the Act, the HFEA is required to maintain a statement of the general principles which it considers should be followed in the carrying on of its functions. This statement is set out below:

**“Purpose**

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

**Principles**

We treat people and their information with sensitivity, respect and confidentiality

We observe the highest standards of integrity and professionalism in putting into effect the law as it governs our sector

We consult widely, listening to and learning from those with an interest in what we do

We keep abreast of scientific and clinical advances;

We exercise our functions consistently, proportionately, openly and fairly”

2.9 The general functions of the Authority are set out in Section 8 of the Act which provides:

*“The Authority shall-*

- (a) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State if he asks it to do so, about those matters,*
- (b) publicise the services provided to the public by the Authority or provided in pursuance of licences,*
- (c) provide, to such extent as it considers appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by this Act, or may wish to do so, and*
- (d) perform such other functions as may be specified in regulations.”*

2.10 From 1st October 2009, the provisions of the Human Fertilisation and Embryology Act 2008 which amend the 1990 Act come into force. From this date, the Authority’s general functions will be amended to include:

*“(ca) maintain a statement of the general principles which it considers should be followed-*

- (i) in the carrying-on of activities governed by this Act, and*
  - (ii) in the carrying-out of its functions in relation to such activities,*
- (cb) promote, in relation to activities governed by this Act, compliance with-***
- (i) requirements imposed by or under this Act, and***
  - (ii) the code of practice under section 25 of this Act...”***

- 2.11 Section 31 of the Act (as amended) requires the Authority to keep a register containing the information falling within section 31(2). This includes information relating to:
- (a) the provision for any identifiable individual of treatment services other than basic partner treatment services;
  - (b) the procurement or distribution of any sperm, other than sperm which is partner-donated sperm and has not been stored, in the course of providing non-medical fertility services for any identifiable individual;
  - (c) the keeping of the gametes of any identifiable individual or of an embryo taken from any identifiable woman;
  - (d) the use of the gametes of any identifiable individual other than their use for the purpose of basic partner treatment services;
  - (e) the use of an embryo taken from any identifiable woman; or
  - (f) information which shows that an individual is a “relevant individual.”
- 2.11 Treatment services are defined under section 2(1) of the Act as medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children.
- 2.12 By S31 (4), the definition of a relevant individual includes an individual who was or may have been born in consequence of:-
- a) treatment services other than basic partner treatment services; or
  - b) the procurement or distribution of any sperm (other than partner donated sperm which has not been stored) in the course of providing non-medical fertility services.
- 2.13 The HFEA undertakes regular inspections in support of its licensing functions, and is required by Section 15A to investigate any serious adverse events and serious adverse reactions that it becomes aware of.
- 2.14 The HFEA is the Competent Authority for the purpose of European Directives, and by Section 8A, is under a duty to communicate with Competent Authorities in other EEA states, and with the European Commission in relation to serious adverse incidents and reactions.

- 2.15 Under Section 25 of the Act, the HFEA is required to maintain a Code of Practice giving guidance about proper conduct of activities carried on in pursuance of a licence, and the proper discharge of the functions of a *person responsible* under a licence. Members of the Appeal Committee will be provided with a copy of the 8<sup>th</sup> edition of the Code as part of their induction.
- 2.16 The HFEA is empowered to issue Directions under Section 23 and 24 of the Act. Copies of Directions issued by the HFEA are also published on the Authority's website. The HFEA has used this power as part of its policy to reduce the incidence of multiple births in the United Kingdom. The HFEA has through Directions, required every centre to produce a "multiple births minimisation strategy". The strategy should set out how each treatment centre intends to reduce their multiple birth rates. The policy aims to lower the national average multiple birth rate from its current rate of 24%(of all live birth events following IVF/ICSI) to 10% over three or four years. A copy of all the Directions currently in force will be provided to the members of the Appeal Committee as part of their legal training.
- 2.17 Under Sections 31, 31A and 31B of the Act, the HFEA is required to maintain a Register containing information specified in the Act (including information about donors, treatments and children born as a result of treatment); a Register of Licences; and a Register of Serious Adverse Events and Serious Adverse Reactions.
- 2.18 As from October 2009, the HFEA will by Section 31ZF be able to maintain a Voluntary Contact Register for persons who have expressed a wish to receive any information about other persons to whom they may be genetically related as a consequence of the provision of treatment services.
- 2.19 Schedule 3B of the Act empowers members of the HFEA board, and HFEA employees to inspect licensed premises and records held by centres; to take possession of material considered, on reasonable grounds, to be relevant to the HFEA's licensing function or for the purpose of taking appropriate control measures. Under the Schedule, the HFEA may apply to a Court for a warrant to enter premises.
- 2.20 As from October 2009, the HFEA will have the power to contract out certain of its functions, and a power to assist other authorities. The HFEA will also be under a statutory duty to carry out its functions effectively, efficiently and economically, and to have regard to the principles of best regulatory practice (transparency; accountability; proportionality; consistency; and to target regulatory action at those cases in which it is needed).

- 2.21 In accordance with its policy on the “Collection, Confirmation and Publication of Register Data”, the HFEA requires licensed centres to provide it with information about donors, patients and treatments via an electronic data interchange system. As part of its duties to provide information, the HFEA publishes a “Choose a Clinic” section on its website. This section provides information about the services offered by licensed centres in the UK and provides data about the treatments provided by them.
- 2.22 The “Choose a Clinic” guide is an invaluable tool designed to assist patients to make an informed decision about where to get treatment. The Guide gives details of every clinic in the UK, NHS and private, with information about their services and facilities, and their success rates according to the age of patients they treat. With over 100 treatment centres in the UK, the HFEA is the only body who can provide this kind of impartial information.
- 2.23 Over the course of the last year the Choose a Clinic guide had 92,154 visits and 1,275,953 page views. The guide is published on the HFEA website at [www.hfea.gov.uk](http://www.hfea.gov.uk).

### **3. INSPECTION**

- 3.1 In the period 1<sup>st</sup> April 2007 to 31<sup>st</sup> March 2008, the HFEA carried out 119 routine inspections, 4 of which were unannounced. During the same period, the HFEA inspectors dealt with 4,482 telephone and email inquiries from licensed centres.
- 3.2 The HFEA has some 14 Inspectors, who come from a range of backgrounds. Inspections are normally carried out by a team of three including a scientist, a clinician, and a generalist. The teams inspecting research facilities normally include two scientists. The HFEA also has access to a large pool of external advisers who can supplement the inspection teams when required. A number of HFEA inspectors have attended the training sessions organised by the European Union Standards and Training for the Inspection of Tissue Establishments Project. (“EUSTITE”)
- 3.3 By Schedule 3B of the 1990 Act (as amended), the HFEA is required to arrange an inspection of any premises in respect of which an application has been made to undertake licensed activities there. The Schedule also provides a general power for the HFEA to enter and inspect premises. This general right of entry is also a standard condition of all licences issued by the HFEA.
- 3.4 The HFEA is required to inspect licensed centres at least every two years. The HFEA is currently refining an inspection risk tool which will assist it to decide the frequency at which various centres should be inspected. For each centre, the frequency and focus of inspections will be based on an explicit risk assessment taking account of the likelihood and potential impact of non compliance by that centre.
- 3.5 In assessing risk, the HFEA will (where appropriate) seek to make use of online services, self assessment and input from centre’s quality management systems.
- 3.6 In addition to the inspections relating to applications, the HFEA carries out a small number of unannounced inspections. These centres are chosen at random and provide an opportunity to check the efficiency of the HFEA’s risk based assessments.

3.7 The purpose of a routine inspection is to:-

- a) assess the extent to which centres comply with the Act; licence conditions; directions and the provisions of the Code of Practice;
- b) provide an independent and professional perspective on the running of the centre;
- c) promote good practice so that centres can improve the quality of service they provide to patients and donors;
- d) provide centres with a positive learning experience;
- e) provide centres with the opportunity to feed back on their experience of the inspection process, in order to assist the Authority to continually improve its procedures;
- f) give patients reliable information about a centre's compliance with statutory and other obligations, and about the quality and safety of licensed activities undertaken at that centre.

3.8 All HFEA inspections aim to:-

- a) be evidence based, consistent, proportionate and open to scrutiny;
- b) be undertaken in a professional and courteous manner;
- c) be focused on risk;
- d) add value for centres and service users.

Before undertaking a routine inspection, the HFEA's compliance department notifies that centre in advance of the process and procedures to be followed, so that the centre is clear what will be required of it, has an opportunity to prepare and to minimise potential disruption to licensed activities being undertaken.

3.9 Prior to the inspection, the Person Responsible is required to complete a pre-inspection questionnaire. The purpose of this questionnaire is to provide the HFEA with details of any changes made since the last inspection and factual information, such as the details of all treatments carried out. In addition, the Person Responsible is required to fill in a self assessment form, so that the centre can identify any areas needing improvement. Questionnaires are also sent to the Centre with a request that they be distributed to patients who are willing to provide feedback. The information from the questionnaires and self assessments is analysed

- prior to the inspection, so that the lead inspector can plan the focus of the inspection visit.
- 3.10 The core assumption will be that centres wish to demonstrate compliance with the Act; licence conditions; directions and the Code of Practice. The onus is on centres to do so, not on inspectors to find fault.
  - 3.11 In addition, the Inspection Team assess a centre against a number of themes, e.g. witnessing arrangements, which are agreed by the Authority each year.
  - 3.12 The Inspection team use a number of tools to record their findings. The HFEA is currently reviewing its inspection tools to ensure full compliance with the guidelines to Competent Authorities issued by the EUSTITE project.
  - 3.13 During the course of an inspection of a licensed centre, the inspection team may identify and require improvements to be made. The inspection team will explain to the Person Responsible for the centre why any improvement needs to be made and the legal basis for requiring it. The team will take account of the challenges a centre might face in meeting a requirement (but must always be mindful of the health, safety and well-being of people who use the service).
  - 3.14 A report of every inspection is prepared. Persons Responsible for licensed centres are shown the report in draft and are provided with a reasonable opportunity to comment on the findings and recommendations of the draft report.
  - 3.15 The final report will be formally signed off by the lead Inspector, on behalf of all the inspection team, as a professional assessment of compliance at the time of the visit; once signed off no changes will be made.
  - 3.16 Once signed off, the report will normally be sent to the relevant decision maker (either an executive Licensing panel of the HFEA or a Licence Committee made up of members of the HFEA board) for consideration within 30 working days (and sooner wherever possible).
  - 3.17 After consideration by the relevant decision maker, routine Inspection Reports will normally be published on the Authority's website. Reports are produced and published in a style which is accessible to all our stakeholders, particularly patients.

## **Improvement Report**

- 3.18 The HFEA publishes an annual report on the performance of licensed clinics in the UK. This report is based on an analysis of the HFEA's inspection reports and patient views about centres, including complaints and incidents received by the HFEA in the previous year.
- 3.19 The purpose of this report is to promote learning and improvement in the fertility sector. The report highlights areas of good practice and also details the concerns noted by inspectors in their visits across the sector. The report is published on the HFEA's website.
- 3.20 copies of the improvements report are available on the HFEA' s website.

## **4. THE CODE OF PRACTICE; IMPROVING QUALITY AND DISSEMINATING GOOD PRACTICE**

- 4.1 Section 25 of the 1990 Act requires the HFEA to maintain a Code of Practice giving guidance about the proper conduct of activities authorised by a licence; and the proper discharge of the functions of the Person Responsible and other persons to whom the licence applies. The Code must be approved by the Secretary of State for Health.
- 4.2 One of the changes introduced by the 2008 amendments to the 1990 Act is a requirement for the HFEA to maintain a statement of the general principles which it considers should be followed in the carrying out of activities governed by the Act (section 8). The HFEA has met this requirement by developing and incorporating a set of regulatory principles to be introduced in the 8<sup>th</sup> edition of the Code of Practice.
- 4.3 The principles are a high level statement of the HFEA's key regulatory priorities. As such, they are a summary of the key behaviours and outcomes that the HFEA expects all licensed centres to demonstrate and a means of communicating to Persons Responsible and the staff of licensed centres (and other stakeholders), the areas of compliance regarded as key by the HFEA.
- 4.4 Each guidance note in the Code is referenced to one or more of these regulatory principles, and the principles will also inform the HFEA's inspection process.

### **The HFEA's Regulatory Principles:**

- 4.5 "The HFEA expects Persons Responsible to ensure that their licensed centres demonstrate adherence to the following principles when undertaking activities licensed under the Human Fertilisation and Embryology Act 1990 (as amended).

Licensed centres shall:

- 1. treat prospective and current patients and donors fairly, and shall not discriminate against them unlawfully;
- 2. have proper respect for the privacy, confidentiality, dignity, comfort and well being of patients and donors;
- 3. have proper respect for the special status of the embryo when conducting licensed activities;

4. take proper account of the welfare of any child who may be born as a result of the licensed treatment provided by them and any other child who may be affected by that birth;
5. provide prospective and current patients and donors with sufficient, accessible and up-to-date information in order to allow them to make informed decisions;
6. ensure that patients and donors have provided all relevant consents, before any licensed activity is undertaken;
7. conduct all licensed activities with proper skill and care and in an appropriate environment, in accordance with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring;
8. ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for purpose;
9. ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice;
10. maintain proper and accurate records and information about all licensed activities;
11. report all adverse incidents (including serious adverse incidents and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately;
12. ensure that all licensed research that they undertake meets proper ethical standards, and is only undertaken where there is both a clear scientific justification and no viable alternative to the use of embryos; and
13. conduct all licensed activities with proper regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK, including:-

- maintaining up-to-date awareness and understanding of legal obligations,
- responding promptly to requests for information and documents from the HFEA, and

- co-operating fully with inspections and investigations by HFEA or other agencies responsible for law enforcement or regulation of healthcare.

- 4.6 The 8<sup>th</sup> edition of the Code of Practice contains some 32 guidance notes covering key areas of practice such as the provision of information and obtaining of relevant consents; storage of gametes and embryos; witnessing processes; record keeping; conducting welfare of the Child assessments etc. The ordering of the guidance notes in the Code broadly reflects the patient pathway.

- 4.7 Each guidance note includes highlighted sections which set out the relevant mandatory requirements contained in the legislation; the standard conditions on all licences issued by the HFEA; or in specific Directions issued by the HFEA. Some guidance notes may also include the HFEA's interpretation of legislative requirements in particularly complex areas. The guidance notes also refer to guidance produced by other professional bodies where relevant.
- 4.8 The Code of Practice also sets out in appendices, the standard licence conditions and Directions issued by the HFEA.
- 4.9 The HFEA is under a statutory obligation to “promote compliance with” the requirements of the Act and the Code of Practice (section 8(cb)).** Non compliance observed on inspection is noted in Inspection reports published on the HFEA's website.
- 4.10 However, a failure to observe a provision of the Code does not automatically give rise to proceedings. Rather, section 25(6) of the Act sets out two situations in which a breach of the Code is relevant.
- 4.11 Firstly, the HFEA is required to take account of the provisions of the Code is deciding whether there has been a failure to comply with the conditions of a licence, and in particular any conditions requiring “proper” or “suitable” practices to be followed.
- 4.12 Secondly, when deciding whether or not to vary or revoke a licence, the HFEA may take account any observance or failure to observe the provisions of the Code.
- 4.13 In deciding whether to take formal action against a licensed centre for non compliance with the Act or the Code, the HFEA acts in accordance with a Compliance and Enforcement Policy which is published on its website. Members will be provided with a copy of this policy as part of their legal training.

## 5. THE HFEA'S CONSULTATION AND ENGAGEMENT PROCESSES

- 5.1 The HFEA's primary method of accessing the feedback and advice of the clinical sector is through the HFEA's **Licensed Centres' Panel**. This is a panel consisting of representatives of centres licensed by the HFEA. It includes counselors; embryologists; fertility nurses; clinicians; and senior staff of licensed centres. The panel meets about 3 times a year.
- 5.2 The panel's role is to provide feedback to the HFEA about the operation of the HFEA's inspection and reporting procedures. It also provides views to the HFEA about the type of information and advice that the centres consider that the HFEA should be providing. The panel also acts as a consultation forum and is asked by the HFEA on occasion to provide feedback on specific issues.
- 5.3 In addition to the formal panel meetings, the HFEA's Chair and Chief Executive have, since April 2008, continued to hold an ongoing series of informal "listening sessions" with small groups of the Persons Responsible for centres licensed by the HFEA. The aim is for the Chair and Chief Executive to meet all Persons Responsible on an individual basis and these meetings therefore provide a valuable opportunity for exchange of views. Members of the HFEA board and the Chief Executive also undertake periodic informal visits to licensed centres as part of their induction, and to observe clinical practice.
- 5.4 The HFEA issues a monthly electronic mailing to all licensed centres "HFEA Update." This mailing informs the Persons Responsible and staff of licensed centres of policy and other developments being made by the HFEA.
- 5.5 In addition, the HFEA issues periodic "Alerts" which inform centres about the learning points arising out of incidents and provides guidance on ways to prevent the re-occurrence of such incidents at other licensed centres.
- 5.6 The HFEA accesses the expertise of the research and development sector through its "**Horizon Scanning Panel**." This is an early warning system that identifies, through a rigorous and systematic appraisal of scientific research, new developments that may impact on the field of assisted reproduction or embryo research. In this way, the HFEA becomes aware of potential new developments that may lead to applications for licences for treatment or research and has the opportunity to consider the

- legal, ethical and scientific implications of such developments. The HFEA is therefore able to develop its policy in relation to such developments and to issue guidance to the sector, or update its Code of Practice where necessary. The panel is composed of about 30 international experts who, in addition to regular liaison with the HFEA by email, hold an annual meeting.
- 5.7 The Horizon Scanning Panel produces an annual report which is launched at the July meeting of the European Society for Human Reproduction and Embryology each year. A copy of the 2007/2008 report is enclosed.
- 5.8 Matters identified by the Horizon Scanning Panel are considered in depth by the HFEA's **Scientific and Clinical Advances Advisory Committee**, and may also be considered by the HFEA's **Ethics and Law Advisory Committee**. These two committees are standing committees of the HFEA whose purpose is to provide advice to the HFEA board. Both committees hold regular open meetings at which experts are invited to contribute to the discussions before the committee, and to provide their expert views, on the basis of which the committees will then tender their advice to the HFEA board. The board will consider the advice of its committees before making policy in relation to new scientific developments.
- 5.9 The HFEA, as a UK public body, has a duty to consult before making important policy decisions. Consultations are conducted in a variety of ways. These include holding public meetings, online consultations and the issue of formal consultation documents. As a public body, the HFEA is required to comply with certain guidelines on consultation issued by the UK government. These include a requirement to provide a three month period in which those who wish to respond to a consultation can provide their comments, and the requirement to conduct and publish detailed impact assessments on the burden that proposed policy decisions may entail on the UK fertility sector. The HFEA maintains and updates a list of stakeholders that we regularly engage with and who take an interest in the activities of the HFEA. Such stakeholders are notified of forthcoming consultations and are specifically invited to participate in them. Consultations are promoted in sector newsletters, at key events, and on our public website.
- 5.10 The HFEA was recently awarded the Sciencewise prize for "excellence in public dialogue" for its 2007 consultation on Hybrids and Chimeras.
- 5.11 The HFEA seeks patient views through its "**Fertility Views Panel**." This is a panel of patients who have elected to complete an online questionnaire periodically. In this way, the HFEA is able to access patient experiences of

- their fertility treatment at licensed centres and to ask such patients to provide views and feedback on proposed HFEA policy from a patient perspective.
- 5.12 The views of patients are also sought during inspections of licensed centres by the HFEA. Whilst feedback during this process is often centre specific, more general issues will be fed back into the compliance and policy sections of the HFEA, for analysis.
  - 5.13 Representatives from the HFEA attend periodic meetings of relevant professional groups such as the British Fertility Society; the Association of clinical Embryologists; Senior Infertility Nurses Group; and Royal College of Obstetricians and Gynecologists.
  - 5.14 A representative of the Human Genetics Commission always attends each meeting of the HFEA Board as an observer and is invited to contribute towards matters under discussion by the board that lie within their expertise.
  - 5.15 In addition to holding two of its board meetings in public each year, the HFEA holds an annual conference in the Autumn. This event provides a valued opportunity to bring together in one forum, stakeholders and those with an interest in the work of the HFEA. The 2008 conference was addressed by the UK minister for Health, Dawn Primarolo, and by Sir Alan Moses, a Lord Justice of Appeal. The DVD of these keynote addresses are available for view on the HFEA's website.
  - 5.16 The HFEA's Chair, Professor Lisa Jardine CBE, is regularly invited by the media to comment on matters relating to assisted reproduction which have captured public interest.