

## THE HFEA CODE OF PRACTICE (7<sup>th</sup> edition)

### Partial Regulatory Impact Assessment

#### 1. Title of Proposal

HFEA Code of Practice (7<sup>th</sup> edition)

#### 2. Purpose and intended effect of measure

##### (i) The objective

To produce a revised and re-designed code of practice for HFEA licensees to deliver:

- **effective implementation of the detailed requirements of the EU Tissues and Cells Directive** giving these appropriate regulatory force;
- **more transparent and efficient regulation**, streamlining the regulatory process by having a more coherent regulatory framework that links the legal and licensing requirements for assisted conception services with standards, guidance, and compliance criteria;
- **modernisation of the regulatory process**, adapting to a ‘quality systems’ approach, and supporting an inspection process that relies on evidence-based criteria that relate clearly and transparently to an agreed set of internally consistent, proportionate and logically-related standards;
- **reduction in the burden of regulation** by, where appropriate, relying on detailed guidance from expert or professional bodies, simplifying HFEA guidance, facilitating the streamlining of the application/inspection process and cutting out unnecessary duplication of documentation;
- **improvement of the clarity and focus of guidance** by modifying or removing provisions which are either not supported by current evidence, disproportionate to the ends to be achieved, over-prescriptive, or not effectively enforceable;
- **reduction in costs to HFEA** in the short term, by reducing the volume of queries, both to the HFEA from centres and between colleagues within the HFEA, as a result of definitive and unequivocal guidance, and, in the medium and long term, by reducing the need for regulatory action through generally higher levels of compliance.

##### (ii) The background

The Human Fertilisation and Embryology Authority (HFEA) was created by an Act of Parliament, the Human Fertilisation and Embryology Act 1990, to license and regulate the clinical practice of donor-assisted conception and the creation and use of human embryos outside the body in treatment and research.

The Act requires the HFEA to produce a code of practice “giving guidance about the proper conduct of activities carried on in pursuance of a licence under this Act and the proper discharge of the functions of the person responsible and other persons to whom a licence applies.” The Code must also include “guidance for those providing treatment services about the account to be taken of the welfare of children who may be born as a result of treatment services... and of other children who may be affected by such births” and may also contain “guidance about the use of any technique involving the placing of sperm and eggs in a woman.”

The last edition of the Code (the sixth) came into force on 1st March 2004. Since then there have been a number of significant material developments which make the publication of a revised Code a high priority for the HFEA. Among these are the

adoption of the European Union Tissues and Cells Directive<sup>1</sup> (coming into effect in April 2007) a number of changes to domestic legislation (e.g. the HFEA (Disclosure of Donor Information) Regulations 2004) and HFEA policy (e.g. as a consequence of the 'Tomorrow's Children' and 'SEED' reviews) and expectations arising from the Hampton Review and the guidance given by the Cabinet Office's Better Regulation Task Force.

In the light of these developments and expectations, the format of the Code and the architecture of guidance available to centres merit significant review. In particular the Code should:

- be focussed on realistic standards which are clear and measurable, both for regulators and those regulated
- contain requirements relating to quality management (a requirement of the EU Directive) which are predominantly outcome, rather than process, based
- lower the burden of regulation wherever possible, consistently with the end to be achieved
- contain prescriptions or prohibitions only where necessary to manage identified risk and which are evidence-based and proportionate to the end to be achieved, and
- be readily accessible to users and others who may wish to refer to it.

Nevertheless it is beyond the scope of this project to address substantive matters of policy which should be properly subject to dedicated review involving targeted research, extensive evidence gathering, detailed deliberation and stakeholder engagement.

### **(iii) Risk assessment**

Owing to the lack of substantive changes which are not consequent upon legislation or resulting from completed reviews (which have themselves involved thorough consideration of relevant risks) the risks relate exclusively to changes in the way in which the Code is made available to users. These are considered comprehensively in the table at the end of this document.

## **4 and 5. Benefits and Costs**

It is not anticipated that any distinctive costs will arise from substantive amendments introduced with this edition of the Code, other than those relating to incorporated measures that have already been brought into effect through other means (Directions, Chair's letters) or those resulting directly from the introduction of new legislation (which have been assessed through Regulatory Impact Assessments accompanying consultations on the draft legislation). The benefits anticipated to arise from the few substantive amendments not previously introduced are indicated in the summary table below, along with costs and benefits associated with the revised mode of delivery and presentation.

## **6. Equity and Fairness**

It is not anticipated that any of the options presented in the consultation will have an effect on the equity or fairness of regulation or treatment provision. The equality impact screening procedure used is set out at the end of this document.

## **7. Consultation with small businesses**

It is not anticipated that the revision of the Code will have a disproportionate impact on small businesses. However as a significant number of private sector treatment providers would fall within the description of a "small business" this position will be reassessed following the consultation exercise.

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<sup>1</sup> Directive 2000/23 of the European Parliament and Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] O.J. L 102/48

## 8. Competition assessment

It is not anticipated that the revision of the Code will affect competition between licensed centres in the private sector.

## 9. Enforcement and sanctions

Enforcement of measures contained in the Code will take place through the Authority's ongoing programme of licensing and inspection. Penalties for nonconformities and non-compliance will depend on the underlying legal sanction. These range from imprisonment (additionally, or alternatively, a fine) for carrying out unlawful activities (e.g. carrying out licensable treatment without a licence) to revocation or variation of a licence for breach of the terms of a licence or Directions (e.g. failing to obtain effective consent of gamete providers before creating embryos). In certain circumstances, failing to comply with guidance (e.g. failure of person responsible to ensure that certain practices, deemed suitable, are used in carrying out licensable activities) may also result in the variation or revocation of a licence. In the Code, standards with which conformity is obligatory (because nonconformity would be either unlawful or invariably a breach of licence) are identified by the use of bold type; other standards and guidance (with which failure to conform or comply may, in certain circumstances, result in revocation or variation of the terms of a licence) appear in roman type. In order to facilitate interpretation, the legislative provision providing for each measure is stated in the Code throughout.

## 10. Monitoring and review

Practitioners' conformity with standards and, where relevant, compliance with guidance given in the Code will be monitored through regular HFEA inspections which will provide feedback on the effectiveness of the measures contained. The HFEA business plan will prioritise work identified through inspection or in the light of other emerging evidence or research as being appropriate for review. Such reviews will ordinarily comprise dedicated research, evidence gathering, consultation with stakeholders and advisors, and consideration by the Authority, as well as identifying appropriate monitoring and review procedures.

## 11. Consultation

The Standards comprising the first part of the Code have developed in collaboration with representatives from relevant professional bodies and subject to lengthy public consultation (beginning in April 2006). Insofar as it differs from the substantive content of the previous edition of the Code of Practice, the guidance contained in the second part of the Code largely incorporates measures which have been subject to independent consultation and have been communicated previously by the HFEA. Proposals for delivery and presentation of the Code have been developed in the light of the findings of an online survey of the three main user groups (HFEA licence committees, inspectors, and practitioners) and refined through an invited user workshop held in August 2006. Other stakeholders are invited to comment in responding to the present consultation.

### Costs and benefits: Table of substantive amendments to content

Amendment	Costs	Benefits
Guidance 1.3.1 ( <i>ex para. 1.8</i> ) Bringing nursing qualification requirements into line with current professional expectations within the sector	None	More appropriate requirement ensuring that staff have reached acceptable standard of competency through at least local training and increased likelihood that centres would take responsibility for this.

<b>Amendment</b>	<b>Costs</b>	<b>Benefits</b>
Guidance 9.7.2 ( <i>ex paras 3.9-3.10</i> ) Increasing consistency in relation to controls on obtaining gametes from those under 18	None	Consolidation and simplification of guidance leading to reduction in enquiries.
Guidance 7.2.4/1 ( <i>ex paras 3.30-3.31</i> ) Remove expectation that those sharing eggs to receive counselling from separate counsellors	None	Reduction in costs to centres and reduction in difficulty in obtaining appropriate local counselling services, leading to reduction in cost and waiting times for patients
Guidance 8.4.1 ( <i>ex paras 8.4-8.5</i> ) Revision of precautionary requirement into a more workable formulation already adequately expressed by existing guidance at para 8.4.1 ( <i>ex para.8.8</i> ) and standard licence condition B.1(a)	None	Reduction in incredulous enquiries to HFEA and removal of absurd and unintended implications.
Guidance 5.2.1(i) ( <i>ex para.8.26</i> ) Removal of requirement to secure unenforceable written agreement from home insemination patients to inform centre of outcome but extension of scope of information about importance of informing the centre of treatment outcomes to all patients (not merely home insemination patients)	One-time update of protocols for providing information to fertility patients required; Centres may actively have to follow up patients	Removal of superfluous unnecessary paperwork; overall increase in compliance by patients with clinic requirements
Standard 7.8.4(b)/2 ( <i>ex para.9.11</i> ) Storage audit to be carried out biennially rather than annually		Significant saving of staff time/ resources Reduced risk of inadvertently causing deterioration to samples Reduced risk to staff wellbeing Reduced risk of introducing new accounting errors /mixing up samples Estimated annual cost saving across sector of £125,102.88

**Costs and benefits: Table of changes in mode of delivery**

<b>Amendment</b>	<b>Costs</b>	<b>Benefits</b>
Linking the legal and licensing requirements for	None	Easier cross referencing for more efficient retrieval of

<b>Amendment</b>	<b>Costs</b>	<b>Benefits</b>
assisted conception services with standards, guidance, compliance criteria, and other sources of advice and information		information whilst on the job; reduced staff time taken up in research or making enquiries; greater transparency and efficiency of regulation
Inclusion of set of internally consistent, proportionate and logically-related standards	None (production of quality manual and introduction of quality system already a consequence of introduction of legislation)	Clearer understanding of outputs required facilitating adaptation to a quality systems approach;  providing a framework of guidance on which centres can develop quality manuals and detailed standard operating procedures (SOPs) as required by the new legislation.
Removing duplication of detailed guidance from expert or professional bodies.	None	Simplification of HFEA guidance, reduction in the burden of regulation by, where appropriate, facilitating the streamlining of the application/inspection process and cutting out unnecessary duplication of documentation
Consolidation of all extant HFEA guidance from the previous Code of Practice and subsequent Chair's letters with the HFEA Standards in one document	None	Greater clarity and consistency leading to reduction in volume of enquiries to be made and consequent delays in the short term;  in the medium and long term, by higher levels of compliance, leading to better quality of service and reduced need for regulatory action.
Clear distinction between mandatory and advisory specifications through the use of bold and roman type (respectively)	None	Clarity of expectation facilitating clearer decision making in areas of clinical discretion.
Having a Code which is updatable, allowing amendments to be incorporated seamlessly rather than added on through a variety of different letters and communiqués, as at present	None	Increased clarity of guidance leading to greater compliance;  Reduction in risk associated with independent methods of updating each centre's information
All information held in central HFEA database and amended using controlled	None	Improved version control, informational integrity and

<b>Amendment</b>	<b>Costs</b>	<b>Benefits</b>
single-point editorial protocol		consistency; capacity for convergence with other informational resources
Available in a choice of media, including online and loose-leaf printed versions (also as a download or stand-alone CD ROM).	Some investment in hardware if centres want to move to introduce more online terminals	Increased functionality arising from fully interactive online version; reduced risk of updating failures using loose-leaf version
Historical 'in force date' searching' (online only)	Some investment in hardware if centres want to move to introduce more online terminals	Allows users to identify provisions in force on any particular date, speeding up auditing and inspection, and decreasing potential for error
Search, filter and hypertext navigation (online only)	Some investment in hardware if centres want to move to introduce more online terminals	Reduction in time taken searching for and verifying information and reduction in risk of error.
Ability to insert user-defined bookmarks, notes and shortcuts to frequently used passages (online only)	Some investment in hardware if centres want to move to introduce more online terminals	Quicker reference to frequently required information
Updating through issuing pages that can be filed directly into the main work	None	Integrity of information; ensuring that information is filed accurately in one place.