

## **IMPROVING REGULATION:**

### **HFEA Consultation on Draft 8<sup>th</sup> Code of Practice & Consent Forms**

#### **Introduction**

1. At the HFEA, we are committed to improving all aspects of our work. Our goals are to:
  - meet the challenges of the Human Fertilisation and Embryology Bill, now approved by Parliament;
  - help and encourage licensed clinics to understand and meet regulatory requirements more easily;
  - improve the way we do business so that our regulatory activities are transparent, accountable, proportionate, consistent and targeted;
  - be more responsive to the needs of patients, donors, the public and the clinics we regulate.
2. We want to ensure that everyone affected by these changes has a chance to shape what we do. This consultation seeks comments on:
  - A draft HFEA 8th Code of Practice;
  - New HFEA consent forms.
3. Responses to the consultation should be made using the questionnaire at <http://cop.hfea.gov.uk/cop/consultation/>. The closing date for the consultation is Wednesday 18<sup>th</sup> February 2009.

#### **Amending the 1990 Act**

4. The Human Fertilisation and Embryology (HFE) Bill was introduced into the House of Lords in November 2007 and received Royal Assent in November 2008. Most of the Bill changes will be incorporated into the existing legislation - from now on known as the Human Fertilisation and Embryology Act 1990 (as amended). However, the new parenthood provisions in Part 2 of the Bill will be known as the Human Fertilisation and Embryology Act 2008.
5. In many ways, the new Act brings onto the statute books what has been HFEA policy for some time. Sex selection for social reasons, for example, is now prohibited by law and various forms of embryo testing are permitted under licence. Research creating human-animal hybrid embryos (known as admixed embryo research in the Act) is also permitted under licence, an area of research that the HFEA has licensed since 2008.

6. The Bill has, however, introduced a number of new provisions regulating IVF and embryo research. The most significant are the new parenthood provisions, allowing for the first time both partners in same sex couples to have a legal relationship with their child from birth. Guidance note 7, Legal Parenthood, lays out these new provisions in more detail. The revised consent forms which form part of this consultation also bring into force new consent requirements around parenthood, as well as consent to treatment, donation, storage and research. These new consent requirements are discussed below.
7. The new Act also gives wider access rights to donors, recipients and donor-conceived individuals for information contained on the HFEA register. Finally, the Act gives the HFEA new “better regulation” responsibilities and increased ability to delegate some of its functions, such as licensing.

### **Implementing the new legislation**

8. The HFEA is responsible for implementing the changes to the Human Fertilisation and Embryology Act 1990 (as amended) and the Human Fertilisation and Embryology Act 2008 (parenthood provisions). The Government has indicated that these changes will be introduced from:
  - (i) 6<sup>th</sup> April 2009 – legal parenthood;
  - (ii) 1<sup>st</sup> October 2009 – all other changes, except for,
  - (iii) 6<sup>th</sup> April 2010 – parental orders
9. To prepare for implementation, we have:
  - developed new Code of Practice guidance to help clinics meet new legislative requirements;
  - revised HFEA consent forms to reflect the new legal requirements
10. We have also:
  - introduced some changes in guidance in response to feedback from patients and licensed clinics;
  - taken the opportunity to improve the style and layout of both the Code and consent forms to improve clarity and usability.
11. These changes are explained in more detail in this document.
12. The 8<sup>th</sup> Code of Practice will be published in July 2009. We will also provide information and support to licensed clinics as far in advance of April 2009 as possible to prepare for the change in the law on legal parenthood. This will include interim guidance for clinics (rather than an update to the 7<sup>th</sup> Code) and information for patients.

## **Draft 8th Code of Practice**

13. The purpose of the HFEA Code of Practice is to give guidance on the proper conduct of licensed activities to clinics regulated by the Authority and the proper discharge of functions of the person responsible. To be successful, the Code should assist clinics in understanding and meeting their regulatory requirements. We know that many clinics found the 7<sup>th</sup> Code unsatisfactory and we have therefore changed the structure, layout and content of the Code. In doing this, we have already taken on board comments from clinics, but we recognise that there is potential for further improvement. We want to use this consultation process to ensure that the new Code will be in a format that works for those that use it and will stand the test of time.

### **Key changes to the style and structure of the Code**

14. Our objectives in redesigning the Code of Practice are:
  - to distinguish clearly between mandatory requirements and best practice guidance
  - to remove the duplication that existed between legislation, Standards, Licence Conditions and HFEA Guidance
  - to reduce complexity and improve the navigation of the code, and
  - to put the guidance into plain English
15. The Code now comprises 32 guidance notes, grouped by subject area, which identify and separate mandatory requirements and HFEA guidance. We have also provided our interpretation of some of the more complex legal requirements. The guidance has also been reordered, edited and put into plain English, with advice from the Plain Language Commission.
16. There is no longer a Standards section. Instead, Standards have either been incorporated into guidance or deleted in cases where they duplicated licence conditions.
17. We have added a new section, Principles, which describes the behaviours and outcomes that the HFEA expects licensed clinics to demonstrate. Clinics' adherence to the Principles will be tested on inspection.
18. There is a new Introduction to the Code which describes the purpose of the Code and how it should be used in practice.
19. The mandatory requirements quoted in the guidance include current licence conditions and HFEA Directions. We are planning a review of licence conditions during 2009. We will need to amend licences to incorporate new conditions introduced by the amended Act, but we will use the opportunity to review the continued relevance of existing conditions and whether the wording can be improved. At the same time, we will review HFEA Directions so that there is greater clarity about

which Directions are currently in force. The references to licence conditions and HFEA Directions will therefore be updated in the final version of the 8<sup>th</sup> Code.

### ***Key changes to the Code of Practice guidance***

20. We have undertaken a thorough review of the Code of Practice guidance. As a result, we have:
- updated the Code to bring it in line with amendments to the Act and introduced new guidance where this is needed to help clinics meet their statutory obligations;
  - introduced new guidance in response to feedback from patients and licensed clinics and to improve legal clarity;
  - removed guidance that now seems over prescriptive;
  - re-worded guidance to improve clarity and understanding.

The key changes are set out below.

#### **(a) Changes to reflect new legislation**

21. Some amendments to the Act have a direct impact on the regulation of licensed activities. For instance, the Act permits or prohibits certain types of embryo research. These do not require the addition of guidance.
22. Other amendments need to be accompanied by new guidance in order to make them work in practice. This guidance includes:
- Information for those seeking donor conception treatment;
  - Assessing whether prospective patients would be supportive parents;
  - Assessing the appropriateness of PGD and tissue typing;
  - Not preferring affected embryos or donors.
23. The consultation questionnaire describes these changes in more detail and can be found at <http://cop.hfea.gov.uk/cop/consultation/>.
24. Some guidance has been developed with the intention of putting the wishes of Parliament into practice. We have not asked for views on these specific issues in the questionnaire as our scope for discretion is limited. However, the questionnaire does provide an opportunity for you to raise any general issues on the draft guidance. Two areas of guidance that fall into this category are:
- (i) Telling children about their conception through donation
25. Clinics will be required to give patients undergoing donor treatment information about the importance of telling any resulting child at an early age that they are donor-conceived. Clinics are also obliged to inform patients about suitable methods for doing so.

26. Our guidance on this complex issue seeks to strike a balance between the obligation on clinics to inform patients of the importance of open communication around children's donor origins and the fact that parents cannot be forced to be open with their children.
27. We have therefore added paragraph (b) to Guidance Note 20.11 in order to incorporate the new legal requirement.

"The centre should encourage and prepare patients to be open with their children from an early age about how they were conceived. The centre should offer patients counselling for this and give them information about:

- (a) the importance of sharing information with any resulting children about their donor origins from an early age
- (b) various methods of helping them share information with such children about their donor origins*
- (c) how counselling may allow them to explore the implications of treatment, in particular how information may be shared with any such children."

(ii) Restricting PGD to serious genetic conditions

28. The new HFE Act requires the HFEA to satisfy itself that a medical condition for which PGD (testing embryos for genetic conditions) might be offered is 'serious'. The previous Act did not mention PGD, and so the HFEA set out the criteria which clinicians should use when deciding whether to apply for a variation to their licence to carry out PGD for a particular couple at risk of passing on a particular condition. These included some patient-specific and subjective criteria. The new Act aims to make the criteria for offering PGD objective. This is a response to concerns that, over time, PGD could be used to avoid less serious conditions
29. Accordingly, guidance for clinics to help them judge whether the provision of PGD might be appropriate in a particular case has been amended to remove certain purely subjective factors. In particular, the following sentence has been removed: 'The seriousness of the condition should be a matter for discussion between the people seeking treatment and the clinical team'.
30. In line with the amended Act, we will in future judge the seriousness of the condition to be avoided when we decide whether or not PGD clinics should be licensed to test for a particular genetic condition. Once clinics have been licensed to test for a particular condition, they will use different criteria (see draft 8th Code of Practice, guidance note 10) to decide whether or not to offer PGD to each couple requesting it.

**(b) Changes and additions initiated by the HFEA**

31. We have revised some guidance in the Code in response to feedback from patients and licensed clinics. This includes guidance on costed treatment plans (guidance note 4, Information: general, paragraph 4.6) and PGS (guidance note 9, Preimplantation genetic screening).
32. The definition of premises in guidance note 25 has also been revised following legal advice. While the definition has been agreed, further work is required to determine how the changes will be applied in practice. Therefore, the 'Changes to the premises' section (paragraphs 25.12-25.14) may be subject to change.
33. We have added a new section of guidance note 29: Treating Patients and Donors Fairly, to reflect our commitment to equality and human rights and to comply with our legal duties.
34. As a public body we encourage clinics to ensure that their procedures comply with equalities legislation by improving accessibility for patients. Guidance note 5, Consent: general, therefore includes a new requirement for clinics to consider the needs of patients who are not fluent English speakers.

### **(c) Guidance which has been removed**

35. A number of treatments regulated by the HFEA started off as controversial, unproven interventions. As a result, the Authority often developed relatively prescriptive guidance to clinics about those new treatments. As time has moved on, those treatments have become more common place and prescriptive guidance is no longer justified. As a result, we have removed the following guidance from the Code of Practice:
  - The requirement that surrogacy only be offered to women who are medically unable to carry a pregnancy.
  - Guidance about the accreditation of ICSI and embryo biopsy practitioners. As a result, clinics are no longer required to notify the HFEA that such practitioners have been accredited, nor are they required to submit performance data.
  - Guidance about the cases in which ICSI should be offered.
36. Other requirements which have been removed are:
  - Guidance on recording the offer of counselling and the patient's response in the patient health records.
  - Guidance on contacting a donor's GP in order to establish the donor's identity.

### ***Consent Forms***

37. Licensed clinics are required to obtain written informed consent from patients and donors before their gametes or embryos are used or stored for treatment, donation or research. Clinics currently meet this

requirement using mandatory HFEA consent forms and accompanying guidance which was issued in 2006.

38. The amended Act makes significant changes to the legislation regarding consent. We have reflected these changes in the revised consent forms for treatment, storage, donation and disclosure of information. We have also taken the opportunity to ensure that the forms are designed in the most user friendly way, are easy to understand and cover all scenarios.

**(a) Changes to reflect new legislation**

39. The main changes to the Act which have consent implications, and are reflected in the forms, are:

- storage period for embryos: which changes from 5 to 10 years;
- use of embryos for training purposes, which can be authorised by a treatment licence;
- broader consent to disclosure of identifying information, including a regulation making power for disclosure of information to researchers;
- signing of consent forms: consent forms can be signed on behalf of the person giving consent (if they are unable to do so due to illness, injury or physical disability), at the direction of and in the presence of the person unable to sign and in the presence of at least one witness;
- agreed parenthood conditions: patients who are not married or in a civil partnership (and who use donor sperm) will need consent to their partner being treated as a legal parent (and the partner will need to consent to parenthood too).

**(b) New Consent Forms**

40. As well as updating the current forms, we have added new forms for:

- consent to parenthood when donor sperm or embryos are used ;
- surrogacy specific consent forms which allow patients to consent to the use of their gametes or embryos in surrogacy arrangements;
- withdrawal of consent and statement of lack of consent;
- long term/extended storage of gametes - allowing clinics to more clearly distinguish consents obtained for initial storage and extended storage
- use of eggs, sperm or embryos for research or training.

**(c) Changes to improve usability**

41. Following consultation with the HFEA Licensed Centres' Panel and the Royal College of Nursing Fertility Nurses Group, a number of changes have been made to the forms to improve their usability. Major changes include:

- guidance notes have incorporated within the forms, making it easier to understand which sections need to be completed by whom and in which scenarios;

- text and fields on the forms are laid out in a user-friendly structure eg, tick boxes placed under questions, different font sizes and styles used to distinguish different types of text, optimum line length, shaded boxes
- features have been added to ensure each page contains uniquely identifying information (in case pages become separated) ie, patient/donor number box and signature box.
- features have been added to improve usability for clinic staff (eg, margin width allows for hole punching, space for clinic sticker for patient details, version control)
- patient consent to long-term embryo storage has been included on the statement from medical practitioners form. This will ensure that the patient consent to long-term embryo storage is always accompanied by the statements to permit it. It will also mean that patients do not need to complete new MT and WT forms when extending their consent to embryo storage;
- fields have been added for consent to egg storage within the WT form and sperm storage within the MT form

#### **(d) Format of consent forms**

42. As now, it will be mandatory for clinics to use HFEA consent forms. We envisage that they will be issued to clinics as PDFs, which clinics will be able to download from the HFEA website and print for patients or donors to complete. Completed forms can then either be stored as paper copies or, if clinics wish, scanned onto an electronic system.
43. It is possible that the number of forms will change following analysis of the consultation responses. Elements of forms may be decoupled or forms may be combined.

#### **Consultation timetable and next steps**

44. The consultation period began on Monday 17<sup>th</sup> November 2008 and ends on Wednesday 18<sup>th</sup> February 2009. Full details on how to respond can be found at <http://www.hfea.gov.uk/en/1743.html>.
45. Following the consultation, the HFEA will agree changes to the Code of Practice and consent forms in May 2009. The Code of Practice will then require approval by Ministers and will be laid before Parliament. The final version of the 8<sup>th</sup> Code and the consent forms will be sent to clinics in July 2009 and come into force on 1<sup>st</sup> October 2009. This will give clinics around three months to implement changes to their systems.
46. A report summarising the feedback received during the consultation period, with an explanation of how the Code and consent forms have changed as a result, will be published on the HFEA website following Ministerial approval.